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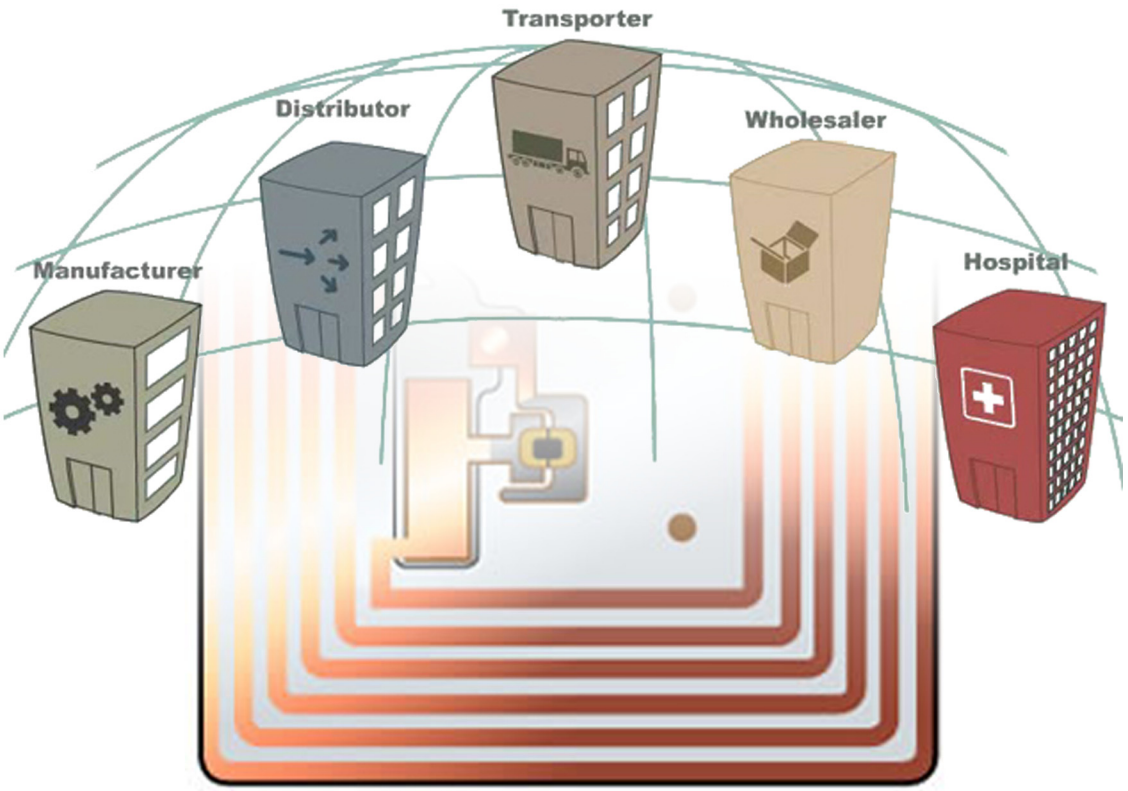
RFID IN THE HEALTHCARE AND PHARMACEUTICAL INDUSTRY

a study about the implementation of RFID in the Danish market



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ABSTRACT

Problem

Counterfeited medicine is increasing rapidly. To ensure patient's safety new technologies might be adapted in the pharmaceutical supply chain. Could RFID be a solution to solve this problem? What other benefits does RFID have? Is the Danish market ready for the implementation? How does the international market influence the Danish industry?

Method

A general technical description of RFID and other ID-technologies is given to ease the understanding of the technological opportunities.

To research the current market situation, different case studies in the different areas of the supply chain has been done during the study. Company meetings gave the necessary information to give a clear picture of the Danish market. Additionally, some telephone interviews to different European companies and researches about the international market were made for comparisons reasons. Furthermore, different regulations in the different countries must be studied to approve the legislative part of RFID.

To suggest solutions and plans for the implementation of RFID technology, the case studies were analyzed and cost calculations were made.

Finally, future ideas concerning a possible evolution of the use of RFID technology for the next years were suggested and this report ends with propositions for further studies about the same topic[1].

Conclusion

RFID could be a solution to solve the problem with counterfeit medicine. However, it seems more important to develop a global database, like the EPCglobal, to secure the pharmaceutical supply chain against illegal copy products. Missing standards slow the process of a successful implementation of RFID. The Danish market is very dependent on the international market as several products are shipped abroad. Law regulations on national and international level seem the only reason for a complete implementation of RFID in the entire supply chain. Currently RFID seems only useful on pallet level as one of the main advantages is the function multiple scanning which will save time and costs.

1 For further details, see Gantt chart in Appendix - Gantt chart

INTRODUCTION

The improvement of patient safety, the decrease of the drug counterfeiting and the increase of the supply chain efficiency are the three key drivers for a change in the European and American healthcare industry. Thus, ID technologies (Identification technologies), especially Automatic Identification and Data Capture (AIDC) , are being developed and upgraded to enable greater certainty of identification – of medicines, devices, patients, assets and locations. The implementation of those technologies which process through reading devices coupled with computer based systems and global standards is a key objective for every organism concerned by the development of the Global healthcare system. Particularly the adoption of standard technologies such as Radio Frequency Identification (RFID), already in common use in other sectors for decades, can bring significant benefits to the healthcare sector.

The aim of this report is to present the current implementation and development of RFID technology in the healthcare system, and to suggest a model of implementation helping the benchmark for traceability systems for the Danish but also international pharmaceutical market.

The first part of this document presents the context of the development of RFID systems, the different ID technologies already used, and the interest of using RFID instead of other technologies. In a second part, it presents the current regulations of the pharmaceutical industry and the RFID standards developed so far. In the third part, different case studies are presented concerning the Danish and the international market. And finally, an example of cost benefit analysis is made to show a concrete interest of RFID.

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PREFACE

The report is written to the Danish Technological Institute (DTI). Danish Technological Institute is an independent, not-for-profit institution approved by the Danish authorities to provide technological services to businesses and the community[2].

The project is written by five European exchange engineering students coming from Spain, Poland, France and Germany/Denmark. In Cooperation with DTI, the aim was clarified and the project work was started. Different companies were contacted to arrange meetings for the case studies presented in this document. Additionally regulations concerning RFID technology are researched to make recommendations for the Danish market.

We would like to thank the following persons and companies for their support and time they invested in helping us with this report:

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2 http://www.dti.dk/ (24.03.2008)

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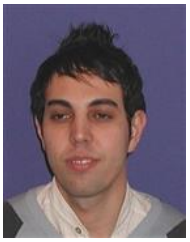

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LIMITATION

The pharmaceutical supply chain is very large. It includes the drug manufacturer's suppliers (ingredients, bags, packaging etc.), the manufacturer themselves (often multinational concerns), re-packager and their suppliers, wholesaler, parallel trade associations, hospitals, doctors, pharmacies and all their other suppliers.

Due to the complexity it is decided to focus on some of the main parameters in the supply chain, manufacturer and wholesaler[3]. The report also gives a short insight into the pharmacies in Denmark as the successful implementation of RFID needs the participation of every link in the industry – an RFID tag would be useless on the drug if only the pharmacies would have bar code scanners.

Representing the manufacturer in Denmark, NovoNordisk and LeoPharma are chosen. Additionally NNE Pharmaplan gives a general insight into the market. It was planned to include the American manufacturer Biogen Idec, which has an office in Denmark as well, because they were testing RFID in the US. Due to the lack of time, from Biogen Idec's side, it was decided to go without this information.

Nomeco, one of the three wholesalers on the Danish market will cover the wholesaler part.

To understand the pharmacies, Apotekerforeningen (Association of Danish pharmacies) is chosen to give a brief overview.

Finally international manufacturer like GlaxoSmith Kline and Pfizer are used to show companies which are actually using RFID somewhere in their production.

As a standard for RFID, only the EPC-Global Network (GS1) is chosen. This company is the most spread and experienced provider of RFID standards and was mentioned by several manufacturer and wholesaler.

It was considered to add Coloplast to the research as several Danish companies suggested it. Due to the lack of cooperation and the fact that this company not really is within the scope of our own limitation, it was decided to skip this company.

3 Figure 1 - Pharmaceutical supply chain, http://www.tagsysrfid.com/modules/tagsys/upload/news/TAGSYS-TI-Philips-White-Paper.pdf

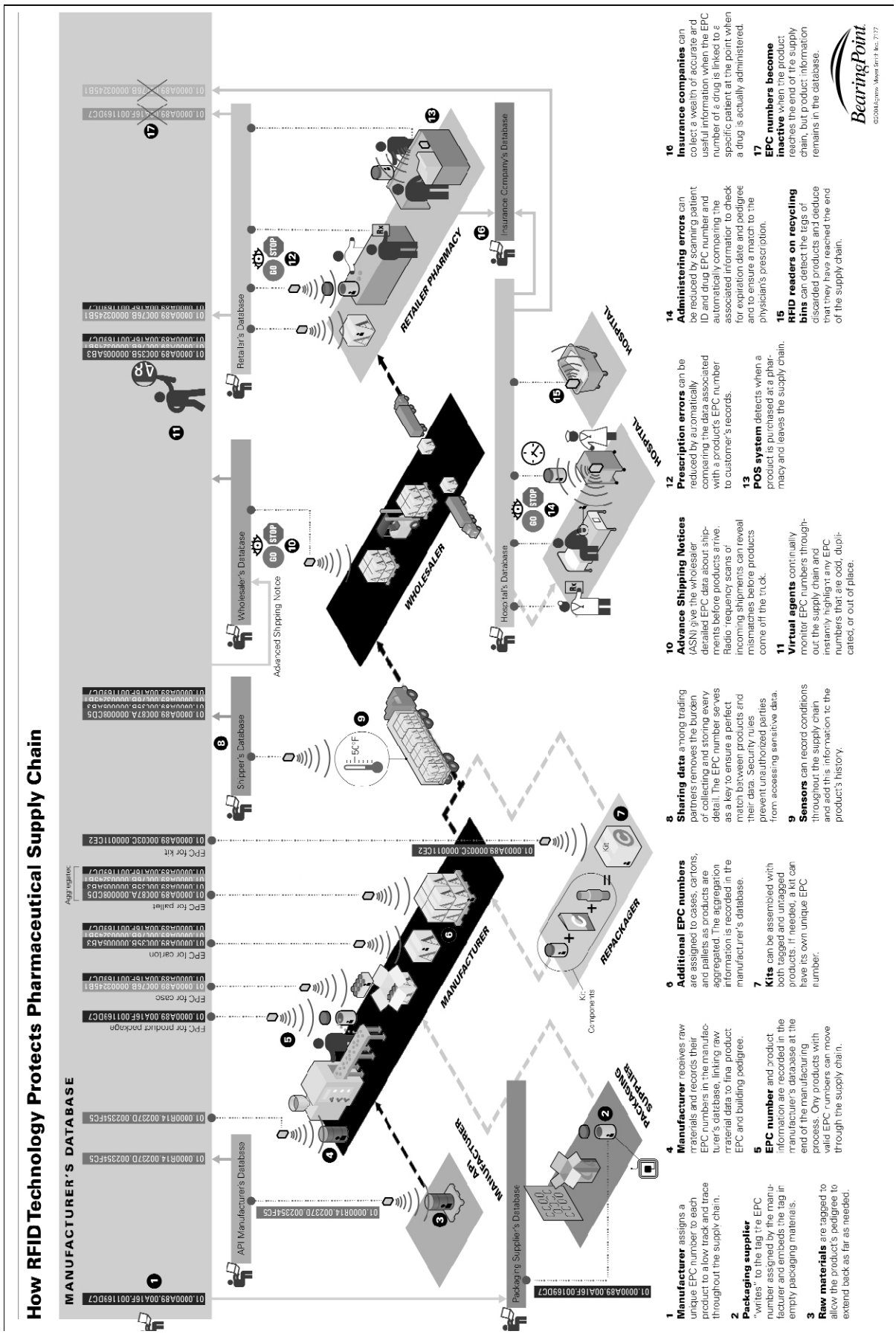


Figure 1 - Pharmaceutical supply chain, http://www.tagsysrfid.com/modules/tagsys/upload/news/TAGSYS-TI-Philips-White-Paper.pdf

CONTEXT OF THE STUDY

What makes RFID interesting for the Healthcare and Pharmaceutical industry?

The European Bridge Project[4], a European Union funded 3-year Integrated Project, developed during 3 years different ways to resolve the barriers to the implementation of RFID in Europe, based upon GS1 EPCglobal standards. The first step was to consider the issues in the healthcare system that could be solved by the use of RFID technology.

The possibility to detect counterfeited drugs (which stood for 51%[5] last year in the European market) is important for brand protection and patient safety reasons.

Thus, the goal of the technical countermeasures against fake medicines is to secure the licit supply chain by giving a unique identifier to each product and by verifying these identities.

RFID technology could be the solution since it is based on unique code definition and provides sharing information about each items produced.

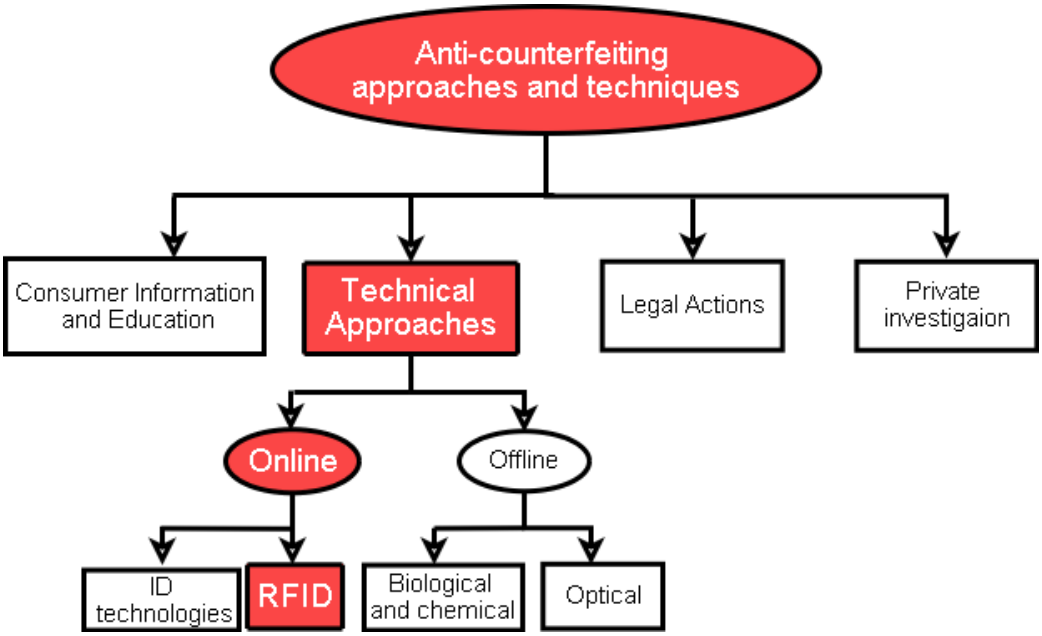


Figure 2 - The position of RFID in the measures against counterfeiting

Moreover, some regulations would be drivers to the introduction of RFID technology into the pharmaceutical industry. For instance, the U.S Food and Drug Administration (FDA) made some

4 http://www.bridge-project.eu/data/File/BRIDGE%20WP06%20Pharma%20Traceability%20Problem%20Analysis.pdf
5 http://www.safemedicines.org/in_the_news/

recommendations about track-and-trace systems and the E-pedigree which might soon become mandatory in the pharmaceutical industry.

According to the European healthcare system, improving patient safety would be possible thanks to the adoption of traceability systems, based on Automatic Identification and Data Capture techniques linked with databases and network systems supported by open and global standards. Those systems identify each medicine, the different steps and the parties involved in the management of this medicine within the supply chain.

The EPC Global network, used in RFID technology, identifies the object identifier type, the manufacturer of the product, the product and the individual unit. The EPC, by uniquely identifying the individual object in this detailed manner, enables any relevant information regarding the individual object to be obtained via the EPC global network.

The information sharing system for anti-counterfeiting should also be used in other logistics information exchange, such as product recalls. In such a way, the system should help the supply chain management, for example for forecasts, automatic replenishment, and inventory management. Even though this is not a functionality of a product authentication application, such services are important for the overall return on investment in RFID technology and expected additional benefits of RFID based product authentication system.

ID TECHNOLOGY

RFID

Introduction

RFID[6] (Radio Frequency Identification) is a method for storing and retrieving remote data, based on the use of labels or "tags" in which the information resides. RFID is based on a similar concept to the bar code system, the main difference between the two is that the latter uses optical signals to transmit data between the tag and the reader, and RFID, on the other hand, uses RF signals (radio frequencies).

Components[7,8]

Mainly each RFID system consists of these elements:

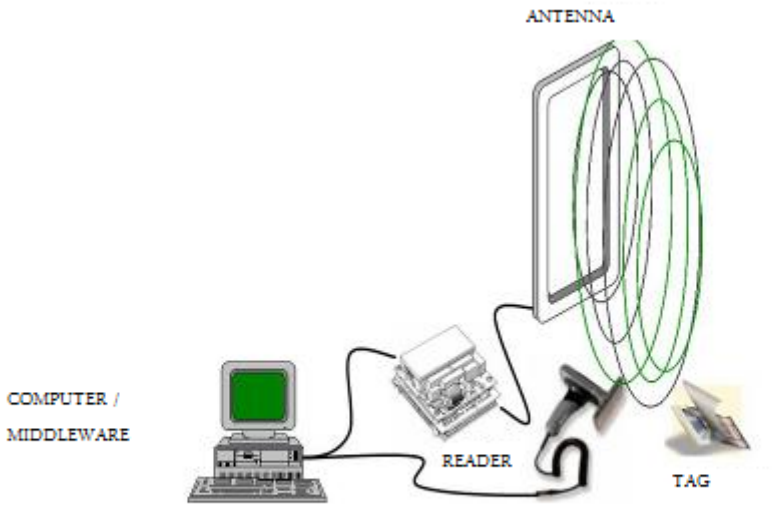
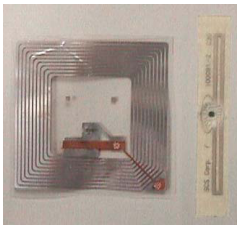


Figure 3 - Components of RFID system. AMIPEM, http://www.amipem.net/index_archivos/Page483.htm

1) An RFID tag, also called a tag or transponder (transmitter and receiver) is a small device like a sticker, which can be attached or incorporated into a product, animal or person, carrying information about the same.



It contains a microchip that stores data and a small antenna that enables the radio communication with the reader.

6 http://en.wikipedia.org/wiki/RFID (27.04.2008)
7 http://www.lyngsoesystems.com/loader.asp?menu=7&page_id=662&Language=0&niv2=112&niv3=223&Grid=199 (27.04.2008)
8 http://www.n-economia.com/informes_documentos/pdf/sintesis_documentos/SINTESIS_NE_09-2008.PDF (27.04.2008)

2) A reader transmits power to the label and it reads the data it sends.

Antenna: Communication between the reader and the tag is via the antenna, which is the element that radiates the RF signal.

The communication between reader and tag happens in these stages:

a) The reader energizes the tag
b) The reader launches commands for Interrogation tag in the field
c) The reader hears the response of the tag
d) The reader communicates the result of reading the application software

3. A computer, or host controller, develops RFID implementation. It receives information from one or more readers and communicates it to the information system. It is able to transmit commands to the reader too.

There are various RFID systems on the market, and the differences are based on several factors:

• According to its programming capacity:
  - Read-only: the tags are programmed during manufacture and cannot be rescheduled.
  - From one writing and multiple readings: labels allow a single reprogramming.
  - Read / write: labels allow multiple rescheduling.

• Depending on the mode of supply:
  - Actives: if the labels require a battery to transmit information.
  - Passives: if the labels do not require battery.

	ACTIVE	PASIVE
Price	**Very High**	**High – decreasing revision 5c tag**
Operating Cost	**High**	**Relatively high**
Reading Tolerance	**Normally none Some frequency problems**	**Normally none Some frequency problems**
Reading Equipment	**Antennas, readers and batteries in tags**	**Antennas, readers also handheld and mobile terminals**
Size Code for ID	**Label (large) or build into the product**	**Different sizes and lengths**
Standardization	**Different standards presently – future vision on global standard**	**Industry standards, presently only UHF as global standard**
Overall Usage	**Credit card shaped for use in access applications in many industries.**	**All shapes for use in different applications. Widely used for anti-theft hard plastic tags in stores.**

Tabel 1 - Table. Active vs. passive tags, http://www.teknologisk.dk

- Depending on the frequency range of work:
    - Low Frequency (LF): refers to the frequency ranges of less than 135 kHz.
    - High Frequency (AF): When is the operating frequency of 13.56 MHz.
    - Ultra High Frequency (UHF): includes the operating frequency bands from 433 MHz, 860 MHz, 928 MHz.
    - Frequency Microwave: comprises the operating frequency bands from 2.45 GHz and 5.8 GHz.

Parameters	Low frequency (<135 KHz)	High frequency (13.56MHz)	UHF (433MHz, 860MHz, 928MHz)	Microwave frequency (2.45GHz, 5.8GHz)
Coverage	Minor ⟷			Major
Size of tag	Major ⟷			Minor
Speed reading data	Minor ⟷			Major
Reading in the presence liquids or metals	Better ⟷			Worse
Reading in the presence EM interference	Worse ⟷			Better

Tabel 2 - Comparison of the characteristics associated with each frequency range

Operation[9]

Every object that has to be identified should be equipped with an RFID tag.

The antenna of the reader or interrogator emits a radio frequency field, which activates the labels.

When a label enters this field it uses the energy and time reference received from the antenna to conduct the transmission of the data stored in its memory. Active tags have their own batteries installed on the label.

The reader receives the data and sends them to a control computer for processing.

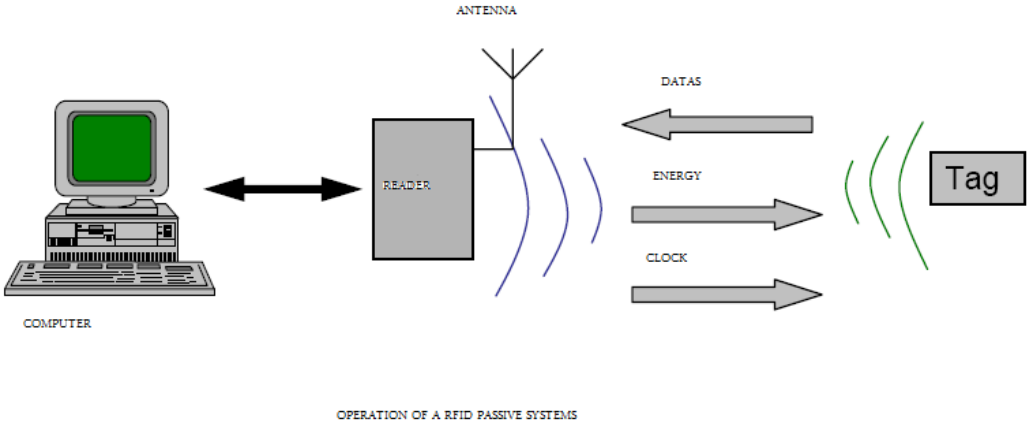


Figure 4 - Operation of a RFID Passive Systems, Tecnología RFID: Aplicaciones en el ambito de la salud, http://www.ceditec.etsit.upm.es/dmdocuments/CITIC%20RFID%20Salud.pdf

9 http://www.n-economia.com/informes_documentos/pdf/sintesis_documentos/SINTESIS_NE_09-2008.PDF (25.05.2008)

RFID Benefits

The wide adoption of RFID across the supply chain will bring significant benefits to companies in the form of improved supply chain visibility, operational optimization and increased profits. The main areas of benefit are[10]:

Improved productivity and cost avoidance

Identifying items by RFID involves less manual work than using barcode scanning and other less automated ways. This leads to greater process effectiveness in many tasks such as receiving and putting away, and picking and shipping goods.

Decreased cycle time and cost removal

RFID scanning is not a serial process, like traditional Barcode scanning, so companies can perform identical tasks much more quickly. This means processing moving goods through a supply chain are more efficient and leads to a reduction in the need for large inventories.

Reduced rework

The number of errors generated and retries required is reduced.

Reduced business risk and control of assets

The ability to track and trace items more efficiently means assets can be located and reassigned more easily.

Improved security and service

Being able to validate information relating to an item enables increased security. This individual identification contributes to more effective access control and the ability to provide fast and efficient services at the point of need. The ability to authenticate information can also help to prevent activities such as counterfeiting and fraud.

Improved utilization of resources

RFID can be used to improve planning and workflow. As processes are improved, time can be saved and assets can be utilized more effectively.

Increased revenues

By making process flows more visible and eliminating bottlenecks and uncertainty, companies are able to optimize product and work flows. This leads to greater item availability and reduced lost sales.

10 http://www.lyngsoesystems.com/loader.asp?menu=7&page_id=694&Language=0&niv2=112&niv3=251&Grid=195(14.04.2008)

Exception management

RFID enables processes and procedures to be measured contributing towards better decision making. The information captured by RFID and its integration with other IT applications will allow managements to be alerted when compensatory business decisions need to be considered.

Characteristics of RFID[11]:

Ability to modify data

It depends on the standard used, but it is possible. For example, using the EPC standard, there are basically various kinds of labels: read-only, writing and multiple readings or read-write.

Data security

In recent generations of RFID devices it is possible to encrypt the data, so that they cannot be read with standard RFID readers.

Costs

In fall 2008 as the latest technological advances were applied. The objective of a few years ago to achieve the € 0.05 per label seems increasingly close, but obviously depends on the type of label.

Standards

There are different standards universally accepted, and related to the frequency band used. The two main standards are the standard EPC Global and ISO standard.

Lifetime

Because there is no need for physical contact or batteries, the lifetime of the passive tags are long. The active tags have a limited lifespan due to its battery life.

Size

Overall, the size varies from the size of a button or caramel to the size of a pack of snuff. However, Hitachi recently announced its muchip, an RFID chip technology with 2.4 GHz and a size of 0.4 x 0.4 mm with a thickness of 0.06 mm.

11 http://www.ceditec.etsit.upm.es/dmdocuments/CITIC%20RFID%20Salud.pdf (41.04.2008)

Distance reading

The passive tags have a range of the order of meters, and active can have a range of tens of meters. In addition, to make reading or writing need not be a direct line of sight.

Number of items that can be read simultaneously

A reader can read hundreds of tags almost simultaneously. Currently readers can only read tags of the same branch, unless they are approved by EPC Global.

Possibility of interference

Depending on the frequency, liquids, wood or metal can prevent the spread of the signals.

A SWOT analysis of RFID can be found in Appendix - SWOT ANALYSIS

Applications[12]:

The main feature of RFID technology is the ability to identify, locate, track or monitor people or objects without need for direct line of sight between the tag and reader. Around this feature have emerged a wide variety of applications perfectly adaptable to a wide range of industrial sectors.

- Transportation and distribution.
  - Tracking assets.
  - Systems location in real time.
- Packaging articles.
  - Managing the supply chain.
  - Follow-up boxes and pallets.
  - Inventory and stocks.
- Industry and manufacturing.
  - Workflow.
- Security and access control.
  - Management passports and visas.
  - Tracking children, animal or baggage.
  - Prevention of counterfeiting.
  - Identification of employees.
  - Access to laboratories, parking, enclosures, etc...
  - Tolls.

12 http://www.rfidc.com/docs/introductiontorfid_technology.htm (20.05.2008)

- Payments automatic.
- Recognition of customers.

• Monitoring and sensing.

- Pressure, temperature, volume and weight.
- Application of location.

• Systems library.

- Access and management of all types of objects.

NFC: Near Field Communication[13,14,15,16]

Near Field Communication or NFC, is a short-range high frequency wireless communication technology which enables the exchange of data between devices over about a decimeter distance. The technology NFC (Near Field Communications) offers new functionality to the RFID technology itself, thanks to the combination of a label and an RFID reader in a single device. This facilitates two-way communication between two devices can act both as a broadcaster and as a receiver. The NFC technology breaks by both the functional separation between the reader and the RFID tag.

The NFC technology is particularly useful applied to mobile devices (phones, PDAs), allowing the user carries on his mobile terminal plus an RFID tag with your data (or information required for each application), a reader to read information from other labels. This will complement communication over short, medium and long distance provided by mobile devices (Bluetooth, Wi-Fi, GPRS, UMTS) to communication at very short range (centimeters) provided by NFC.

NFC emerged in 2002 as a result of cooperation between Philips, Sony, Nokia and thereafter. This is a standard ISO, ECMA and ETSI working in the band HF frequency (13.56MHz) and therefore with a range of coverage small (<10cm).

NFC is not designed to transmit large volumes of data, but rather to exchange information quickly, efficiently and safely. Like the rest of RFID technology, the protocol covers the NFC modes of operation assets and liabilities (passive and active).

The choice of tag to use depend on the type of application is required.

13 http://en.wikipedia.org/wiki/Near_Field_Communication (24.03.2008)
14 http://www.nfc-forum.org/home (24.03.2008)
15 http://embedded-system.net/lang/es/adoption-of-nfcrfidcontactless-smart-card-in-mobile-phones-by-nxp-and-sony.html (24.03.2008)
16 http://www.ceditec.etsit.upm.es/dmdocuments/CITIC%20RFID%20Salud.pdf (24.03.2008)

NFC is especially useful in its application to means of payment, although it is trying to introduce in transport applications, access control settings or even in health and health care.
In the area of health, technology NFC offers interesting application scenarios, especially in the management of patients suffering from chronic illnesses and requires regular monitoring. In this sense, NFC offers patients the opportunity to access systems monitoring in the home. The measuring equipment equipped with NFC technology communicates with the mobile patient, which sends the information collected to the health centre. This process of self-management ensures the provision of appropriate treatment and upgradable in real time, depending on the patient, a quality especially useful in the case of chronic diseases.

Another significant opportunity might arise in caring for patients, allowing health professionals caring for patients who are in their homes. The same is true for home visits, in which the practitioner, who performs the visit, can, read patient information and manage the impact on services or appropriate treatments.

Finally progress and implementation of the electronic prescriptions allow for the purchase of medicines directly from the mobile phone NFC.

The future of this technology is still uncertain. Although currently there are some experiences in this respect and pilots, still are inadequate to show the market potential of this technology[17].

RFID and NFC/HF

The advantage of NFC compared to HF tags is the fact that NFC can use the same tags and readers as the UHF system. The only change will be the antenna. However, when using HF tags in combination with UHF tags, different tags and readers must be installed.

Bar codes (1D and 2D)

Bar codes have been used for several years and it is a mature technology with a high penetration in the market.

A barcode (also bar code) is a machine-readable representation of information (usually dark ink on a light background to create high and low reflectance which is converted to 1s and 0s). Originally, barcodes stored data in the widths and spacing's of printed parallel lines, but today they also come in patterns of dots, concentric circles, and text codes hidden within images. Barcodes can be read by optical scanners called barcode readers or scanned from an image by special software. In this way, Barcodes make possible to recognize quickly a product all over the supply chain and mange the

inventory or consult its associated characteristics. Barcodes are widely used to implement Auto Identification and Data Capture (AIDC) systems that improve the speed and accuracy of computer data entry. [18]

One of the biggest advantages, compared to other AIDC methods, is that it is less expensive to implement. It costs about US$0.005 to print a barcode compared to a passive RFID which still costs about US$0.07 to US$0.30 per tag. But Barcodes presents some other advantages apart from the easy implementation like huge development of the technology or the availability of the products. However, the Barcodes have some limitations as the impossibility of reading some codes simultaneously, or the limited amount of storage space. Furthermore a line of sight between the code and the reader is needed.

When a bar code scanner is passed over the bar code, the light source from the scanner is absorbed by the dark bars and is reflected by the light spaces. A photocell detector in the scanner receives the reflected light and converts the light into an electrical signal. As the wand is passed over the bar code, the scanner creates a low electrical signal for the spaces (reflected light) and a high electrical signal for the bars (nothing is reflected). The duration of the electrical signal determines wide vs. narrow elements. This signal can be "decoded" by the bar code readers' decoder into the characters that the bar code represents. The decoded data is then passed to the computer in a traditional data format.[19]

Although the technology is the same for all types of barcodes a distinction between three different types of Barcodes could be done:

- Linear Barcode
- 2D Barcode
- Matrix Barcode

Lineal Barcodes

Figure 5 - Conventional 1D barcode (Code 39)

Figure 5 - Conventional 1D barcode (Code 39) shows a conventional linear barcode. It has a single row of bars- similar to a picket fence. The barcode is called 'one dimensional' because all the data is

18 http://en.wikipedia.org/wiki/Barcode (24.03.2008)
19 http://www.barcodehq.com (24.03.2008)

encoded in the horizontal width. Increasing the data content can only be achieved by increasing the width. Beyond a certain point the barcode becomes too wide to scan easily.

These are the conventional barcodes. Widely used in the last years, nowadays they can be found on almost every product. As explained before they are a representation of dark ink on a light background of widths and spacing of printed parallel lines. Inside this code is codified the information. Its reading can be done by LED scanners or lasers.

Figure 6 - Bar Code Structure, http://www.barcodehq.com (24.03.2008)

The most important characteristics of the 1D codes are:

- Possibility of modify the data: impossible, once data is printed on the label.
- Security of the data: easy to copy.
- Amount of data storage: 128 characters maximum.
- Cost: very low, only printing costs.
- Standards: although there are more than 200 formats of Barcodes in use, there are four dominant types: UPC/EAN, Interleaved 2-of-5, 39 Code and 128 code, all of them are supported by the International Standardization Organization (ISO).
- Lifetime: very short, its printed information tends to disappear with time.
- Readability distance: the system needs a physical line of sight between the code and the reader, because of that the distance must be short.
- Number of elements able to be read simultaneously: only one.

- Possible harm of interferences between the systems: barcodes do not usually include protection against this kind of errors and physical harms in the label could make the reading impossible. Moreover, the system is sensitive to dust and dirt.

2D Barcodes

2D means 'two dimensional'. 2D barcodes contain more information than conventional one dimensional linear barcodes. Conventional barcodes get wider as more data is encoded. 2D barcodes make use of the vertical dimension to include more data. 2D barcodes have become possible as auto scanning CCD and laser scanners have replaced the original 'light pen' type of scanner. At this time most conventional CCD and Laser scanners cannot read 2D barcodes but this is likely to change with the first generation of low cost combined 1D/2D scanners.[20]

What do 2D barcodes look like?[21]

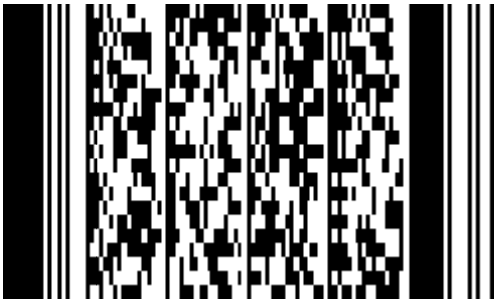


Figure 7 - 2D Barcode (PDF417)

Figure 7 - 2D Barcode (PDF417) shows a PDF417 two dimensional barcode, the most common 2D barcode standard. Data is encoded in both the horizontal and vertical dimensions. As more data is encoded the size of the barcode can be increased in both the horizontal and vertical directions thus maintaining a manageable shape for easy scanning.

Mainly, 1D and 2D are very similar in all its characteristics but those are the most obvious differences:

- Security of data: 2D codes use checksum by Reed-Salomon code, with this system the information on a destroyed label could still be recovered.
- Amount of data: 1Kbyte maximum.
- Cost: very low, when changing from 1D to 2D codes only the programme of the printers has to be changed.

20 http://www.barcodehq.com (24.03.2008)
21 http://www.barcodeman.com/faq/2d.php (24.03.2008)

- Standards: PDF417 is an ISO standard.
- Possible harm of interferences between the systems: better in reading errors compared to 1D codes, although big amounts of dust or dirt can destroy the code completely.

Matrix Codes

This codes are made of simple elements (dots or squares) building a 2D model.

While traditionally barcode encode schemes represented only numbers, newer symbologies add new characters such as the uppercase alphabet to the complete ASCII character set, and beyond. The request to encode more information in combination with the space requirements of simple barcodes led to the development of matrix codes (a type of 2D barcode), which do not consist of bars but rather a grid of square cells. Stacked barcodes are a compromise between true 2D barcodes and linear codes (also known as 1D barcodes), and are formed by taking a traditional linear symbology and placing it in an envelope that allows multiple rows.[22]

The most important differences compared to conventional barcode are:

- Cost: higher than simple 2D codes.
- Standards: there are different standards, but the most important are: Data Matrix, QR codes and MaxiCode.
- Security of data: 2D codes use checksum by Reed-Salomon code, with this system the information on a destroyed label could still be recovered.
- Amount of data: 1Kbyte maximum.

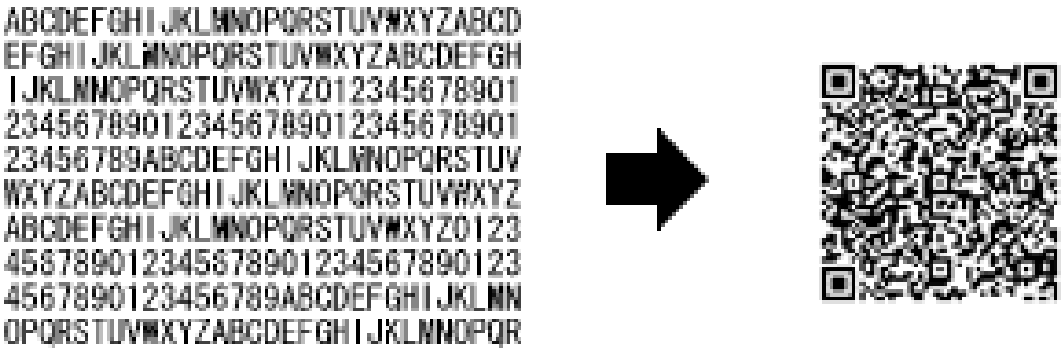


Figure 8 - QR code, www.QR_Code.com

Readers

1D codes are optimized to be read by a laser scanner, which sweeps a beam of light across the barcode in a straight line, reading a slice of the bar code light-dark patterns. Imaging does not require

22 http://en.wikipedia.org/wiki/Barcode (24.03.2008)

moving parts, like a laser scanner does. In 2007, linear imaging is surpassing laser scanning as the preferred scan engine for its performance and durability.

2-D codes cannot be read by a laser as there is typically no sweep pattern that can encompass the entire symbol. They must be scanned by a camera capture device.

Nowadays most of the scanners can read 1D and 2D codes with the same device. It is possible to purchase readers which can read both 1D and 2D codes and RFID tags.

Comparison between 1D & 2D barcodes

Will 2D barcodes replace conventional 1D barcodes?

No. Both technologies will co-exist. 2D barcodes will be used where 1D barcodes cannot hold the necessary amount of data but 1D barcodes have the advantage in low capacity applications like serial numbers.

When are 1D barcodes better than 2D?

Although 1D barcodes hold a smaller amount of data it is 'spread' over the whole height of the barcode. The barcode contains a high degree of redundancy. This means the barcode can be read even with considerable degradation. If your application needs only a few characters (up to about 15) then a 1D barcode is probably the best solution. Increasing the height of a 1D barcode does not increase its capacity but it does increase its redundancy thus making it more resistant to degradation and obliteration and making it easier to scan.

Advantages of Barcodes

In point-of-sale management, the use of barcodes can provide very detailed up-to-date information on key aspects of the business, enabling decisions to be made much more quickly and with more confidence. For example:

- Fast-selling items can be identified quickly and automatically reordered to meet consumer demand,
- Slow-selling items can be identified, preventing a build-up of unwanted stock,
- The effects of repositioning a given product within a store can be monitored, allowing fast-moving more profitable items to occupy the best space,
- Historical data can be used to predict seasonal fluctuations very accurately.

- Items may be repriced on the shelf to reflect both sale prices and price increases.

Besides sales and inventory tracking, barcodes are very useful in shipping/receiving/tracking.

- When a manufacturer packs a box with any given item, a Unique Indentifying Number (UID) can be assigned to the box.
- A relational database can be created to relate the UID to relevant information about the box; such as order number, items packed, qty packed, final destination, etc…
- The information can be transmitted through a communication system such as Electronic Data Interchange (EDI) so the retailer has the information about a shipment before it arrives.
- Tracking results when shipments are sent to a Distribution Center (DC) before being forwarded to the final destination.
- When the shipment gets to the final destination, the UID gets scanned, and the store knows where the order came from, what's inside the box, and how much to pay the manufacturer.

The reason bar codes are business friendly is that bar code scanners are relatively low cost and extremely accurate – only about 1/100,000 entries will be wrong.

Comparison between Bar codes & RFID[23]

Advantages of RFID versus Barcodes

RFID tags and barcodes both carry information about products. However, there are important differences between these two technologies:

- Barcode readers require a direct line of sight to the printed barcode; RFID readers do not require a direct line of sight to either active RFID tags or passive RFID tags.
- RFID tags can be read at much greater distances; an RFID reader can pull information from a tag at distances up to 300 feet. The range to read a barcode is much less, typically no more than fifteen feet.
- RFID readers can interrogate, or read, RFID tags much faster; read rates of forty or more tags per second are possible. Reading barcodes is much more time-consuming; due to the fact that a direct line of sight is required, if the items are not properly oriented to the reader it may take seconds to read an individual tag. Barcode readers usually take a half-second or more to successfully complete a read.

23 www.europen.com.br/html_new/download/SATO-rfid-forum-aim-04.pdf (24.03.2008)

- Line of sight requirements also limit the ruggedness of barcodes as well as the reusability of barcodes. (Since line of sight is required for barcodes, the printed barcode must be exposed on the outside of the product, where it is subject to greater wear and tear.) RFID tags are typically more rugged, since the electronic components are better protected in a plastic cover. RFID tags can also be implanted within the product itself, guaranteeing greater ruggedness and reusability.

- Barcodes have no read/write capability; that is, you cannot add to the information written on a printed barcode. RFID tags, however, can be read/write devices; the RFID reader can communicate with the tag, and alter as much of the information as the tag design will allow.

Advantages of Barcodes versus RFID

- RFID tags are typically more expensive than barcodes, in some cases, much more so.

- Nowadays the barcode technology is more extended than RFID one, which causes a inertia in the companies of continue using barcodes.

- Technological problems not still solved in RFID technology, like 100% readability, reading liquid products, interferences with other RF, different standards.

- Costs of changing the actual majority technology to another one.

- In most of the cases there is no a real needing of change the technology (see business case).

PATIENT PRIVACY CONCERNS

New technologies often scare the public, especially the older generation. When it comes to RFID, the society is scared that even more personal information will be shown in public. Comments reach from the idea that every product in the fridge continuously sends out information which is available for everyone to comments about keeping track on persons shopping behaviour.

Almost every country has a personal data secure regulation which states who is allowed access to any requested information. This regulation also covers the data which is obtained via RFID.

The issue with RFID is the question about the "ownership" of the newly obtained data. To address this question, RFIDsec[24] tries to find different solutions to deal with this topic. It is not possible to have a general solution for this new technology as it is used for different applications, e.g. a drug manufacturer has different privacy concerns compared to the end customer buying the drug in a pharmacy.

An idea for the end customer would be that when purchasing the drug in a pharmacy, the ownership of the tag changes from the pharmacy to the customer. The customer will be asked who is allowed to have access to the information on the tag, e.g. doctor, pharmacy and hospital. This information will be stored on the global database and every time someone tries to access information from the tag, the database will check if the person or company is allowed or not.

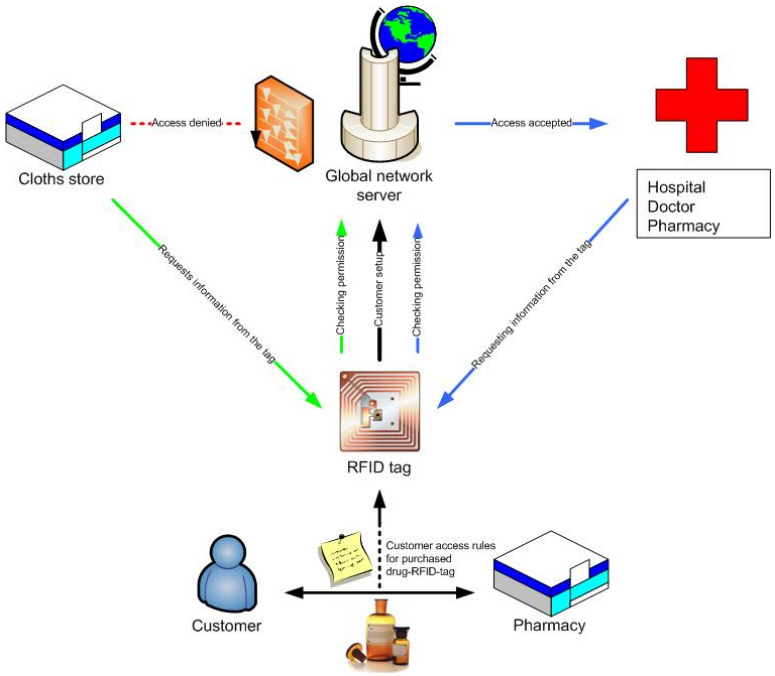


Figure 9 - RFID tag information authorization (own creation)

24 http://www.rfidsec.com/solutions/index.html (10.05.2008)

PHARMACEUTICAL INDUSTRY

U.S. Food and Drug Administration (FDA)

The information in this section is based on the latest Task Force report of the FDA which is currently available. The Task Force report is written in June 2006[25]. The recommendations given in this section are recommendations of the FDA.

The status of electronic track and trace across the drug supply chain

In 2004 the Task Force report stated that adoption and widespread use of reliable track and trace technology is feasible by 2007. This should help secure the integrity of the supply chain by providing an accurate drug "e-pedigree," an electronic record documenting that the drug was manufactured and distributed under secure conditions. It was noted that RFID is the most promising technology to meet this need.

In 2006 research was done on the progress of the e-pedigree. Most comments agreed that it was necessary to adopt mass serialization with unique identifiers on each package as an important step to facilitate e-pedigree, while some comments stated that it is not needed. A majority of the comments stated that although widespread use of e-pedigree is not far off, it is hard to predict when that might happen or set a new timetable or a new target date. It was suggested that the FDA should set a specific date by which all products must have an e-pedigree to stimulate the adoption of an e-pedigree.

It was proven that complete adoption of an e-pedigree by the end of 2007 was unrealistic even though stakeholders in the drug supply chain thought it was a realistic goal.

The progress of the use of RFID on drug product packages

Current obstacles to wider adoption of RFID technology on product packages are:

- A lack of standards (for e-pedigree fields and format, data systems, international transmission standards, and hardware specifications);
- Privacy concerns;
- Concerns about the ownership of confidential business transaction data;
- Challenges in serializing all products;
- Concerns over the accuracy and speed of electronic devices and systems; and
- A lack of definitive data to determine how RFID will affect sensitive products (e.g., liquids, biologics).

25 http://www.fda.gov/oc/initiatives/counterfeit/report6_06.html (05.04.2008)

Many comments stated that it is not possible to predict or estimate a timetable for widespread adoption of RFID, or stated that widespread RFID adoption is at least many years away. Some comments estimated that it will take up to 10 years. Many comments suggested that technical issues (e.g., adoption of standards, product/software development) would need to be settled before a more accurate timetable could be estimated.

Recommendation by the FDA:

- *We recommend that stakeholders work cooperatively to continue to expeditiously implement widespread use of electronic pedigrees across the drug supply chain.*
- *We recommend that FDA provide technical assistance if legislation related to electronic pedigrees is considered in Congress.*

The FDA is disappointed with the lack of overall progress across the drug supply chain. In the 2004 Task Force Report, laid out milestones and goals for RFID implementation based on credible information that stakeholders gave. Many of these milestones have not been met.

Recommendation by the FDA:

- *We recommend that stakeholders continue moving forward in implementing RFID across the drug supply chain.*
- *We recommend that stakeholders consider a phased-in approach, placing RFID tags on products most vulnerable to counterfeiting and diversion as a first step.*
- *We recommend that FDA remain committed to facilitating RFID implementation and working with stakeholders, standards organizations, and others.*

Mass serialization

Mass serialization involves the incorporation of a unique identifier number on each drug package in order to track the individual drug package as it moves through the drug supply chain. Comments recommended that industry use a single numbering convention to reduce costs and complexity. One comment noted that multiple numbering schemes could lead to conflicts (e.g., duplicate numbers for the same item) and incompatibility between points in the distribution chain. Using random numbers for the product identification component of the electronic product code (EPC) could increase security, while concealing proprietary information about the product or manufacturer. However it was also stated that EPC should include the manufacturer ID as part of the code.

It is suggested that the national drug code (NDC) should be included in the EPC as the information systems currently identify products by using the NDC and significant costs might incur to change

these systems if they used an EPC that did not include the NDC. It was also noted that the NDC plays an important role in the dispensing process and it would be disruptive to workflow to have to consult another database to link the EPC number to the NDC number.

Recommendation by the FDA:

- *We recommend that the NDC number should continue to be closely associated with the product.*
- *We recommend that for non-line-of-sight technology, such as RFID, the unique identifier for the product should either include an encrypted NDC number or an accessible link to the NDC number to protect privacy.*

"Turning Off" the RFID Tag

Some people have suggested that the RFID tag should be "turned off" or deactivated before it leaves the pharmacy, or that patients should be given the choice of whether it is "turned off".

Deactivating or removing the RFID tag when purchasing a product would address privacy concerns on the other hand, it may also prevent post-sale benefits (e.g., recalls) which would have been possible had the tag remained active/in place.

Some pharmacy groups agreed that the tag should be deactivated prior to arrival at the pharmacy retailer to ensure that no patient is inadvertently sent home with an active tag. It was also mentioned that in practice, deactivating the tag at the point of sale is not feasible because it would place too much responsibility on pharmacists.

Recommendation by the FDA:

- *We recognize that this is an important issue, but do not have sufficient information to make a recommendation at this time.*

European Commission (EC)

The information given in this section is based on EC's "Public consultation in preparation of a legal proposal to combat counterfeit medicines for human use. Key ideas for better protection of patients against the risk of counterfeit medicines" (Brussels 11.03.2008)[26]

The European Commission has observed some worrying trends within the medical industry

26 http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2008/2008_03/consult_counterfeit_20080307.pdf (24.03.2008)

- A sharp increase in seized counterfeit medicines
- A trend towards counterfeiting of life-saving drugs
- A trend towards targeting the classical supply chain

The EC states that some reasons for these trends might be:

- Certain deficiencies in supply chain integrity, as there is uncertainty as to whether certain participants in the distribution chain are subject to pharmaceutical legislation (e.g. brokers, traders, business-to-business platforms)
- Lack of transparency for economic operators as to whether wholesalers and other actors in the distribution chain comply with Good Distribution Practice (GDP)
- Certain shortcomings in product integrity, especially when packs are opened for repackaging and changed for relabelling purposes
- Difficulties in conducting targeted recalls, in particular in the case of counterfeit products

The different Member States start taking different actions to prevent counterfeit medicine. Different methods might lead to compatibility problems in the international market. Furthermore this might lead to different levels of protection of public health and safety. This could result in that counterfeiters focus on targeting Member States with a lower level of protection.

Key ideas for better protection of patients against counterfeit medicine

The EC has identified three areas of regulation of medicinal product where improvements could make a difference against counterfeit medicine:

- Medicinal products placed on the market (traceability, product integrity, and distribution chain)
- Medicinal products brought into the Community without being placed on the market (import/export and transit)
- Active ingredients supplied to the manufacturer of medicinal products placed on the market

To protect the legal supply chain against counterfeiting the Commission is e.g. considering improving product integrity and traceability and increase transparency.

In order to improve the above mentioned considerations, the EC suggests some “Key ideas for changes to EC legislation submitted for public consultation”.

Improved product integrity:

- *"Require the outer packaging of medicinal products to be sealed. This would reveal any subsequent opening of the packs. The right to opening the outer packaging would be restricted to the market authorisation holder and end-user (hospital, health care professional, or patient)."*

Improve product traceability:

- *"Require the possibility of tracing ownership and transactions of a specific batch. This should be achieved by making a specific record (pedigree) obligatory. The record should be accessible by all actors in the distribution chain."*
- *"Require the possibility to trace each pack and perform authenticity checks. This could be attained by a mass serialisation feature on the outer packaging. Technical details would be further defined in implementing legislation and/or by standardisation organisations."*

Increase transparency:

- *"Establish a Community database of wholesalers (including distributing manufacturers) documenting GDP compliance. This could be achieved via extension of the EudraGMP database." (Good Manufacturing Practice)*

  See EPCglobal, page 39

RFID[27]

Both the Commission and the pharmaceutical industry consider that RFID technology has great potential to increase the quality of care and patient safety and to improve both compliance with EU law and logistics in the supply chain. The use of RFID in hospitals and health care should be researched.

In July 2007 a more specific study on the requirements for actions in RFID in healthcare was ordered by the Commission. Based on the outcome of this study, the EC will make new proposals for large-scale, effective and secure implementation of RFID in EU. Currently the EU is co-funding e.g. the BRIDGE project for the RFID research.

The Commission clearly favours RFID technology but the industry prefers the 2D Matrix Bar Code solution. It is important to create a harmonised European system rapidly, in order to keep the costs and complexity of implementing such a system to the minimum.

27 http://www.whitecase.com/files/Publication/6ea615f4-cff9-46f0-8aed-64bf3434b773/Presentation/PublicationAttachment/d5a9128b-3625-4185-8b2c-6c02f683e622/article_TrackingandTracing_v2.pdf (24.03.2008)

Reason why the pharmaceutical industry favours the 2D Matrix Bar Code is the fact that even though the industry acknowledges RFID as one of the best solutions to secure the supply chain, it does not seem mature enough.

Due to the need of a single system for the identification of pharmaceutical products, the European Federation of Pharmaceutical Industries and Associations (EFPIA) has launched an initiative for a 2D Data Matrix Bar Code system. Four different data will be encoded into a matrix:

- Identification of the manufacturer with its products (e.g. Global Trade Identification Number)
- Product-unique serial number for each products pack
- Batch/lot number
- Product expiry date

Additionally this information will be saved in a database system which can be accessed by the main stakeholders in the pharmaceutical supply chain.

GS1 THE GLOBAL BUSINESS LANGUAGE

The creation of GS1[28] and its members

The healthcare system is, as all current market, characterized by a globalisation since almost all the actors of that system are located and work in a global environment.

As a result, the definition of a global standard is needed. Indeed, without standards, business processes would be very complex, especially for companies that manufacture products from a large number of components coming from different places or a company that distribute its products in different places in the world.

Standards are the solution for clear and understandable exchanges between companies and for keeping costs low for everyone.

All those considerations trigger the creation of GS1 organism in 2005 which gather 104 associations and stand for 150 countries. GS1 corresponds to the alliance of the European standard EAN (European Article Numbering) and the American standard UCC (Uniform Code Council).

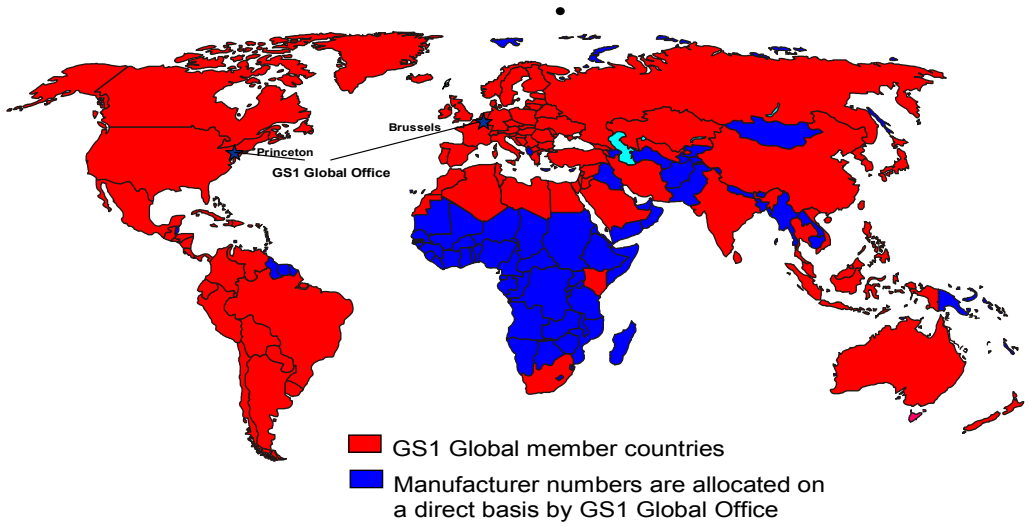


Figure 10 - GS1 Working together around the world

28 http://www.gs1.org/

The aim of GS1

GS1 standards provide a framework that allows products, services, and information about them to move efficiently for the benefit of businesses and the improvement of people's lives, everyday, everywhere.

GS1 enable all companies representing all parts of the supply chain to work together under the leadership of GS1 to create standards.

Concerning the healthcare system, GS1 aims to help the right patient to get the right medicine at the right dose in the right way at the right time.

The different standards developed by GS1:

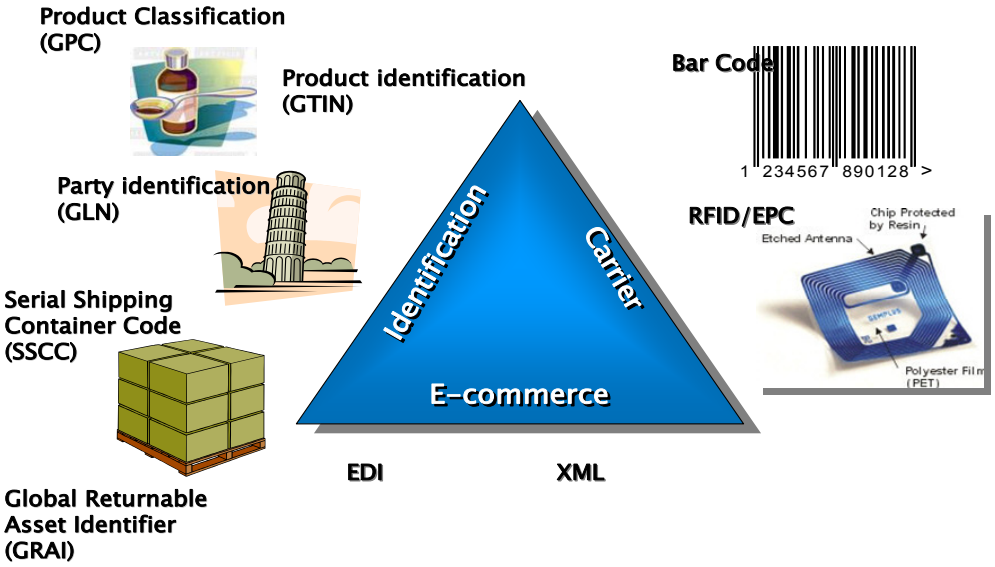


Figure 11 - *The GS1 toolbox*

The different standards of identification are:

- GTIN (Global Trade Item Number): This identification answers the question WHAT? In a bar code, this standard enables to define a product in general but not a unique product. A serial number is needed to identify each unique item.
- GLN (Global Location Number): This identification answers WHERE the product is? For the identification of physical locations and legal entities.
- SSCC (Serial Shipper Container Code): This code identifies each pallet/ship/box… by a unique number. Its structure enables to guarantee a worldwide unique number.

The different carriers used for those standards are:

- The bar codes that exist in different format, such as EAN-13, EAN-14, EAN-128 etc.
  Some of them such as EAN-128, are too big for a little drug box.
- RFID tags.

The use of all those codes and standards globally defined needs the development of services accessible for companies. Those services are:

- LE@N for the use of the Web and the EDI (Electronic Data Interchange).
- GEPIP who owns EAN identity number. Companies can have access to the different items and the different choice of packaging.
- Almost 260 Danish companies use it today.
- GLNDAS (GLN Data Alignment Service) for the all the location researches about an item.

EPCGLOBAL[29]

EAN International and the UCC (Uniform Code Council) formed EPCglobal Inc™- an open, worldwide, not-for-profit consortium of supply chain partners working to driver global adoption of the EPCglobal Network.

EPCglobal's aim the common use of technology based on Electronic Product Code (EPC) between companies in global scale. The organization's goal is increased visibility and efficiency throughout the supply chain and higher quality information flow between companies and their key trading partners.

EPCglobal Network is a combination of two technologies: Radio Frequency Identification (RFID) and the Internet, which allows tracing every product with an EPC tag in the whole supply chain in real time. As a result, it will provide a pedigree of product movement. EPCglobal Network ensure access for companies to global and open standards by using GS1 identification standards (saved in EPC tags), and also access to all information saved on it via the Internet.

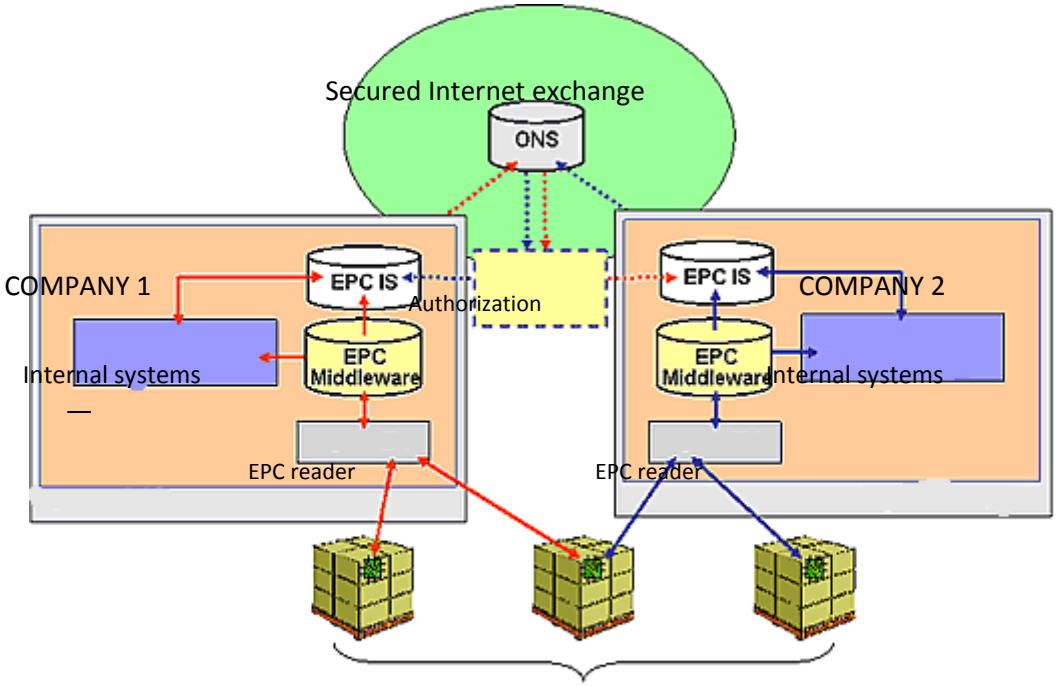


Figure 12 - How information is going between companies within EPCglobal Network system. Based on figure from (14.05.08): http://www.epcglobal.pl/index.php?id=35

29 All information is from: The EPCglobal Network™: Overview of Design, Benefits, & Security (released 27.10.04) .pdf version: http://www.epcglobalinc.org/about/media_centre/Network_Security_Final.pdf

There are five components of the EPCglobal Network:

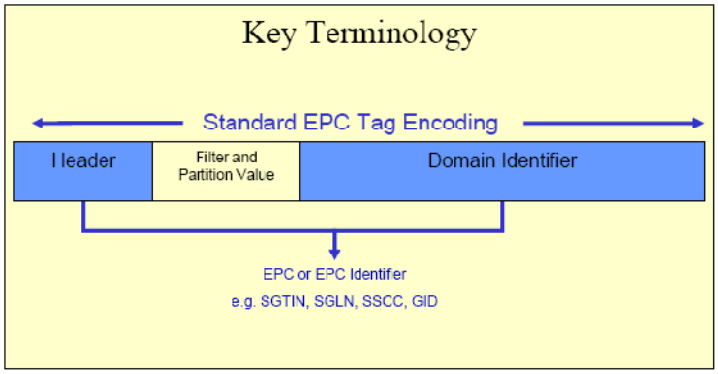
ELEMENT	DESCRIPTION
Electronic Product Code	Unique number that identifies a specific object in motion in the supply chain.
ID system	The ID System consists of EPC tags and EPC readers. EPC tags are RFID devices that consist of a microchip and an antenna attached to a substrate. The EPC is stored on this tag, which is applied to cases, pallets and/or items. EPC tags communicate their EPCs to EPC readers using RFID. EPC readers communicate with EPC tags via radio waves and deliver information to local business information systems using EPC Middleware.
EPC Middleware	EPC Middleware manages real-time read events and information, provides alerts, and manages the basic read information for communication to EPC Information Services (EPC IS) and a company's other existing information systems.
Discovery Services	A suite of services that enable users to find data related to a specific EPC and to request access to that data. Object Naming Service (ONS) is one component of Discovery Services.
EPC Information Services	Enables users to exchange EPC-related data with trading partners through the EPCglobal Network.

Tabel 3 - EPCglobal Network Components, downloaded from: The EPCglobal Network™: Overview of Design, Benefits, & Security (released 27.10.04) pdf version: http://www.epcglobalinc.org/about/media_centre/Network_Security_Final.pdf

EPC tags

As mentioned, EPCglobal Network is a combination of two technologies: Internet and RFID. To use a common database it is necessary to have an Electronic Product Code (EPC) as an identification scheme for universally identifying physical objects. EPC is a unique way to identify each single product and is written on the EPC tag according to the standards.

The EPC is a meta-coding scheme designed to support the needs of various industries. The various coding schemes are referred to as Domain Identifiers, to indicate that they provide object identification within certain domains such as a particular industry or group of industries[30].



30 Description and drawing .pdf file of: EPCglobal Tag Data Standards Version 1.3 Ratified Specification March 8, 2006

EPC specific coding schemes include (for version: EPC Version 1.3):

- the General Identifier (GID),
- the EAN.UCC Global Trade Item Number(GTIN®) - serialized version,
- the EAN.UCC Serial Shipping Container Code (SSCC®),
- the EAN.UCC Global Location Number (GLN®),
- the EAN.UCC Global Returnable Asset Identifier (GRAI®),
- the EAN.UCC Global Individual Asset Identifier (GIAI®),
- the DOD Construct.

See GS1 The Global business language page 36

Benefits of the EPCglobal Network

The EPCglobal Network gives three main advantages to product identification in the supply chain.

- The creation of a unique number for individual objects in motion in the global supply chain.
- The removal of line of sight requirement for reading product identification numbers. An EPC reader instantly detects all EPC tags passing through its radio frequency field.
- A network of information that provides real-time object movement data for individual items to authorized and authenticated users.

The most important advantage for the healthcare and pharmaceutical sector is the possibility of proving a product pedigree. This allows the protection of medicines against counterfeit, monitor conditions of transport, check position and status (i.e. “delivered to...”) of product in the whole supply chain, save manpower and time for reading tags which provide to decreasing transaction cost. The e-pedigree of medicines is also required by the American regulation on their market, so products with EPC tag attached are appropriate.

Implementations of EPCglobal Network: current situation

The implementation and adoption of the EPCglobal Network is still in its early stages. Utilization of the EPCglobal Network in the supply chain is occurring gradually with a phased approach to implementation that begins in the Fast Moving Consumer Goods (FMCG) industry at the pallet and case level, not the item level. Phasing provides the necessary time for the business community and solution providers to learn about the network and the technology, and to establish the necessary standards.

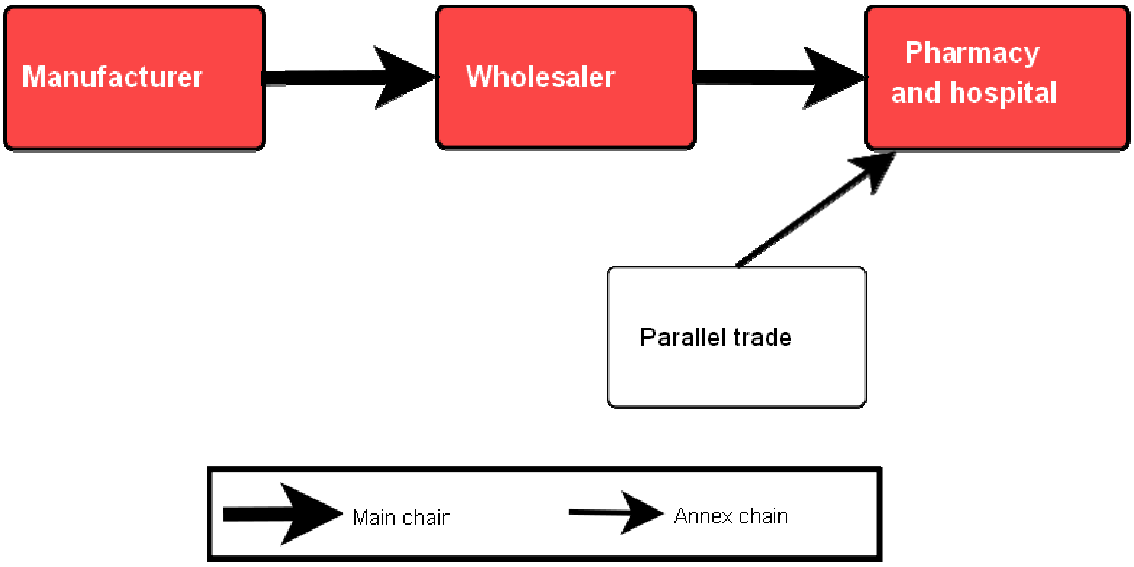
To date, numerous industries are researching and beginning to implement components of the EPCglobal Network whose standards have been developed and approved by the EPCglobal community (i.e., the EPC, EPC tags and EPC readers). Companies, in the Fast Moving Consumer Goods industry, are pilot-testing these network components on the pallet and case level.

THE DANISH MARKET

The Danish supply chain

The Danish pharmaceutical market is very small and it is made up of a limited number of actors.

Thus, this supply chain is very simple and its organisation can be represented by this scheme.



The main chain is made up of 3 parts.

First, the manufacturer produces the different drugs.

Then the wholesaler makes the link between the manufacturers and the pharmacies, or the hospitals, packaging the drugs and managing the different orders.

There are just 3 wholesalers in Denmark: KV Tjellesen, Max Jenna and Nomeco which is the most important within the market.

Finally, the pharmacies and hospitals provide the patients by drugs they need.

The medicine agency is regulating all the Danish supply chain, defining all the products that can be sold and their prices. Thus, it is very difficult to enter in this supply chain if you are not allowed to.

The parallel trade is present within the Danish supply chain but its access to it is much controlled. Thus, according to Helle Jacobsgaard, a member of the association of Danish Pharmacies we met, the parallel trade is not a disturbing problem for the security of the Danish supply chain.

General overview by NNE Pharmaplan

NNE Pharmaplan is the world's leading engineering and consulting company focused exclusively on the pharma and biotech industries.

They cover the entire pharmaceutical supply chain, from product development to manufacturing. Their services include consulting, engineering, construction, validation and complete solutions for automation, clean rooms, and modular and turnkey facilities.

They not only help their clients build facilities, but also help them analyse their production plans and advise them on business-critical decisions.

NNE Pharmaplan is headquartered in Copenhagen, Denmark; employs over 1,500 people at more than 20 locations around the world.

NNE Pharmaplan is a fully independent subsidiary of the healthcare company Novo Nordisk A/S. In 2006, prior to acquiring Pharmaplan, NNE's turnover was DKK 1.174 million (EUR 157.52 million).[31]

Contact person at NNE Pharmaplan

Carsten Holm Pedersen
Senior Automation Engineer, Automation Solution Architects MSc Eng.

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General overview

RFID is a new technology without any real application – no Danish company is using it for the moment. The Danish pharmaceutical supply chain is very simple and short. There is a low risk of counterfeiting. In the manufacturing processes, the production chain is characterized by a constant change of storage conditions and of format packaging. So RFID could be used for those specified parts of the supply chain enabling to track the temperature and other storage conditions of the product. RFID could be implemented in each case only for some parts of chain or even process. The costs of implementing this technology are still too high to apply it in general.

Using 2D bar codes is a future for Denmark and Europe. This kind of bar codes can store much more information and fills less space on labels and packages. Additionally, scanners which are used for 1D codes, could be used for 2D codes as well. Printing on label is also cheaper than adding a tag.

31 http://www.nnepharmaplan.com/np/en/About-us/NNE-Pharmaplan-in-brief/ (06.05.2008)

It might be that EPCglobal will use 2D codes for their system as well. Then everyone will have access to the data base and it will be much easier to prove e-pedigree for the American market, where it is required.

Although a lot of companies are interested in this technology, its development, predictable benefits - without any governmental obligations or any law regulations RFID will not be implemented into the European market in the nearest years.

DANISH CASE STUDIES

Novo Nordisk

Novo Nordisk is a healthcare company and a world leader in diabetes care. In addition, Novo Nordisk has a leading position within areas such as haemostasis management, growth hormone therapy and hormone replacement therapy.

Novo Nordisk manufactures and markets pharmaceutical products and services that make a significant difference to patients, the medical profession and society.

With headquarters in Denmark, Novo Nordisk employs approximately 26,000 employees in 79 countries, and markets its products in 180 countries.

Contact person at Novo Nordisk

Ole Wulff

OW@nnepharmaplan.com

The contact to Ole Wulff was established via Carsten Holm Pedersen who is working for NNE-Pharmaplan and who we met Thursday 13th of March 2008.

Ole Wulff send a very long e-mail[32], in Danish, explaining the process of implementing bar-codes and testing RFID tags at Novo Nordisk. On Thursday 15th of May 2008 a meeting at NNE-Pharmaplan with Ole Wulff took place for a deeper explanation of RFID within NovoNordisk

ID technology

Approximately thirteen years ago, Novo Nordisk started to introduce bar-codes in their production line. It started in a small amount and to avoid that this technology should run in several directions; a standard had to be developed. This standard described in details how and where those bar-codes should be used. The standard is based on the EAN-128 code. This code offers a variety of information such as batch and product number, serial number, expiry date, quality status etc.

32 Appendix - Mails information, Ole Wulff, NNE Pharmaplan / NovoNordisk

After six to seven years of the implementation of bar-codes, the technology was spread all over Novo Nordisk and was also supported by MES (Manufacturing Execution System) systems in the production as well as the global ERP (Enterprise Resource Planning) systems.

With the EAN-128 bar-code, data can be reused between the single systems even though they are not directly linked together. When a product is received at the warehouse system and a bar-code is attached, e.g. the batch number can be used by the underlying production systems even though there is no direct connection to it. Subsequent new data can be added directly into the general ERP systems via the bar-code.

Current testing

Ole Wulff is responsible for any kind of AutoID technology at Novo Nordisk and due to this he also followed the development of RFID. As WallMart (USA) started to demand that their suppliers should attach RFID tags on every product, Novo Nordisk started to focus even more on RFID. One of the reasons why Novo Nordisk tried to avoid RFID, is an almost 100% implantation of bar-codes at their company and because a cost/benefit analysis did not show the advantages of RFID.

Approximately three years ago, Novo Nordisk started a pilot project to test the opportunities of RFID within the company. At that time Danish Technological Institute and a number of suppliers such as Siemens, Intermec and IBM was supporting the project. The biggest issue at that time was that both the equipment and the tags to the EPC (Gen1 tags) were only prototypes and only available in such a small amount that Novo Nordisk could not purchase them. However, opening experiments, which showed that the readability of the tags, within the company environment, would give problems *(tags which were placed at some drug boxes which included several hundreds of capped vial filled with insulin and additionally where stabled as 2x44 boxes).* It was decided to wait for the Generation2 of the EPC-tags. As RoHS directive (Restriction of Hazardous Substances) started in the EU, the new equipment run out of stock and Novo Nordisk had to wait for the new products (primary scanners) again.

Last summer the new scanners and tags (Generation2) finally were available. Fast tests showed that previous problems with the readability were solved and therefore it was decided to start the pilot project again. Intermec who earlier worked together with Novo Nordisk changed its structure. Therefore IDZone became the new partner. The tags will be purchased from TagSYS. It was decided to test both UHF EPC2 tags, due to the existing standard, and HF tag (13.56 MHz) as these can be used to scan a single capped vial.

The reason for those tests is the counterfeit issue but also the fact that it appears to become the future technology on the US marked in connection with the e-pedigree.

The pilot project will run until summer 2008 and the results will show what RFID can be used to at Novo Nordisk and what future projects should be started.

Ole Wulffs concerns about the implementation of RFID:

- There are already 1000 bar-code readers implemented in NovoNordisk worldwide. It would be difficult and it would take several years before a complete implementation of RFID readers.
- There are still no agreements between all the countries concerning the way to put and to use the data stored in the EPC Global Network.
- A lot of pilot projects are going on today and have been developed so far but the current results are not clear enough to make sure that RFID can be used.
- If an RFID tag is faulty, it can not be read, whereas a faulty bar code is acceptable.

Ole Wulffs positive aspects of RFID Technology:

- Thanks to RFID and the EPC, every product can have its own code. With the different standards of bar coding, the amount of possible codes is limited.
- It is more difficult to copy an RFID tag than a bar code, so RFID could be a more secure technology. It is not possible to encrypt data into a 1D or 2D barcode.

The implementation of 2D bar codes is not so difficult, since it is based on the same technology as 1D bar code and needs almost the same equipment.

It is still hard to find enough reasons to implement RFID in a pharmaceutical company to justify the extra costs. Ole Wulff believes that RFID will be the future but that an implementation most likely will be forced through governmental law regulations.

LEO Pharma

LEO Pharma was established in 1908 by chemists August Kongsted and Anton Pedersen as Københavns Løveapoteks Kemiske Fabrik in the basement of the Copenhagen LEO Pharmacy. The ownership of the company in its entirety was transferred to the LEO Foundation in 1986.

The Foundation is an independent, private institution with the objective to further develop the position of LEO Pharma as an independent, pharmaceutical group of companies with its own research, development, manufacturing, distribution, sales and marketing.

The objective of LEO Pharma is to discover, develop, manufacture and market efficiency and innovative drugs on the basis of substantial and growing earnings. By 2010, LEO Pharma will be the world's leading pharmaceutical company within dermatology based on innovative and efficacious products and associated services.

LEO Pharma is headquartered in Denmark (Ballerup) since 1908. They employ more than 3,000 people in 40 countries and have market for their products in 90 countries; i.e. in: Morocco, Latin America, Canada, Algeria, Saudi Arabia, Spain, UK, France, Germany, Scandinavia, Austria, Greece, Asia.[33]

Contact person at LEO Pharma

Steen Winther
Director Logistics

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+45 4492 3800

Searching and selecting companies suitable for our project LEO Pharma seemed the right choice. The contact with LEO Pharma was established via a phone call and followed by an e-mail. A meeting with Steen was agreed on Wednesday, 9th of April 2008 in LEO Pharma headquarters on *Industriparken 55, DK-2750 Ballerup.*

Current solutions

LEO Pharma uses a unique printed number and internal IP system, which make all data traceable. The internal IP data system is working in a clear production/supply chain.

33 http://www.leo-pharma.com/41256A68003EB2EE/sysOakFil/Image%20Brochure/$File/Image_Brochure.pdf 29.05.2008

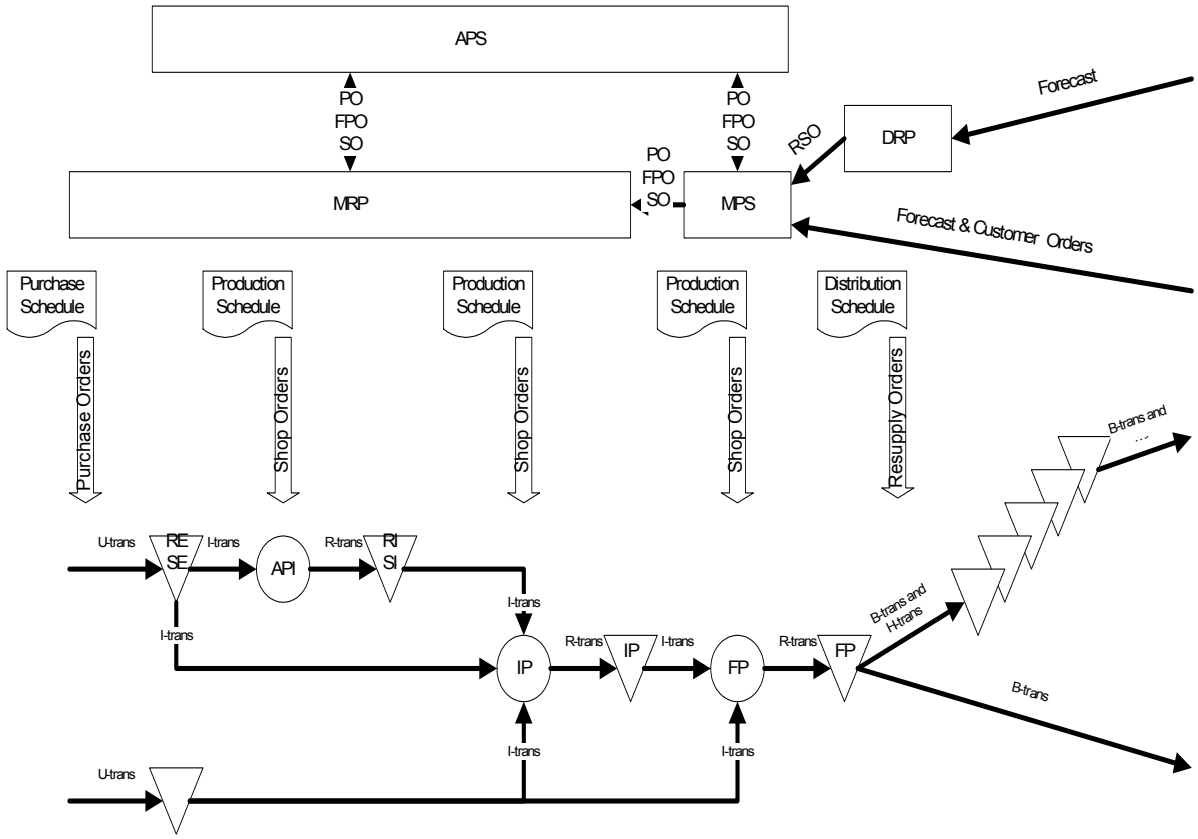


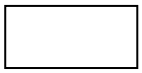
Figure 13 - LEO Pharma's Supply Chain Model (created by LEO Pharma)

Production Processes:

Picking materials up

Process, operation

Administration Processes:



Process, acting

Document, data saving

Distribution Resource Planning(DRP) depends on forecasts and as well as customer orders influences on Master Production Scheduling(MPS). MPS and APS (Advanced Production Scheduling) give information about material requirements (MRP – Material Requirements Planning). Then according to purchase, production and distribution schedules – the whole process is going. Materials are picked up, intermediate items are produced and then final products are distributed.

34 Descriptions of symbols translated from: (07.05.2008)
http://www.ipo.pl/zarzadzanie_w_firmie/jakosc/narzedzia_jakosci_-_mapowanie_procesow_592703.html

LEO Pharma is aware of the threat of counterfeit medicine. For their company, the most desired product would be some kind of penicillin. However, no issues of counterfeit products have been recorded on the Danish market yet.

The transportation and transportation conditions are important issues in pharmaceutical industry. LEO Pharma is outsourcing this part of the production chain. By checking via audits and inspections, the quality of the companies is controlled. LEO uses Lot numbers to allow constant access to monitor the condition parameters (temperature, etc.) in cooperation with checking points. Leopharma has only a few products which need it e.g. temperature control.

Future plans

LEO Pharma plans to implement 2D data matrix codes for products due to European standards – identification number and 2Dcode. 2D codes can include more information compared to 1D codes and is enough to prove e-pedigree on American market, which require that.

Nomeco

Nomeco is Denmark's largest pharmaceutical wholesaler and an international competency center for the pharmaceutical industry.

Nomeco specializes in health logistics. They ensure that the Danish population always has timely access to pharmaceuticals.

This goal is realized via a value adding partnership with pharmacies and the pharmaceutical industry. Nomeco is undergoing constant development in close contact with the market and authorities. This development rests on a solid base of knowledge and values.

Nomeco is a Danish company deeply rooted in the pharmaceutical industry while at the same time being part of an international organization

Nomeco uses VMI. VMI is an abbreviation of Vendor Managed Inventory. The VMI department ensures the day to day operation of VMI, as well as the daily contact with those pharmacies that are a part of this agreement. Nomeco is responsible for handling the pharmacy's orders, so that the ordering of goods happens automatically based on electronic exchange of the pharmacies sales and stock figures.

Contact person at Nomeco

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Market Development Manager

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+45 3614 2255

Claus Faurschou Larsen
Market Developer

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+45 3614 2117

The contact to Kasper Lund-Jacobsen was established via Karin Siegumfeldt. As he was very busy it was agreed to send an e-mail with questions and after receiving the answers to have a telephone interview. Anyhow, this process was exchanged with a company meeting Wednesday 23rd of April 2008 at *Nomeco, Borgmester Christiansens Gade 40, 1790 København V*.

ID technology

Nomeco uses 1D barcodes, EAN-13 for all their processes *(see Figure 14 - Nomeco's process, own creation)*. They receive a product from the manufacturer, add their own EAN-13 code and place it on a storage shelf. After some time, the product is sorted on a different shelf which is connected to the line where employees fill blue boxes with different products. In this shelf, the product gets a new EAN-13 number. When a blue box for a pharmacy has to be packed, an employee finds the product on the shelf and packs it into a blue box. Another EAN-13 code is added to the box and set ready for transport. When the blue boxes containing drugs for the pharmacies leave Nomeco, there is no tracking information. Nomeco also does not receive any information if or when the blue boxes arrive at the pharmacy.

Sometimes medicine might be returned from the pharmacy to Nomeco as there is no need at the pharmacy. In this case, the returned drug receives another EAN-13 code and the process starts all over again.

The reason why Nomeco uses this standard is because they have simple processes with little information. However the use of several EAN-13 numbers is a clear disadvantage.

Problems with the current ID-technology and possible solutions

As mentioned, the use of several EAN-13 codes is a clear disadvantage. If every product from the very beginning at the manufacturer would have a unique product code (e.g. EPC) which would be on an RFID or 2D code, it would no longer be necessary to add several codes during the processes at Nomeco. Additionally it would be much easier to find a product which was returned by the pharmacy and put it on the right shelves at Nomeco.

Another issue for Nomeco is the fact that after the product is distributed from Nomeco there is no track and trace information as well as there is no information about if and when the product was received at the pharmacy. If an RFID tag would be placed on the blue boxes that go out to the pharmacies and a scanner would be placed both at the transporter and the receiving point at the pharmacy, Nomeco could get information about the delivery process. To make this process work, a common database is needed which both the pharmacy and Nomeco can access. The EPC Global Network could be the right solution to this process.

Future plans

Nomeco plans to add 2D data matrix codes for the veterinarian products due to governmental requirements about including batch number and expiry date on every veterinarian product. 2D data matrix codes can store more information compared to a 1d bar code system. Additionally the 2D data matrix code system fills less space on the product.

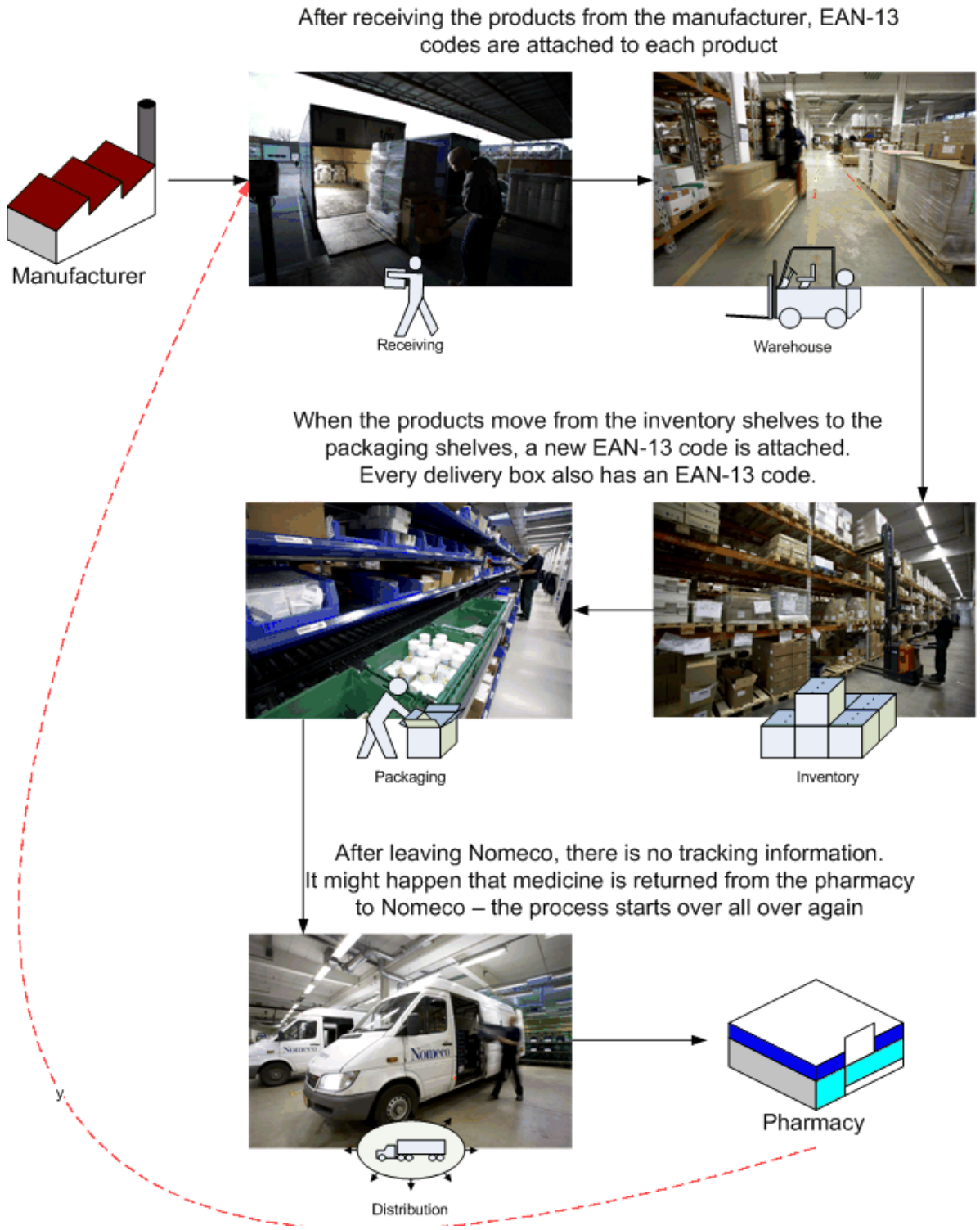


Figure 14 - Nomeco's process, own creation

Association of Danish Pharmacies

Description of the association

It is the employer and professional organisation of the Danish pharmacies. The 252 members of the Association are all proprietor pharmacists in Denmark.

Contact person at Nomeco

Helle Jacobsgaard

Specialkonsulent

hj@apotekerforeningen.dk

A meeting on Wednesday 9th of April with Helle Jacobsgaard was established via e-mail contact. The meeting took place at Danmarks Apotekerforening, Bredgade 54, 1017 Kbh K.

The current ID technology used in Danish pharmacies:

The technology used for all the medicines that the pharmacists receive is printed 1D bar code, which respects European standards (EAN-13).

This technology enables a good inventory management; for instance, the orders are made automatically when a medicine is out of stock.

Indeed, more and more pharmacies have implemented robots which by dint of bar codes can automatically find the right medicines for a patient and which enable to order the products that are out of stock.

Three numbers are manipulated for each product:

- A batch number
- A bar code
- A product number

The pharmacists are not planning any changes in the ID technology they use to identify each product since it would be too expensive to implement other technologies that are not useful for the moment.

However, some problems where underlined.

Problems with the current ID technology and possible solutions:

The unsecured Internet market where people cannot really define from where the products bought are can be a problem for the patient safety.

The definition of an E-pedigree for each product and the use of more efficient ID technologies could be a good initiative for some products particularly exposed to counterfeiting such as Viagra® or expensive drugs that can lead to an important turnover loss, such as Insulin.

Conclusion (Danish market)

Currently only Nomeco considers the use of RFID for internal use. No other company on the Danish market could be found which either uses or plans to use RFID technology. No problem with counterfeit medicine has been reported in Denmark yet and the supply chain is very simple and hard to enter. The price of this new technology and a lack of information is the reason for a strong defensive position to this topic. Few pilot projects have been started but the fact that the progress on the US market is slower than expected made that some projects were cancelled and the few remaining are progressing rather slow. Every member of the Danish pharmaceutical supply chain agrees on that an implementation of RFID seems only possible if any law regulations require this technology. There is no doubt about that UHF RFID tags will work well on pallet level to reduce time but on item level RFID seems rather unlikely within the next 10 years.

THE INTERNATIONAL MARKET

The American Pharmaceutical Supply Chain

The description of the American pharmaceutical supply chain is based on The Health Strategies Consultancy LLC's report "Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain" [35] March 2005.

The general supply chain is very simple. A manufacturer produces a certain drug which is send to a wholesaler. The wholesaler then distributes the drug to a pharmacy where the patient will purchase the needed medicine.

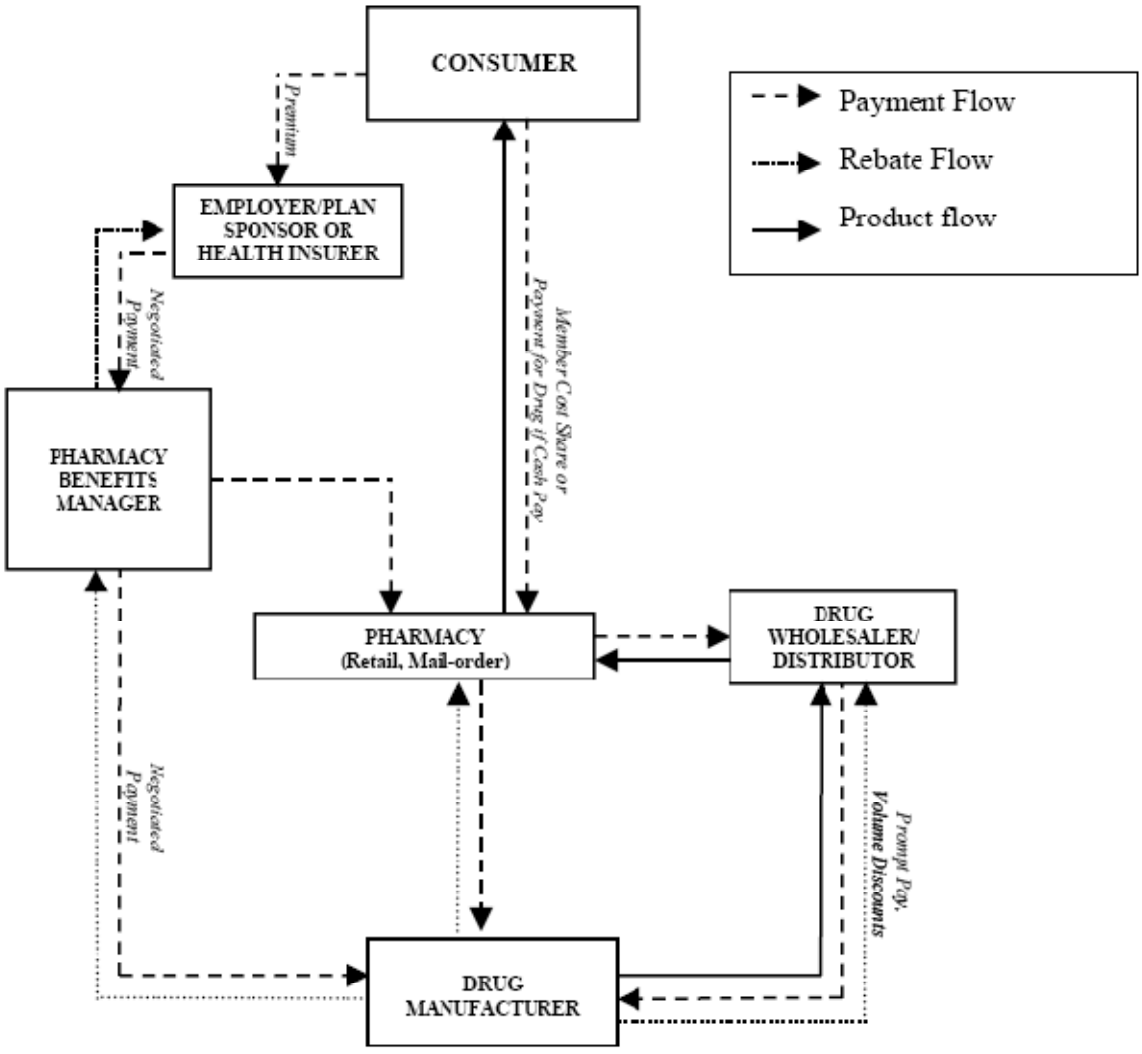


Figure 15 - Flow of Goods and Financial Transactions Among Players in the U.S. (http://www.kff.org/rxdrugs/upload/Follow-The-Pill-Understanding-the-U-S-Commercial-Pharmaceutical-Supply-Chain-Report.pdf)

35 http://www.kff.org/rxdrugs/upload/Follow-The-Pill-Understanding-the-U-S-Commercial-Pharmaceutical-Supply-Chain-Report.pdf (10.05.2008)

Pharmaceutical Manufacturers

Manufacturers are the source of the prescription drugs in the pharmaceutical supply chain. The pharmaceutical manufacturing industry is composed of two distinct business models: manufacturers of brand-name drugs (e.g., Pfizer, Merck, and Novartis) and manufacturers of generic drugs (e.g., Mylan, Roxane, and Barr). There are a few pharmaceutical companies that participate in both the branded and generic parts of the industry, and both models focus on the manufacturing and packaging of pharmaceutical products, but there are other important differences. Most brand manufacturers devote a portion of their expenses to the scientific research and development of new drug therapies. Generic drug manufacturers typically do not develop new drug therapies, but instead manufacture generic compounds that compete directly with the original branded version of a drug once the brand product's patent protection has expired.

Manufacturers also play an important role in ensuring the safety of the pharmaceutical supply chain by producing informational labelling for prescribers and consumers that is approved by the U.S. Food and Drug Administration (FDA).

In 2004 the top-10 multinational pharmaceutical companies accounted for almost 60%. In 2003 the U.S. represents the largest single national market for pharmaceuticals, accounting for 44 percent of global industry sales.

Rank	Corporation	U.S. Sales ($ Billions)	% Growth Over Previous Year	% Market Share
1	Pfizer	$30.7	5	13.1
2	GlaxoSmithKline	18.8	1	8.0
3	Johnson & Johnson	16.2	7	6.9
4	Merck & Co.	15.0	8	6.4
5	AstraZeneca	11.3	12	4.8
6	Novartis	10.2	7	4.3
7	Sanofi-Aventis	10.0	13	4.3
8	Amgen	9.5	23	4.1
9	Bristol-Myers Squibb	9.2	-4	3.9
10	Wyeth	8.2	11	3.5
	Total, Top 10	139.1	--	59.3

Tabel 4 - Top-10 Pharmaceutical Manufacturers (http://www.kff.org/rxdrugs/upload/Follow-The-Pill-Understanding-the-U-S-Commercial-Pharmaceutical-Supply-Chain-Report.pdf)

Wholesalers

The wholesale distribution industry has gone through significant change and consolidation in the last 30 years, due in part to the increasing pressures to lower costs. Between 1975 and 2000, the number

of wholesale distributors in the U.S. declined from approximately 200 to fewer than 50. The top three wholesale distributors, McKesson, Cardinal Health, and Amerisource-Bergen, account for almost 90 percent of the entire wholesale drug market.

Pharmacies

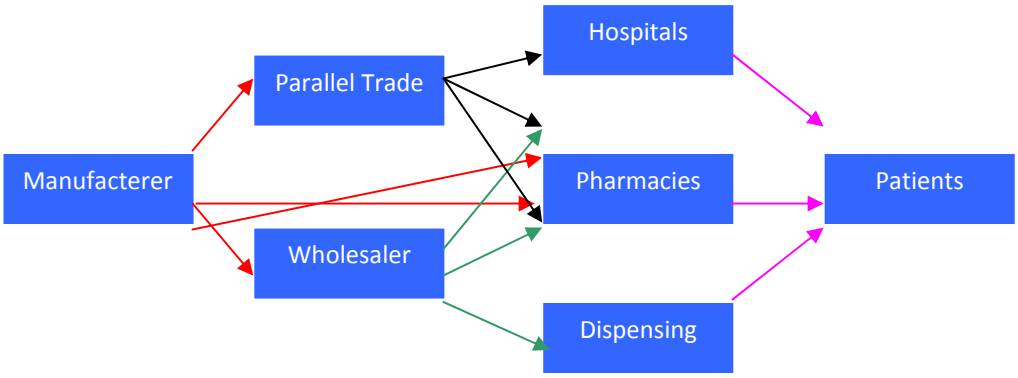
There are several types of pharmacies, including independent pharmacies, chain drug stores, pharmacies in supermarkets and other large retail establishments, and mail-order pharmacies. Most pharmacies purchase their drug supply from a wholesale distributor, although in some cases, large institutional and retail chain pharmacies, specialty pharmacies, and mail-order pharmacies obtain drugs directly from a manufacturer. These organizations can deal directly with manufacturers because they already possess the operational infrastructure necessary to bypass wholesalers – warehousing facilities, distribution vehicles, and inventory control systems. Once a pharmacy takes possession of the drug products, it distributes the products to physicians or directly to consumers. In addition, there are specialty pharmacies, which specialize in the distribution of high-cost and more complex drug therapies (e.g., self-injectable drugs and biologics). As the final actor in the supply chain, it is up to the pharmacy to take action based on the information provided. For example, the pharmacy is expected to contact the prescribing physician if the drug prescribed is not on the patient's health plan's formulary or if a lower-cost therapeutic alternative is available.

Specialty pharmacies	serve patients with chronic diseases by dispensing highcost biotechnology drugs. Specialty pharmaceuticals typically are administered by injection or infusion (intravenously), and often, are administered by a clinical professional in a doctor's office.
Mail-order pharmacies	receive prescriptions by mail, fax, phone, or Internet at a central location; process the prescription in large, mostly automated centers; and mail the prescribed drugs back to the consumer.
Institutional pharmacies	are a third type of specialized retail pharmacy. institutional pharmacies address the special needs of nursing homes, providing packaging for controlled administration (called unit-dose supply or bubble packs), and special services that are more extensive than those provided by retail pharmacies.

Tabel 5 - Overview of different types of pharmacies in the U.S. (self created)

The British Pharmaceutical Supply Chain

The UK pharmaceutical industry does not differ too much from the rest of the supply chains. It has the typical structure of manufacturers, wholesalers (include parallel trade associations) and pharmacies (public and private ones).



The total UK market for pharmaceuticals was worth an estimated £13.65bn in 2007.[36] The UK is home to the most important pharmaceutical industry in Europe in terms of development and marketing. In 2006, the industry exported £13.8bn worth of medicines and showed a trade surplus of £4.3bn. The UK market is also one of the most cost-effective in Europe and, arguably, the world. Since 2005, the introduction of a new Pharmaceutical Price Regulation Scheme (PPRS) and the wider use of generic products have brought a reduction in per capita expenditure on medicines by the NHS.

Europe, and the UK in particular, provide a strong market for medicines and have traditionally been important sites for drug-related R&D.

The UK industry operates within a highly regulated environment. The way in which it undertakes research, produces, licenses and markets its products are all subject to a detailed regulatory system.[37]

Making a comparison between simple markets like the Danish one and UK market, it can be noticed that the standard actors of the market (manufacturer, wholesaler and pharmacies) have a different role e.g. the manufactures can sell directly to the pharmacies.

Manufacturer

The drugs are produced by a very large and successful industry. It employs 83,000 people directly and many more indirectly, and makes a huge contribution to the balance of trade each year. Overall, the

36 http://www.pr-inside.com/ageing-population-to-keep-the-uk-r542641.htm (22.05.2008)
37"The Influence of the Pharmaceutical Industry" of House of Commons Health Committee

industry represents the country's third most profitable economic activity, after tourism and finance. It is of great importance to the UK economy.

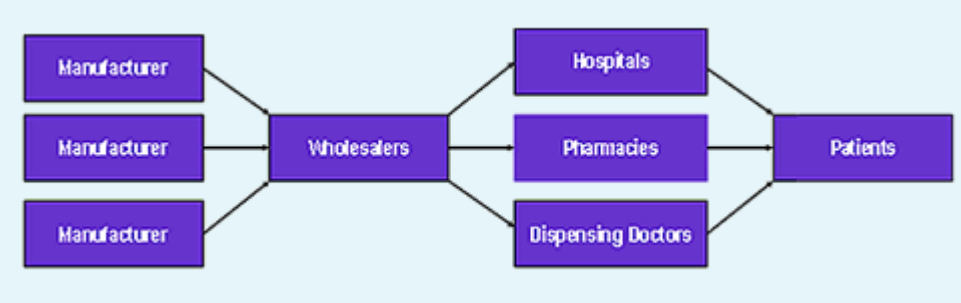
The traditional model of pharmaceutical supply chain in Europe is under threat as major pharmaceutical manufacturers in the UK attempt to change the way they distribute their products. The adoption of a Direct-to-pharmacy (DTP) model by some of the industry's most powerful players in the UK signifies a new trend that could spread across Europe.

The report comes in the wake of Pfizer's decision to use a single distributor to supply pharmacies with its products on a fee-for-service basis. Pfizer's rational for this system was that closer control of the supply chain would minimize the opportunities for counterfeit products to reach patients. Since then, AstraZeneca has said that it will work with just two distributors starting in February.

Wholesaler[38]

Wholesalers are a vital part of the supply chain which sees medicines delivered quickly and safely to patients. The British wholesalers are represented in the British Association of Pharmaceutical Wholesalers (BAPW) which is the trade association for an essential part of the medicines supply chain - wholesalers.

Pharmaceutical wholesalers supply medicines to doctors, pharmacists and hospitals, making sure that patients don't have to go without vital drugs by making deliveries across the country, up to four times a day.



Wholesalers act as the link between manufacturers and doctors, pharmacists and hospitals, taking delivery of medicines; storing them safely and securely until they are needed by customers; then delivering them, as required, quickly and efficiently to wherever they are needed by patients. But full-line wholesalers don't just provide a simple supply service:

- They stock the entire range of 20,000 licensed medicines, ready for dispatch at any time.

38 www.bapw.net/about_pharmaceutical_wholesaling.php (22.05.2008)

- They operate around the clock, around the year.
- They provide around half of all the computer equipment used in pharmacies.
- They offer banking, merchandising and business development advice to pharmacists.

In some countries, elements of full-line pharmaceutical wholesaling are viewed (pharmaceutical full-line wholesalers are the central element of the healthcare supply chain, around which the legally required guaranteed availability of medicines via pharmacies to the general public revolves) as a public service and receive state subsidies, although in the UK this is not the case. Wholesalers buy most of the medicines they supply direct from manufacturers to meet the demands of the customer - the NHS.

Pharmacies

Traditionally, the United Kingdom has had a number of medicines wholesalers who compete for business with pharmacies. While some of them have the same owners, there remain a healthy number of independent pharmacists who are free to choose which wholesaler they deal with. If drug companies tie up supply with specific wholesalers, these independents may now have to deal with several different distributors in order to get all the supplies they need. [39]

The historical system involves pharmaceutical companies offering their drugs to wholesalers at a discount from the list price at which it is reimbursed under the Pharmaceutical Price Reimbursement Scheme (PPRS). This discount is typically 12.5 percent. The drugs will then be offered by the wholesalers to the pharmacy, again at a discount from the list price, normally about 10.5 percent, with that two-percentage-point difference representing the wholesaler's profit margin. The pharmacy is reimbursed by NHS, which then claws back some of its profits. In effect, this means that NHS pays less than list price for meds. But the UK Government is studying the possibility of reduce the range of wholesalers for the drugs companies. This could change the traditional operation of the UK market.

If the discounts offered by wholesalers are cut—as could happen if the pharmaceutical companies limit the number of suppliers they work with and therefore competition is reduced—then the profits the pharmacists make drop. And, thus, NHS would end up paying more for medicines—OFT (Office of Fair Trading) estimates that each percentage-point reduction in discount would cost NHS £50 million.[40]

39 http://pharmexec.findpharma.com/pharmexec/Global+Report/Wholesale-Change-UK-Responds-to-the-Single-Supplie/ArticleStandard/Article/detail/490701 (19.05.2008)
40 http://www.pr-inside.com/ageing-population-to-keep-the-uk-r542641.htm (19.05.2008)

The French Pharmaceutical Supply Chain

The pharmaceutical sector used to be much protected from foreign companies and external entities. Nevertheless, a lot of barriers are disappearing and today this supply chain is more complex and is dominated by foreign companies.

Organisation of the supply chain in France:

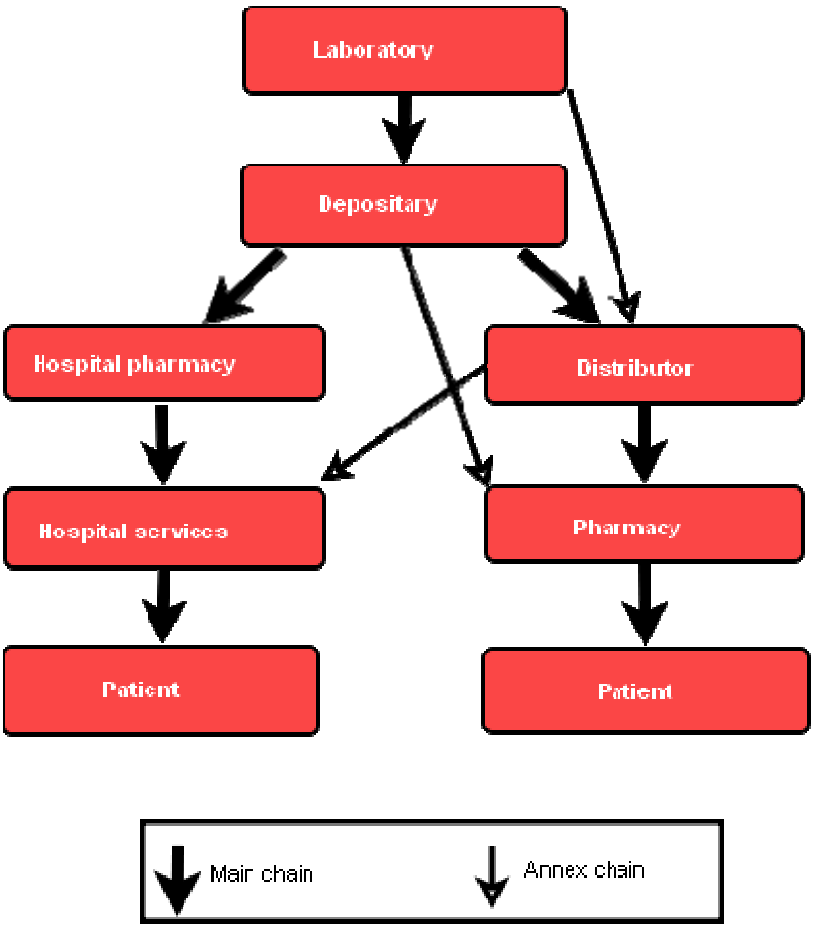


Figure 16 - *French Supply Chain*[41]

Manufacturer (laboratories)

Laboratories focus on selling drugs. The manufacturing activity is contracted out with subsidiary companies or independent laboratories; and the order preparation activity is managed by pharmaceutical depositaries.

The international competition is going more and more important concerning this part of the supply chain.

Wholesaler (depositaries)

41 http://ameliorezvotreswinglogistique.hautetfort.com/files/avenirdistrib.pdf (17.05.2008)

The pharmaceutical depositaries provide services such as storage of products, selling administration, preparation and distribution of orders.

Distributor

The pharmaceutical distributors are those who buy medicines from laboratories to sell them back to pharmacies. The pharmacies have the choice between different distributors. However, because of a growing competition, the government decided to regulate this part of the supply chain which will rapidly be represented by only 2 or 3 distributors.

The main links in the French supply chain are representing by the large pointers in the Figure 16 - *French Supply Chain***.**

The laboratories manufacture drugs. Then, the logistic of those drugs are managed by the depositary who distributes the products to distributors in one side and to hospitals in the other side. Finally, the distributor has to provide pharmacists with all the products they need and hospitals is able to provide services and drugs to the patient.

Figure 16 - *French Supply Chain* also underlined some annex links between the different actors of the French supply chain.

The distributors can provide the hospitals for emergency cases.

Moreover, the depositary can directly provide the pharmacies for important orders.

Finally, the laboratories tend to use depositaries for the providing of hospital and can provide the distributors directly to have a better storage and order control.

France is relatively protected against the problem of counterfeiting because of a controlled and regulated structure of the supply chain. However, due to the evolution of the annex links, counterfeit medicine could become an increasing.

Parallel trade associations

The traditional way for the drugs to arrive to the hospitals, pharmacies and doctors is through the wholesalers but there is another alternative way, the parallel trade associations. This consists basically on buying goods abroad, normally at a cheap price, and selling them in another country for a higher price.

Parallel trade is on the verge of breaking its confines of the EU and diffusing into other global markets. This global practice is far from simple, and the loopholes that have made it possible refuse to close. Whether parallel trade is considered as a benefit or a cost, the reality is that it is affecting the whole pharmaceutical industry on a wide scale. The European Commission and other trade regulation bodies do not have any law concerning this trade.

Although consumers may think that imported drugs into their country come from Canada, UK, or other Western European nations, it is impossible to definitively verify an imported drug's country of origin. For the moment, the system has to believe in the association’s tests. And until now, there have not been many scandals.

Patients who have to pay less for drugs, general practitioners, healthcare agencies and national governments are all benefiting from this gray market import. However, there are actual 'real' winners in this trade, parallel traders themselves. They gain the most benefit from such a trade, which is profit. On the other hand, pharmaceutical companies are blaming parallel trade, for huge losses in revenue, which affects a decreased innovation level. Parallel trade is seen for them as a gateway for counterfeit drugs entering the supply chain.

The latest case of counterfeit drugs entering the UK supply chain was that of Eli Lilly's antipsychotic drug, Zyprexa and Sanofi-Aventis and Bristol Myers Squibb's Plavix. Three batches were recalled by the MHRA.

Parallel Trade acts as an important driving force for market integration where there are important differences in price between member states. And also can collaborate to the unification of laws, standards and production conditions.

INTERNATIONAL CASE STUDIES

Pfizer

Pfizer Incorporated is a major pharmaceutical manufacturer, which ranks number one in the world in sales.

The company is based in New York City, but it is implemented internationally and has R&D labs in different locations such as France, England, and Japan. While Pfizer colleagues at each center employ unique technologies to focus on site-specific functions and therapeutic areas, together they comprise an integrated global network of discovery and development. Global databases and streamlined distribution work to create a synergy of ideas, tools, and expertise.

Pfizer is organized into four divisions: Human Health, Consumer Healthcare, Animal Health and Corporate Group. They commit their selves to deliver the value their patients and consumers need and their shareholders deserve focusing on continually improving the way they do business; on operating with transparency in everything they do; and on listening to the views of all of the people involved in health care decisions.

Contact person at Pfizer France:

The French R&D site of Amboise was contacted and a phone interview with Philippe Roux who explained the implementation of RFID in Pfizer was established.

ID Technology:

Since 2005 Pfizer uses RFID Technology to fight Viagra fakes, a drug which is a major target for counterfeiters.

The drug maker has integrated a tag application and verification process for Viagra sold in the Unites States, which is their main market (3 million bottles produced each year for USA in the site of Amboise). As each bottle of Viagra moves down the packaging line, a label with an integrated *Tagsys* passive high-frequency (13, 56 MHz) tag is applied. The first RFID reader then encodes an EPC to each label and the second one verifies that the tag has been successfully encoded and can be easily read. The reader also reads the unique ID number stored on the tag's chip by the chip's manufacturer, enabling Pfizer to record both the chip ID and the item's EPC in the database. Pharmacists and wholesalers will use the tags to authenticate the drug.

Pfizer is also tagging the stock-keeping items of Viagra at the case and pallet levels, using Ultra High frequency tags from *Alien Technology* for authentication purposes.

Glaxo Smith Kline

GSK is one of the few pharmaceutical companies researching both medicines and vaccines for the World Health Organisation's three priority diseases (HIV/AIDS, tuberculosis and malaria), and are very proud to have developed some of the leading global medicines in these fields.

Headquartered in the UK and with operations based in the US, they are one of the industry leaders, with an estimated seven per cent of the world's pharmaceutical market.

This means that they have a significant responsibility and they have to care about the impact they have on people.

They produce medicines that treat six major diseases areas – asthma, virus control, infections, mental health, diabetes and digestive conditions. In addition, they are a leader in the important area of vaccines and are developing new treatments for cancer.[42]

Pilot project

In 2006, GSK begun to distribute a medicine tagged with radio frequency identification (RFID) technology as part of a pilot project.

The tags were placed on all bottles of Trizivir® (an HIV medicine) distributed in the United States. This specific medicine was selected for the project because it has been listed by the National Association of Boards of Pharmacy as one of 32 drugs most susceptible to counterfeiting and diversion.

As one of the first pharmaceutical companies to test RFID, GSK is working closely with the FDA to assess the technology and its prospects for reducing counterfeiting. The project has cost several million dollars.

Why could RFID be useful?

This pilot project was launched to find the best technology that could help protecting patient safety. Moreover, the U.S. Food and Drug Administration (FDA) has asked the pharmaceutical industry to develop standards and pilot processes for RFID that may lead in the next few years to broad adoption and use of the technology.

A technology that enables to track and trace

RFID uses a tiny chip and antenna attached to each bottle of medicine. The chip stores a unique product code that reflects information about the drug's manufacturing and shipping history. The

42 http://www.gsk.com/media/pressreleases/2006/2006_03_22_GSK771.htm (01.05.2008)

product code can be read by pharmaceutical wholesalers and pharmacists using a hand-held or stationary electronic device that is placed within 2-18 inches of the tag. The tag can be read by wholesalers when it is received from the manufacturer and when it is shipped to pharmacies, who would then record when they have received the medicine. This allows manufacturers to more precisely account for medicine as it moves through the distribution chain and to authenticate medicine at the point of dispensing.

The limit of privacy

To assure a respect of patient's privacy, the technology does not collect any patient information. The RFID tag contains information about the product only. GSK will not collect any personally identifiable information about patients through this technology.

Future plans:

The testing of the RFID technology on additional products will be evaluated by GSK with guidance from the FDA as the Trizivir® pilot progresses.

Conclusion (International market)

RFID technology is already implemented in the international market for some specific cases. The U.S. FDA is the first who triggered the development of such a technology asking the pharmaceutical industry to find the best solution to prevent the market against counterfeiting.

The European Commission is also aware of this situation but suggests 2D data matrix code for the European market. European companies only use RFID tags for the products that are shipped to the US market. The implementation of RFID on the US market was expected to happen faster as does at the moment. The most progressed State is California. Due to the e-Pedigree which is requested by the FDA for every product, RFID seemed the only solution. However, an e-Pedigree could also be provided with 2D codes in combination with a global database.

The importance of the evolution of the use of RFID depends on the level of safety for each supply chain. In UK and in the US, the supply chains are still weak in front of the problem of counterfeiting and thus need more secure ID technologies. That is the reason why GSK in UK and Pfizer in the U.S. are using RFID for some of their products.

This international study underlines also the importance of a global standard and the consideration of the needs of the different countries involved in a global market. Indeed, France had to implement RFID in their internal supply chain so as to respect the new standards implemented in the U.S. market.

COST ANALYSIS

The setup

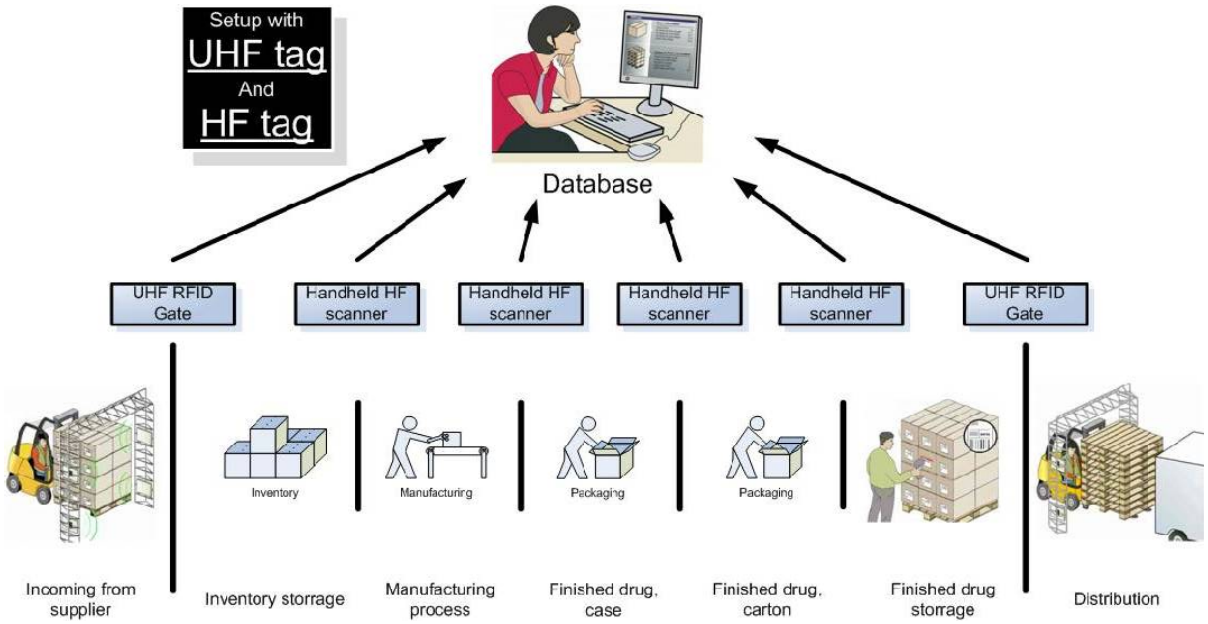


Figure 17- Possible company setup with RFID, own creation, approved by DTI

1. Incoming products from supplier have HF tags on item and box level and an UHF tag on the pallet. The pallet belongs to the supplier and will be returned after delivery. The UHF tag on the pallet is read by the first UHF RFID gate and gives information about the boxes on it. The Data is stored in an internal database.
2. The boxes are stored in the stock.
3. When a new drug is manufactured, a new batch number is created in the database and every ingredient will be scanned by a HF handheld scanner and stored in the database belonging to the batch. In this way, scanning the items when incoming from the supplier and when leaving the inventory, a precise management of the stock is possible.
4. When the drug is completed, an HF tag is placed on the bottle. This tag includes the batch number, lot number, EPC product code, expiry date and production date.
5. A number of e.g. bottles are packed into cases and a HF tag is placed on the case, including the EPC case code
6. The cases are put into boxes where a new HF tag including the EPC carton code is attached.
7. Several boxes are placed on a pallet with an UHF tag including the EPC pallet code. This pallet is placed in the finished goods storage.
8. When the products have to be distributed, they pass an UHF gate where the UHF tag on the pallet is scanned.

This is a very general setup. In reality, a drug manufacturer often has several gates for trucks to unload their goods. Additionally there might be several production lines within the manufacturer.

The HF scanners and the HF tags of from the Figure 17- Possible company setup with RFID, own creation, approved by DTI could be replaced by 2D readers and 2D codes, in this way another alternative is possible for the item level.

The previous process which was explained for the Figure 17- Possible company setup with RFID, own creation, approved by DTI helps to save time, money, errors and manpower but does not ensure that the product is well manufactured. To check the correct operation of the processes in the manufacturing of the drugs, sensors are needed and there are two possibilities on how to use them. On one hand you can use independent sensors that could monitor the process sending the parameters to the database and check if something is going wrong. On the other hand, RFID tags with sensors able to measure shock, temperature, humidity and other conditions, to track whether medications are made on the manufacturing without damage.

A cost calculation for this general set up could be made with the prices of the Tabel 6 - Cost calculation and the next equation:

$$P_t = (P_x \times X) + (N \times P_y \times Y) + [(P_z + P_i) \times Z] + (P_{we} \times We) + (P_{se} \times Se) + (P_{ni} \times Ni) + [(P_a + P_b) \times A)] + (P_{pr} \times Pr) + M + Af$$

Where:

P_t : Total price
X : Sumatium of inputs and outputs of the factory where the UHF readers are installed.
P_x : Price of one UHF reader.
Y : Number of HF or 2D codes reader
N : Number of production lines
P_y : Price of HF or 2D codes reader
Z : Number of RFID tags or 2D codes
P_z : Price of HF tag or cost of printing a 2D code depneding of the decision taken
P_i : Price of integration the tag in the label
A: Number of pallets needed = Number of UHF tags needed
P_a : Price of a pallet
P_b : Price of the UHF tag
P_{we}: Price of work station
We: Number of work stations
P_{se}: Price of server
Se: Number of server
P_{ni}: Price of network infraestructure
Ni: Number of network infraestructure
M : Maintenance (after first year, the first year is exented of guarantee)
Af : Initial EPCglobal subscription fee (first year) or EPCglobal annual fee (next years).
P_{pr}: Price of the printer
Pr: Number of printers

For the money conversions it has been used the relation value between $ U.S.A dolar and danish crowns at date 26/05/2008. 1 DKK = 0.211402 USD / 1 USD = 4.73033 DKK, 1 EUR = 1.54934 USD / 1 USD = 0.645434 EUR

As a result of the equation and the price table it is possible to make a cost calculation for each option and compare them:

	INCLUDED	PRIZE $	Number
UHF Reader	4 antennas	3465[43]	6
	Cables		
	mounting brackets		
HF Handheld Readers		3323[44]	20
2D Code reader		348[45]	20
Print a 2D code		0.005[46]	4E+06
Cost of work station	HP x w9400 Workstation 1[47]	3391.08	12
Cost of RFID printer	Zebra R110xi RFID Printer[48]	5019.62	4
Cost of server	HP ProLiant DL380 G5[49]	3732.96	3
Cost of networking infrastructure	Routers	462	10
	Cables	77	10
Initial EPCglobal subscription fee		43120	1
Annual variable system costs			
Maintenance costs		62662	1
EPCglobal annual fee		13013	1
Tag		0.21[50]	4E+06
Cost of integration		0.0308	4E+06

43 Price taken from a consult to DTI, Finn Zoega
44 http://www.nextag.com/handheld-rfid/search-html
45 http://www.barcodepower.com/ds6707u.asp reference of Symbol DS6700 Series Handheld Digital
46 http://en.wikipedia.org/wiki/Barcode (24.03.2008)
47 http://h10010.www1.hp.com/wwpc/pscmisc/vac/us/en/sm/workstations/xw9400.pdf
48 http://www.barcodemegastore.com/catalog/zebra/r110xi.htm
49 http://h10010.www1.hp.com/wwpc/es/es/sm/WF06b/781-783-380983-380983-12083397-12568370-81162457.html
50 Price taken from a consult to DTI, Finn Zoega

Tabel 6 - Cost calculation, one time cost for setup like Figure 17- Possible company setup with RFID, own creation, approved by DTI

Annual inspection, reaction costs to the counterfeit products could be necessary and this will increase the price of the annual variable system costs.

Servers, work stations and network infrastructure have been estimated for the amount of items produced. Inside the factory locations will be equipped with RFID reading station(s) and a workstation where the products are read. A lack of transponder or a false EPC number in a product indicates counterfeit origin. In addition, the product authentification system detects suspicious products (e.g. possible cloned tags) for further investigations. A custom-built interface allows an inspection team to monitor the complete supply chain for counterfeit products. Six network servers are needed to run the EPC-IS and EPC-DS services.[51]

For a company already using 1D code the total cost in USD when using UHF and HF tags for a production with 3 entrances, 3 exits and 5 production lines will be:

$P_t = (3465 \times 6) + (5 \times 3323 \times 4) + (0.24 \times 4000000) + [(P_a + 0.21) \times A)] + (3391.08 \times 12) + (3733 \times 3) + (539 \times 10) + (5019 \times 4) + 62662 + 43120$

$P_t = 1.230.389 + [(P_a + 0.21) \times A)]$

For a company already using 1D code the total cost in USD when using UHF and 2D codes for a production with 3 entrances, 3 exits and 5 production lines will be:

$P_t = (3465 \times 6) + (5 \times 348 \times 4) + (0.005 \times 400000) + [(P_a + 0.21) \times A)] + (3391.08 \times 12) + (3733 \times 3) + (539 \times 10) + 62662 + 43120$

$P_t = 210.813 + [(P_a + 0.21) \times A)]$

It is considered that the set-up for the company was previously using 1D codes ID technology; therefore it is not needed to include costs about a barcode printer. Another factor to consider is the fact that the same costs for the UHF reader, work stations, server, network infrastructure, EPC global fee and maintenance are used for both options.

$P_{RFID} = 1.230.389$ \$ **$P_{2D} = 210.813$ \$**

Now it can be concluded, that for a solution with five production lines and each one with four handheld readers, the HF solution is 6 times more expensive than the barcode solution and also that

51 Anti-counterfeiting Business Case Report, Authors: Mikko Lehtonen (ETH Zürich), Jasser Al-Kassab (SAP), Florian Michahelles (ETH Zürich), Oliver Kasten (SAP)

the price of the readers is a small amount of money compared to the price of the labels. But that is only for the item level because it is in the pallet level where for the moment a company can obtain the major benefits reading a lot of items at the same time, saving money and time. Due to this situation of high costs in the item level the companies which are using or studying the use RFID technology, are doing it only on pallet level.

Looking at the pallet level an example with data from LEO Pharma´s manpower is given. The use of RFID gates is compared to the use of barcodes.

	Without RFID	Whit RFID
1 Man puting in stock 10 pallets	60 minutes[52]	6 minutes[53]

This means that the use of RFID will save 90%. The minimum sallary is 100.65 DKK/h[54] which leads to an approximately cost saving of 90 DKK/h. An average work week has 37 hours[55]. To calculate the saving for a year the equation will look like this:

90 DKK/h x 37 h/week x 52 weeks/year = **173,160 DKK/year.**

52 Data provided by LEO Pharma
53 For the " with RFID" case it is considered a 100 m distance between the receiveing point and the warehouse and a limitation of 10 km/h in the speed.
54 http://da.wikipedia.org/wiki/Mindstel%C3%B8n (28.05.2008)
55 http://180grader.dk/nyheder/Medarbejdere_m_ikke_overskride_37-timers_arbejdsuge_-_heller_ikke_frivilligt.php (28.05.2008)

RECOMMENDATIONS

To protect the pharmaceutical supply chain against counterfeit medicine, it is recommended to use a global database and a unique product number. The best provider for this service is the EPC Global Network. This way, only products that have an EPC tag are allowed to move through the supply chain – both national and international. Currently the EPC only uses the RFID standards for HF and UHF frequencies. As the price for RFID tags still are very expensive and a 2D or 1D code in combination with a global database could work just as fine as RFID, it is recommended to use 2D data matrix codes on the item level if the EPC will add this service. A 2D data matrix code can store enough necessary information about the product. For pallet level, the best solution will be the use of UHF tags. This way a pallet can just drive through a gate and the content will be scanned and registered in the companies system. Here is where the biggest time saving happens.

For special drugs that needs to be stored and transported under certain conditions, active read and write tags might be considered as they, in combination with e.g. temperature and shock sensors, can store the entire process on the tag. A higher cost for this tag can be justified with an already high price for the drug.

However, if the company plans a complete automation of their production chain, a complete implementation of RFID would be very useful as this technology need no line of sight and the products do not have to be turned into a certain direction.

For a wholesaler like Nomeco, UHF RFID tags are recommended on the pallet and “blue” box level. Those boxes are filled with several different amounts of drugs and transported to the pharmacies. Depending on what solution the manufacturer decides to use on item and package level (HF or 2D), new readers must be installed. Currently there is no tracking system at Nomeco. By the use of UHF RFID tags on each of those boxes and in combination with an RFID gate at the exit of Nomeco and the entrance at a pharmacy, Nomeco will be able to track the boxes to a certain level. Additionally the current solution with a digital photo of every box’s content should be sustained. Due to the fact that every item has a unique product code, returning products from the pharmacy to Nomeco could be easier identified and sorted in the right shelves.

Just like a wholesaler, the same ID technologies should be used for the pharmacy. The RFID gate at the entrance will scan every new box immediately and register the content on the database. When a product is sold, an HF or 2D code scanner at the shelter will register this action.

Final recommendations

If EPC Global Network decides to implement 2D codes to their system, the recommended solution will be UHF RFID tags on pallet level and 2D codes on item and package level.

However, if the EPC Global Network will not change their system, the recommended solution will be to use UHF RFID tags on pallet level and HF RFID tags on item and package level as the most important reason is to have a global database.

If the European commission favours the 2D data matrix system but the US continues on forcing manufacturer to attach RFID tags, the recommended solution will be to only attach RFID tags in the end of the production line to those products which will be shipped to the US market.

CONCLUSION

RFID can be a possible solution for the counterfeited medicine. However a global database is the real solution for a successful prevention to this issue. Both 1D and 2D codes as well as different RFID solutions will, in combination with e.g. the EPCglobal, solve the problem of illegal copy products. Currently the lack of standards is slowing the process of the implementation of RFID technology. Additionally the gap, between the technologies that the pharmaceutical industry is ready to implement and the solutions suggested by the standard developers, is still too big to enable a definition of a global standard.

Thanks to RFID technology each actor in the supply chain could possibly run a fully automated production line. Due to the fact that RFID need no line of sight, several products can be scanned at the same time and the identification and registration of products will happen faster and with fewer errors. An RFID tag can store more information compared to a bar code and data can be encrypted into the tag.

The Danish market might be ready for this technology but currently it is not needed. The costs of the tags are still too high compared to a printed 1D or 2D code. The amount of space on a 2D code is enough to store a unique product ID, batch number and other important information. Considering that 2D codes would work with a global database, the need for RFID on item level will be unnecessary. The concerns about patient privacy are an important issue when talking about RFID on item level. A clear regulation of how to protect this privacy is needed before implementing this technology. When looking at pallet level, RFID seems a useful solution also on the Danish market as this could save serious time when registering incoming and outgoing products.

The international market has a huge impact on the Danish industry. Several Danish companies sell their products to both the European and the U.S. market. A change in the regulations for the American market will directly affect the Danish drug manufacturer if they want to continue to sell abroad. Denmark is a very small country which is very dependent on their international customers. The companies all agreed on that the implementation of RFID will only happen if any regulations via e.g. the law will force this technology into the industry. This regulation does not only have to be on the Danish market.

A critical study of RFID was made; trying to take every aspect of an implementation of a new ID technology into account. It is difficult to suggest clear recommendations as no standards are widely spread. Additionally it is not possible to find just one solution that fits to every kind of company. However, few options for RFID in the supply chain could be found, e.g. on pallet level.

DISCUSSION

During internal meetings, different points of view were discussed. For each proposition the advantages and disadvantages of a possible implementation were to underline.

2D Bar Codes, High Frequency RFID tags or Near Field Communication tags for the item level?

In the general scheme of RFID implementation inside a company, Ultra High Frequency RFID Tag is used for the pallet level, but different solutions for the item level are possible.

When using the EPC Global Network, only limited information on the RFID tags are necessary as the rest of the product information can be found in a global database. The information that should be stored on the tag itself is the EPC product code, batch number, expiry date and production date. This information could easily fit in a 2D code which is much cheaper than an RFID tag. No big changes would be necessary to also add a 2D or 1D code service for the EPC but the EPC decide to base their standard on only RFID technology. Maybe this will change in future as the development of RFID is progressing slower than predicted and 2D codes seems to spread more and more. Currently the veterinarians are changing all their systems to 2D codes, so why not also use it for human drugs?

If a company plans to reduce its manpower and to raise the speed of the production line an HF RFID tag would be the better solution as this technology needs no line of sight.

Near field communication (NFC) tags is another hot topic for the item level. Currently not enough research is done on this technology. It can use the same tags and readers as the one for the UHF technology but the reading distance is much shorter. NFC is used on some mobile phones to e.g. purchase tickets for busses and trains[56].

The EPC Global Network might take this new technology and the 1D and 2D code solution in account when developing a Gen3 standard.

Indeed, for a better efficiency and to enable the use of a common global standard like the EPC Global Network, the solution which consists of a combination of UHF and HF RFID tags seams to be the best solution.

Does the Danish supply chain need RFID technology?

When talking to the pharmaceutical association, it became clear that the Danish market is very simple and working without any problems - so why to change a system that works fine? So far no

56 http://www.pressetext.ch/pte.mc?pte=070904033 (23.05.2008)

problems with counterfeit medicine have been documented but the increasing amount of internet sales might change this picture in the future. The fact that Danish manufacturer also produce for the international market is also an important issue for a reason to implement RFID. It might not be necessary for the Danish market to use RFID but because e.g. the US law says that every product on the American market has to have an RFID tag, Danish manufacturer will have to attach RFID tags on their product to sustain their international customers.

However, this technology is not only meant to secure the supply chain against counterfeit medicine but also to help automate processes and save manpower and time which in the end will save costs. Currently every product has to be scanned by hand. The 1D codes have to be found and turned in the right direction to get scanned by a laser light. All this processes only take few seconds but when talking about millions of products, few seconds mean a lot. When using RFID all those actions could be skipped. This will lead to enormous time saving. Additionally it would be easier to automate processes in the production line as it no longer would be necessary for product to turn in a certain direction to get scanned. This fact also will make the work for the robots in the pharmacies much easier, faster and fewer problems will occur.

What will be the reason for implementing RFID?

During the research, it became clear that no one really wants to be the first to implement RFID in the Danish market. The pharmacy association suggests that the implementation should start at the manufacturer. The manufacturer suggests that an implementation should be requested by the pharmacies and the wholesalers are just in the middle of everything and have not the right to request anything as they are dependent on both the manufacturer and the pharmacies.

However, large multinational concerns have a huge impact on the market. E.g. when Walmart decided that all their suppliers should attach RFID tags, every supplier had to change their identification system because Walmart is their largest customer.

Due to the fact that the EPC Global network only is based on RFID, even though the system easily could work with both 1D and 2D codes[57], it is assumed that they are trying to force the companies to implement RFID. This might trace back to the fact that GS1 is a global company which tries to make standards that satisfy every member, also the US.

When asking members of the Danish pharmaceutical supply chain about if they think that an implementation of RFID only will happen when the government will force companies to use this technology by law regulations, every company agreed on that statement. It could be the Danish

57 Meeting with Per Kiilholm, GS1 Denmark

government that decides a change in the law but it seems more likely that the European Commission has to work out some regulations in order to have the same standards all over Europe.

Possible errors due to missing transaction costs

Several companies were asked for their transaction costs. Transaction costs[58] are costs that occur when making an economic exchange. For example, most people, when buying or selling a stock, must pay a commission to their broker. That commission is a transaction cost of doing the stock deal. Or consider buying a banana from a store. To purchase the banana, your costs will be not only the price of the banana itself, but also the energy and effort it requires to find out which of the various banana products you prefer, where to get them and at what price, the cost of traveling from your house to the store and back, the time waiting in line, and the effort of the paying itself. The costs above and beyond the cost of the banana are the transaction costs. Transaction costs are often higher than the real price for the good itself. That is why it is so important to consider the transaction costs before making a new transaction. The idea, when implementing a new ID technology and change to a more automated system, is to reduce the transaction costs by saving manpower.

However no company was able to give any numbers. To make a cost benefit analysis, only the data given by Leo Pharma could help to give an estimate about how much the implementation of RFID or 2D codes would cost. The numbers take in account, receiving the goods, registration via barcode, labeling the single units on the pallet, take samples for the quality control and place the goods on stock. The cost calculation would for sure look different if more information would have been available.

International information

The section about the international market is mostly based on internet research. Several international companies were contacted but due to strict safety reasons only few companies could provide new information. It was found that only the largest multinational manufacturers are working with RFID technology mostly on the American market. Their information about their experience would have been very useful. If more international companies would have liked to participate in this study, the outcome of this report might have been different.

58 http://en.wikipedia.org/wiki/Transaction_cost (25.05.2008)

FUTURE IDEAS

RFID in pharmaceutical supply chain in the next years

Nowadays, RFID technology is still developing, its effectiveness is increasing by making researches on it, and its advantages are approved. A lot of companies implemented RFID technology into their production lines or providing services. The healthcare and pharmaceutical sector is special. In this case the implementation of RFID will allow to save money (by cost controlling), time, manpower and – what is the most important- prevention against counterfeit medicines. But it is not done.

Nowhere in the Danish pharmaceutical supply chain, it was possible to find the implementation of RFID. Also in the others part of Europe, only pilot project or for testing reasons, RFID was implemented. Only few companies, which are exporting their products to the American market are using RFID, because it is required to prove e-pedigree there.

Possibilities for RFID – current situation

RFID technology could be used within the European, also Danish, supply chain. Implementing it on pallet-level and support it by 2D codes on item-level could be one of the solutions at once for manufacturers, wholesalers, hospitals and pharmacies, which will make coordinating medicines flow easier. RFID on pallet-level makes it possible to read all packs/boxes on each pallet fast and precisely, but also the use of the EPCglobal Network to monitor their position will be necessary. Then, if it is known where particular pallets are and what is supposed to be on it, the company will have a clear view on their resources. EPCglobal Network does not work with 2D codes in today. It is possible theoretically and may be practically in future. Instead of 2D codes, companies can also use RFID technology (the best solution is to use another technologies for pallet- and item-level: i.e. UHF and HF), and in this case EPCglobal Network could work as an idea was.

High costs for readers and tags, time for training courses, adaption of new standards and one of the most important reason – not enough information about RFID technology does not allow increasing demand in pharmaceutical supply chain. The market is interested in new technology and to know their development, but cost calculation show that the implementation of RFID now is unprofitable. These are possibilities for approx. next 10 years.

RFID – working in the entire supply chain

One predictable application for RFID technology in the pharmaceutical sector is to implement it in the entire supply chain. The idea and theoretical plans are very promising. Information about the product is written on a tag (if assume using read/write tags) from the very beginning, during the whole entire process: starts with production process and ends in clients hands. In case of wrong medicine or any mistakes of the way how the medicine is working – it is easy to trace it back and give

it back to manufacturer. If the whole part of a production is wrong, the manufacturer can easily remove it from the supply chain – the faster and more effectively, the safer for patients. Finally consumers can be sure that the medicine is right and traceable.

Using RFID on the item-level by every member of supply chain[59] also opens a window of opportunities to fully using EPCglobal Network and common data base. That makes all transaction faster, less complicated by simplification data stream.

RFID – far future

In far future RFID applications could simplify many issues. It possibly will become a supply chain management tool for automation processes – it will replace manual processes for tracking supplies in warehouses and at loading docks. A networked RFID system on a loading dock can transmit information about it to a common data base. This facilitates automated creation of shipping manifests and other data, whose generation currently involves some degree of manpower. Speedy data generation by RFID means that information can reach a destination even before the operation is done. Automation of processes could go even further – the whole process of receiving goods, repackaging, labelling, storing etc. can be done automatically, based on strict information about the product and its current position. Storage could be served by robots and manpower could be saved or used somewhere else in production line. How this future production process could looks like is described in points below:

1. Goods from a supplier are coming to the stock in packages on pallets. Those pallets are equipped with UHF tag (which is carrying information about what is on it) and read when going through the gate. The information from UHF RFID tag appears immediately in the data base as current material resources.

2. Received goods (using HF RFID tags on item-level is assumed) are driving directly to the right place on shelves by robots.

3. When the goods from storage are needed on the production line, they are found and taken from the shelf automatically thanks to the information about their position.

4. The whole production process is going without human intervention. Ingredients are correctly added and mixed by machines. Finished medicine is only checking by pharmacists.

59 See: Appendix - GS1 France

5. Prepared medicine is put into vials or little packs and then boxes. Labelling is also done by robots. Then new HF RFID tags concerning necessary information about manufactured product are attached.

6. From the production line all boxes are transported to the packaging line and then to the distribution point. The possibility of getting information by simply passing an HF RFID gate allows preparing shipping on pallets (with UHF RFID tag) fast and without any mistakes.

7. Information about leaving the ship (and what exactly was sent on it) is appearing in a data base as soon as pallet passed through the UHF RFID gate.

Additionally it could make patients life easier. For example – it might be possible to return RFID-tagged items of medicine without a pharmacy receipt, or some 'smart appliances' may help by alert when running out of some kind of medicine that is needed or when the product has expired.

RFID – researched forecasts

RFID technology is currently used in different areas of the industry. The bar charts below Figure 18 - Global RFID market division in 2007, forecasts for 2012 and 2017 shows RFID market division and global investment for RFID technology all over the world without splitting it up into sectors, but what can be concluded from a general view certainly reflect the situation on each particular sector. The next two figures show global "tags-situation" – expected number of sold tags and their prices depending on one another.

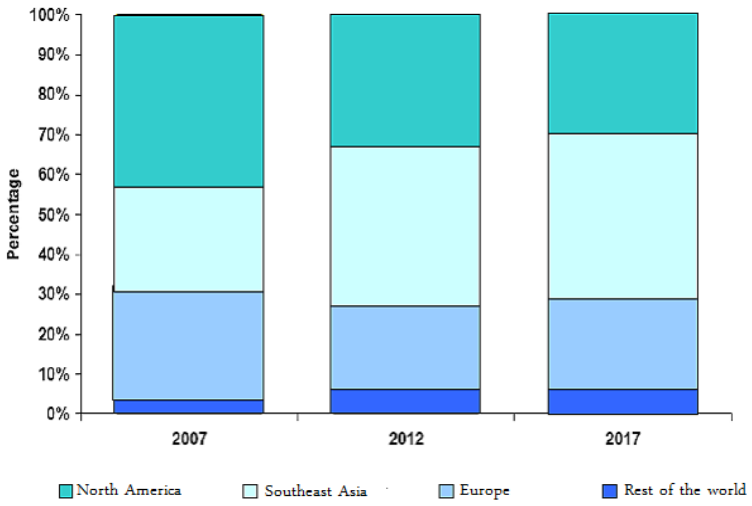


Figure 18 - Global RFID market division in 2007, forecasts for 2012 and 2017

Mainly the North American pharmaceutical industry is using RFID technology now – analogically more than 40% of global applications and it can be predicted that for the healthcare and pharmaceutical sector it is much more than 40% because the US market is the only one which

requires implementing RFID technology to prove e-pedigree of medicines. This situation is going to change in the next 10 years. Using RFID will be more evenly distributed. On the Figure 18 - Global RFID market division in 2007, forecasts for 2012 and 2017, clearly increase of using RFID in Southeast Asia, but this is probably not caused by a number of estimated implementations of this technology in the pharmaceutical market.

Also global investing costs for RFID have been increased rapidly between 2004 – 2010 Figure 19 - Done and expected global investments (in millions US dollars) for RFID in years 2004 - 2010. Spending more and more money on new RFID application will certainly decrease the cost for using this technology – high prices of tags and equipment are the main reason for a low number of current RFID implementations in the Danish pharmaceutical sector.

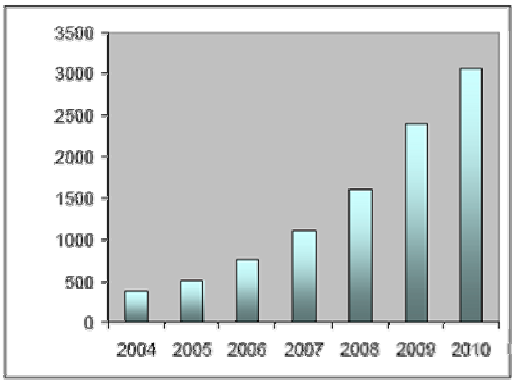


Figure 19 - Done and expected global investments (in millions US dollars) for RFID in years 2004 - 2010

The number of sold tags will also rise in the next years. Only in 2007, Figure 20 - Global value of sold active and passive tags between 2007-2017, the sum of money spend on tags reached 2 billions US dollars (1.000.000.000.000; short scale: one trillion; long scale: one billion).

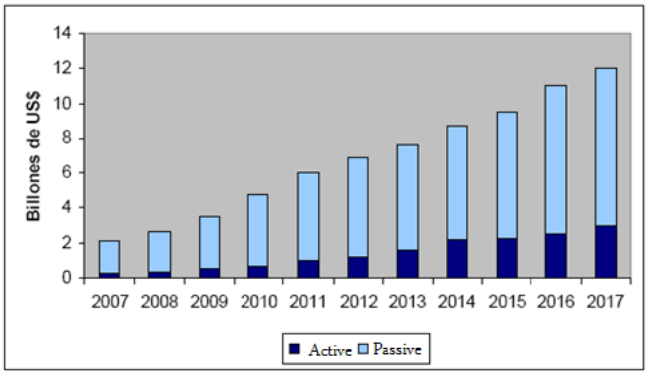


Figure 20 - Global value of sold active and passive tags between 2007-2017

The price of a tag depends on the number of sold tags – due to predictions it will be decreasing, Figure 21 - Average tag price versus number of sold tags. It makes a possibility of further development of RFID technology and a more popular use in the industry in general.

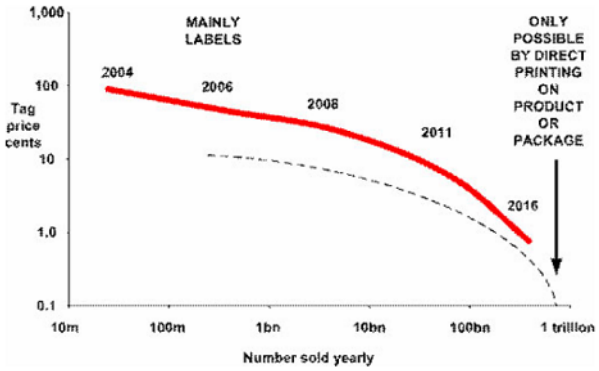


Figure 21 - Average tag price versus number of sold tags

SUGGESTIONS FOR FURTHER STUDY

It could be interesting to study the implementation of RFID in the last part of the supply chain, pharmacies, laboratories, hospitals, patients...

It is seems very likely that RFID technology can help this part of the supply chain when seeing the next statistics;

It is estimated that the cost for theft of property and equipment in U.S. hospitals is close to 4000$ per year for each bed[60]. This implies a potential loss of 3.9 $ billion annually. Nor are negligible figures associated with elements that are left forgotten in the patient's body after an operation: in 10,000 interventions, forgets an object in the patient's body, making a total of 1500 objects per year, with the consequent risks to health (in 2000, 57 deaths were associated with this error) and economic losses, increased hospitalization time.

And here, the error rates of UK[61]:

Prescribing 56%

Administration 34%

Dispensing 4%

Transcription 6%

"*A Spoonful of Sugar*" (Audit Commission Report), gave the following statistics that have been multiplied up to illustrate the national picture:

7000 drug administration per day.

The error rate is about 5% (varies between 3% and 10%).

In an average DGH there are 350 errors per day from administration alone.

Some of these cause adverse drug events (ADEs), which increase the length of stay in hospital by on average 8.5 days (Vincent BMJ).

It is hard to determine what proportion of errors cause ADEs – however 1 in 1000 of all administration errors is potentially fatal.

60 http://www.ceditec.etsit.upm.es/dmdocuments/CITIC%20RFID%20Salud.pdf
61 When Medication Errors Happen' (Bates et al): JAMA1998. 280 No.15 (21 October)

So the average DGH potentially kills 1 patient every 3 days from administration errors

Or for England with approximately 180 DGHs that's 60 patients per day.

In fact, there are already cases of application of RFID technology in hospitals, through which many lives are saved, many preventable errors, saving a large amount of money and time, such as labeling of medical material, labeling of bags blood or labeling the hospital staff, control the access to restricted areas. Some examples of them are[62]:

*Medline Industries is a company that offers RFID systems to track surgical gauze during operations. *In the Hospital Ospedale Maggiore Bologna (Italy) developed a system which equips patients with RFID bracelets. The labels contain codes that can be compared with the codes that have blood units. Only allow an exact match to open the seal of the unit to perform blood transfusion, leaving no place for mistakes. The same application has also been deployed as a pilot in the AMC Hospital (Netherlands).

*The Ave Maria Foundation (Spain) has launched an automatic dispensing of medicines with RFID technology. The most important provision is detecting errors in drug administration. The dispensing medical alerts if the patient later than the scheduled time and also when the caregiver forgets administer the medicine. In addition to other benefits: the management and control of drugs of nursing, conducting statistics on the annual consumption of drugs, crossing reports among administrators of medicines and pharmaceutical department, and the identification of patients and caregivers (across a chip on clothing).

It is also a good tool to monitor patients at home.

- In Finland (Imatra), Medixine Ltd, conducted a pilot in 2006. This pilot is intended that persons who are in the early stages of the disease can continue living at home. This gives the person with a mobile phone with NFC technology and a "Dashboard Communication."
- The research center Austrian, Austrian Research Centers GmbH has developed a prototype system for monitoring cardiac patients to show the market potential of the NFC technology. The application consists of a prototype that incorporates NFC in the terminal patient monitoring. The patient, rather than having to go to hospital conducts periodic reviews of their health status, they can perform at home, and also more often.

62 http://www.ceditec.etsit.upm.es/dmdocuments/CITIC%20RFID%20Salud.pdf

- It may also be interesting to make a deeply study of Real Time Localization Systems (RTLS) that allows the immediate location, good point when you need the faster localization of a doctor or a medical equipment in an urgent in a hospital.
- AT4Wireless (Spain) has faced the deployment of diverse experiences of implementation of RFID technology in health care settings. One of them has been developed at the Hospital of High Resolution of Benalmadena in Malaga. It is a system in Real Time Location (RTLS) based on active RFID technology, applied to the location of electro equipment and people in different areas of the Hospital. Also it used to receive emergency alerts issued by the medical staff.

  The technology providers claim that, in hospitals where there is already a wireless communications system is flexible and easy to add components to deploy an RFID system RTLS (Real Time Location System).
- It would be very useful also in centers for people with disabilities;

  Since 2006, the Centre d'Estudis Tecnològics per la Dependència (CETpD) (Barcelona), is developing a project for blind people using RFID technology that is subsidized by the IMSERSO.

Another good idea is to make a study on the importance of the implementation of RFID in the management of dangerous materials.

Study the implementation of RFID in others sectors. RFID has a lot of applications which we can found many advantages with his use.

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(Visited between 05.02.2008 and 31.05.2008)

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www.europen.com.br/html_new/download/SATO-rfid-forum-aim-04.pdf

APPENDIX

RFID TECHNOLOGY IN DETAIL

INTRODUCTION

RFID[63] (Radio Frequency Identification) is a method of storage and retrieval of remote data, based on the use of labels or "tags" in which the information resides. RFID is based on a concept similar to the bar code system, the main difference between the two is that the latter uses optical signals to transmit data between the tag and the reader, and RFID, on the other hand, uses RF signals.

The origin[64] of RFID is sadly related to the war, specifically II War World, which allowed the use of radar detection aircraft miles away, but not be identified. The German army discovered that if the pilots balance their planes to return to the base would change the radio signal reflected back. This method did well to distinguish aircraft German allies and became the first passive RFID device.

Radar systems and advanced radio communications in the decades of 50 and 60 where scientists worked to explain how to identify objects remotely. The companies soon began working with anti-theft systems using radio waves to determine if an object had been paid or not. Used with a label in which 1 single bit has been paid decides whether or not the object in question. The first patent for RFID devices were applied in the United States, specifically in January 1973 when Mario W. Cardullo was presented with an active RFID tag that was carrying a re-writable memory. The same year, Charles Walton received a patent for a passive RFID system that opened the doors without keys.

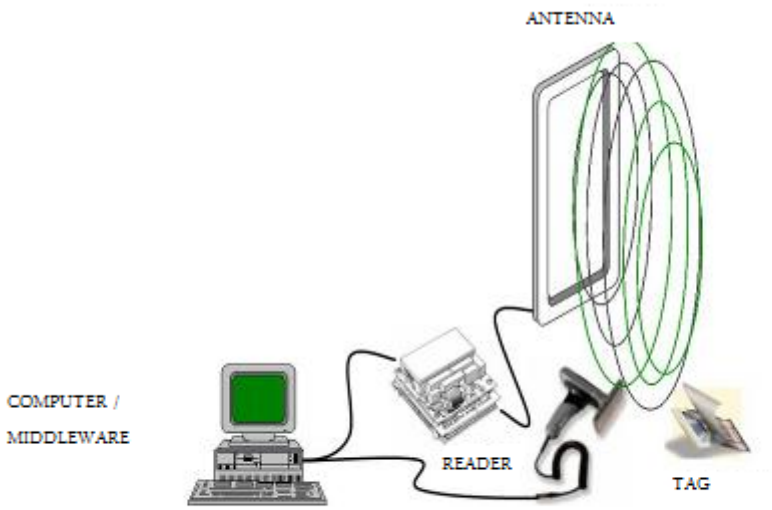
The U.S. government also was working on this technology in the 70 and they set up similar systems for handling doors at nuclear power plants, whose doors were opened to the passage of trucks carrying materials. It also developed a system for control of cattle had been vaccinated inserted under the skin of the animals passive RFID tag.

Then there have been improvements in the capacity of transmission and reception, as well as in the distance, which has led to extend its use in areas both domestic and national security.

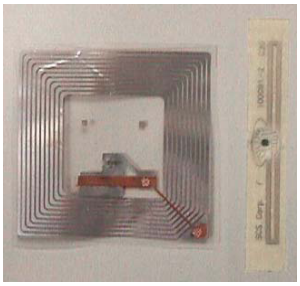
63 http://www.n-economia.com/informes_documentos/pdf/sintesis_documentos/SINTESIS_NE_09-2008.PDF
64 http://www.it.uc3m.es/jmb/RFID/rfid.pdf

COMPONENTS[65,66]

Mainly each RFID system consists of four elements:



1) An RFID tag, also called a tag or transponder (transmitter and receiver) is a small device like a sticker, which can be attached or incorporated into a product, animal or person, carrying information about the same.



2) A reader or interrogator, it transmits enough power to the label and it read the data it sends.

   It consists of an RF module (transmitter and receiver), a control unit and an antenna to interrogate the tags via radio frequency.

   Readers are equipped with standard interfaces that allow communication to send the data received from the label to a data processing subsystem, such as a personal computer or a database.

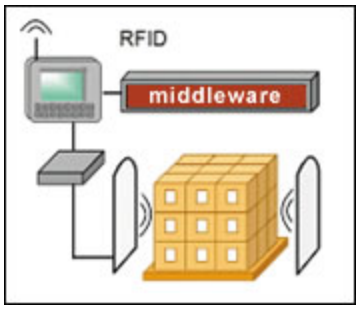
   Some readers integrated with a leading developer added to its reading ability, the ability to write information on the labels.

   The communication between the reader and the tag is via the antenna, which is the element that radiates the RF signal.

65http://www.lyngsoesystems.com/loader.asp?menu=7&page_id=662&Language=0&niv2=112&niv3=223&Grid=199
66 http://www.n-economia.com/informes_documentos/pdf/sintesis_documentos/SINTESIS_NE_09-2008.PDF

The power of the reader in combination with the type of antenna most appropriate for each case determines the distance reading.

3) A computer, or host controller, which develops RFID implementation. It receives information from one or more readers and communicates it to the information system. It´s able to transmit commands to the reader too.
4) In addition, the software middleware is in charge of filtering duplicates, purification errors, etc. And RFID integrates with enterprise applications.



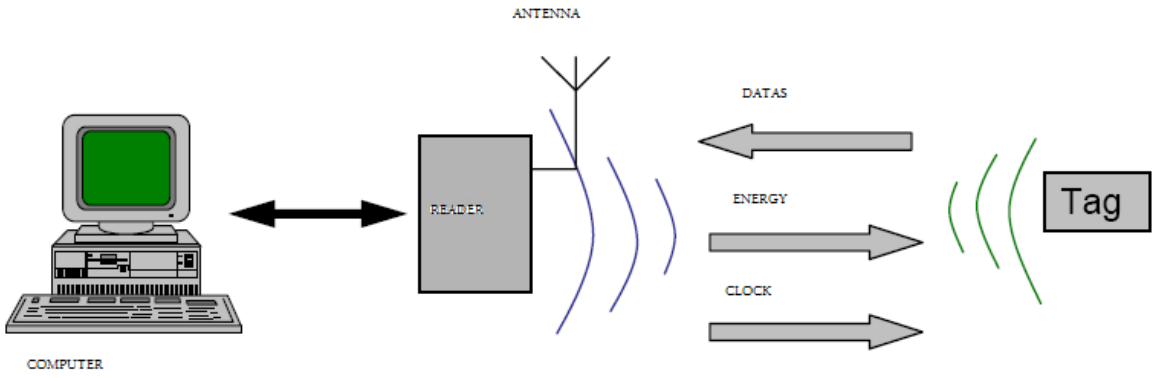
OPERATION[67]*:*

It equips all objects to identify or control with an RFID tag.

The antenna of the reader or interrogator emits a radio frequency field, which activates the labels.

When a label enters this field uses energy and time reference received to conduct the transmission of the data stored in its memory. In the case of labels active energy necessary for the transmission comes from the battery's own label.

The reader receives the data and sends them to control computer for processing.



OPERATION OF A RFID PASSIVE SYSTEMS

67 http://www.n-economia.com/informes_documentos/pdf/sintesis_documentos/SINTESIS_NE_09-2008.PDF

TAGS[68]

The transponder is the device that is embedded in a label or tag and contains information associated with the object to which it is attached, and it transmits when the reader asks. It is composed mainly by a microchip and an antenna. Additionally can incorporate a battery to power their transmissions or even some labels may include a more sophisticated circuitry with extra functions additional input / output, such as time records or other physical states that can be monitored by appropriate sensors (temperature, humidity, etc.)

The parameters that characterize the RFID tags and understand the basis for their design specifications are: how power, capacity and type of data stored, the read speed of data, programming options, fitness and costs.

Mode Power

Depending on how they obtain their power, the labels are classified as active or passive. *Active tags*, in addition to collect energy from the reader, feed on a battery. Normally incorporate a battery that has a high power-weight and are capable of operating at a range of temperatures ranging from -50 ° C to 70 ° C.

Although the use of batteries implies a finite lifetime for the device, placing a battery fitted in an appropriate manner to the low power circuitry, can ensure a lifetime of just over 10 years, depending also on conditions Work on that is, that is, temperatures, cycles of read / write and use. Typically devices are read / write.

Overall active RFID tags allow a radius of greater coverage, better immunity to noise and transmission rates higher when working at high frequency. These benefits translate into a higher cost, so apply when the property to identify so warrant.

There are two types of labels active:

• Those that are normally off (sleep mode) and are activated (wake up) when the reader asks. This will save battery.

• Those that regularly send signals, although a reader not questioned.

They operate at frequencies lower and lower rates of transfers, to save battery. The *passive tags* operate without an internal battery, getting the power they need to operate the field generated by the interrogator.

The absence of battery causes passive transponders are much lighter, smaller, flexible and cheaper than assets, it is in fact that may be designed in a wide range of forms. In addition, offering a virtually

68 http://www.n-economia.com/informes_documentos/pdf/sintesis_documentos/SINTESIS_NE_09-2008.PDF

unlimited lifetime. In return, few possess radios coverage minors and require much more energy from the interrogator to transmit data. They also have restrictions when it comes to storing data and do not work too well in environments with electromagnetic interference. Also, their sensitivity and orientation are limited by the power available.

However, despite these limitations, passive tags offer better advantages in terms of cost and longevity.

We summarize the comparative of the main features in Table:

	Active tags	**Passive tags**
Incorporate battery	Yes	No
Cost	Major	Minor
Time of life	Limited	Almost unlimited
Coverage	Major	Minor
Capacity data	Major	Minor

Table. Tags active vs. active tags.

Capacity of data storage

In terms of capabilities are common data tags that allow a single bit from store to hundreds of kilobits, although prototypes are already on the agenda Mbit. Whereas 8 bits represent a character, a capacity of 1 kilobit can store 128 characters.

The devices have a single bit two states: "label reader is in zone" or "label is not in the area of the reader." Some allow the option to activate and deactivate the device. They do not need microchip transponders, so its manufacturing cost is very cheap.

Its main area of application is in the field of anti-theft devices, particularly in applications EAS (Electronic Article Surveillance), for purposes of electronic surveillance articles sales. The bit allows

firing an alarm when the tag passes through the scope of the interrogator. Moreover, such labels also commonly used in applications counting objects or individuals.

By increasing capacity, the service can also allow the organization of data in fields or pages that can be selectively interrogated during the reading process.

Speed Reading Data

The reading speed of the data depends primarily on the carrier frequency. Broadly speaking, the higher the frequency is for the higher the speed of transfer.

One aspect to consider is the speed with which the labels are moving within the area of reading. The time it takes to cross a label on an area of reading should be higher than the reading time of one's own label, or time will not give the reader so that it can adequately perform the reading. This problem may worsen if there are several labels that the interrogator must detect, since when several tags trying to transmit their data to a single reader, reading time is multiplied by the number of tags.

For labels that have a high capacity data storage, when it comes to read all the information stored in the tag reading times are accordingly high. In this regard, the option that some labels have to do selective readings, block or sector, can be very beneficial to significantly reduce the time reading.

A low frequency (<135KHz) a unit standard reader take approximately 0,012 seconds to capture the information of a label, allowing a speed of 3 m / s.

For faster speeds would require larger antennas. For instance was made possible when reading the labels moved speeds of 65 m / s (about 240 kph).

Options Programming

Depending on the type of memory that incorporates the transponder, the data can be transported:
-- From just reading. They are low-capacity devices, programmed by the manufacturer at the outset. Normally carry an identification number or a password to a database where information exists on the dynamics object, animal or person you are attached.

-- From a writing and multiple readings. They are programmable devices by the user, but only once.
-- From reading and writing. They are also programmable by the user but allow further modify the data stored on the label. Programmers allow writing directly on the label affixed to the object in question, provided they are within the coverage area of the developer.

Physical form

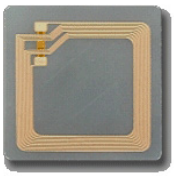
RFID tags can have many different shapes, sizes and protective housings, depending on the value for which they are created.

With respect to size, it is possible to develop labels on the order of millimeters to a few centimeters. For example transponders used in the identification of cattle, which are inserted under the skin of the animal, measuring between 11 and 34 mm, while those which are encapsulated in discs or coins, usually have a diameter of between 3 and 5 cm. The RFID smart labels have standardized measures 85.72 mm x 54.03 mm x 0.76 mm ± tolerances.


a)

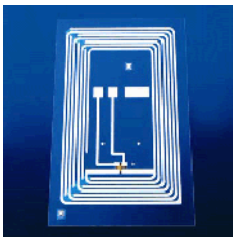
b)

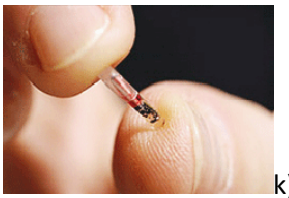
c)

d)

e)

f)

g)

h)

i)

j)

k)

l)

a) P-LABEL TAG Adhesive labels paper b) K-TAG Key rings for identification at entrances c) ACTIVE CARD TAG identification card very far-reaching d) TEX TAG plastic tags for textile and high resistivity e) METAL TAG Tag adhesive metallic materials f) ACTIVE COMPACT TAG Tag far-reaching for objects g) ACTIVE W-TAG identification bracelet very far-reaching h)PHONE TAG Tag special phones and customizable for Mobile PHONES i) THERMRF TAGS tags with temperature sensor integrated j) HAM TAG Tag non-toxic and reusable for spare meat k) Micro TAG Tag glass for insertion into humans, animals or objects l) INMOULD TAG tag for plastic injection

Costs

The main variables affecting the cost of the labels are the type and quantity to be procured. With regard to the quantity, the relationship is clear: the more labels are purchased, the lower its price.
Relation to the type of labels can be considered the following factors:
-- The complexity of the logic circuit, construction of the label or its memory capacity, will influence both the cost of transponders and readers and programmers.

-- The shape of the label, namely how the device is encapsulated to form the label. Some applications may require robust mechanical housings or chemically, or high tolerance to variations in temperature, because of working conditions to which they must operate. The encapsulated in such circumstances can represent a significant proportion of the total cost of the transponder (30%).

-- The frequency of work of the label. In general, low-frequency transponders are cheaper than the high frequency.

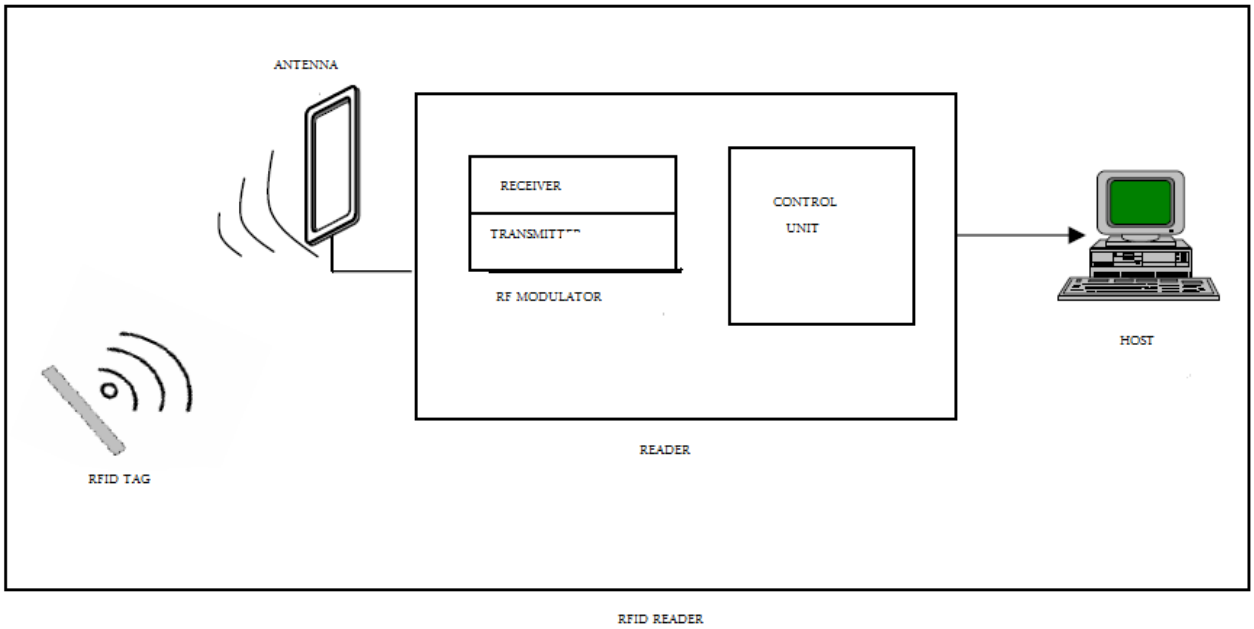
-- The type of label: possibilities read / write, active or passive. The passive tags are cheaper than assets.

For large quantities of labels, the price can vary from a few cents, for very simple labels to tens of Euros for more sophisticated devices.

The target price is currently 5 cents per label, but how to achieve this involves a broad debate, as the path to achieve it surely will involve reducing existing capacities can be expected from the label.

READERS[69]

A reader or interrogator is the device that provides energy to the labels read the data coming back to it and sends the information system. Also, also manages the sequence of communications with the reader. In order to fulfils these functions, is equipped with a radio module (transmitter and receiver), a control unit and an antenna.



RFID READER

The reader can act in three ways:

69 http://www.n-economia.com/informes_documentos/pdf/sintesis_documentos/SINTESIS_NE_09-2008.PDF

-- Asking its coverage area continuously, whether it is hoped the presence of multiple labels from a continuous basis.

-- Asking periodically to detect new presences labels.

-- Interrogators timely manner, for example when a sensor detects the presence of a new label. The components of the reader are:

• The radio module, which basically consists of a transmitter that generates the RF signal and a receiver that receives, also via radio, data sent by the labels. Its functions are therefore: Generate the radio signal to activate the transponder and provide energy.

Modulating transmission of the signal to send the data to the transponder.

Receive and demodulating signals sent by the transponder.

• The control unit, consisting basically of a microprocessor.

The control unit is responsible for carrying out the following functions:

Codify and decode data from the transponders. Check the integrity of data and store them.

Manage or access to the media: activate the tags, starting the meeting, authenticate and authorize the transfer, detect and correct errors, manage the process multiples readers (collision), encrypt and decrypt data, and so on.

Communicate with the information system, executing orders receive and transmit information from the labels.

One of the most critical functions to be performed by the control unit is to manage access to the media. When transmitting information via a technology that requires no physical contact, the possibility exists that appear interference causing unwanted changes to the data transmitted and therefore errors during transmission. Avoid this problem by using verification procedures (checksum).

The number of labels that can identify a reader in an instant of time depends on the frequency of work and the protocol used. For example, en la band High Frequency usually 50 tags per second, while en la band de Ultra High Frequency can reach the 200 tags per second.

• The antenna is the element that enables communication between the reader and transponder. The antennas are available in a variety of shapes and sizes. Its design may become critical, depending on the type of application for the development. This design may vary from small handheld devices to large antennas independent. For example, the antennas can be mounted in connection with access doors to control personnel passing, or on a toll booth to monitor the traffic flowing.

The main aspect to consider when choosing an antenna is the coverage area required for implementation, so that is big enough to detect the labels but small enough to avoid spurious invalid readings that can affect and confuse the system.

Another aspect that may affect the coverage is the orientation of the antenna of the reader regarding the label, which influences the amount of power transferred to the tag, affecting sometimes significantly to reading.

Despite that labels can be read in all directions, generally the field generated by the antenna of the reader has a certain direction. This has implications especially in AF and UHF, could reduce coverage to 50% or even impossible to read the label. Therefore, it is desirable seek optimal coupling between the two antennas, and whether the orientation of the tag cannot be controlled must seek compensation through a proper design of the antenna.

All these aspects must be taken into account before buying the reader, because in general all RFID antennas are presented as final products, so it is necessary to analyze their characteristics previously. However, most are tunable so they can adjust to the frequency of operation selected for the system. This makes them susceptible to many external factors, such as:

Variations of RF.

Losses on near metals.

Variations of the environment.

Harmonics' effects.

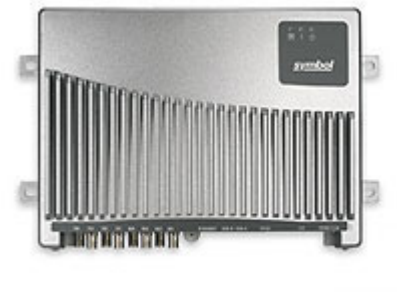
Interference with other RF sources.

Reflections of the signal.

Crosstalk (cross-talk).

Readers may vary considerably depending on their complexity functions to be developed. One possible classification divides them into mobile or fixed depending on the application you consider.

The fixed readers are positioned at strategic locations such as gateways, places of passage or hot spots within a chain of assembly, so they can monitor the implementation of the labels in question.



Fixed RFID reader

Readers are often mobile handheld devices. They incorporate an LCD display, a keyboard to enter data and a built-in antenna inside a portable unit. For this reason, its radio coverage is generally lower.

Readers RFID hand

The main parameters that characterize a reader RFID are:

• Frequency of operation. The reader can operate at low frequency, high frequency, ultra high frequency and microwave frequency. There are already on the market multifrequency readers.

• Protocol operational. Many companies offer support Multi (ISO, owners…), but do not support all existing protocols.

• Type of regulations that follow. For example, there are different regulations frequency and power in the United States and Europe:

Band UHF operates at 902 to 930 MHz in the U.S. and 869 MHz in Europe. The maximum allowable power or is 2 Watts in the United States and 0.5 Watts in Europe.

• Interface with the host system:

TCP / IP.

WLAN.

Ethernet (10BaseT).

Series: RS 232, RS 485.

• Ability to multiplex many readers:

Across hubs.

Across middleware.

• Ability to update the software online reader:

Via the Internet.

Via interface with the host.

• Ability to manage multiple antennas, typically 4 antenna / reader.

• Ability to interact with other middleware products.

• Input / output to connect other digital devices such as external sensors or additional control circuits.

MIDDLEWARE[70]

The middleware is software that handles the connection between the RFID hardware and existing information systems (and possibly prior to the introduction of RFID) in the company. Just as a PC, RFID systems hardware would be useless without software that enables work. This is precisely the middleware. It deals, inter alia, the routing of data between readers and tags and information systems company, and is responsible for the quality and usability of RFID-based applications.

70 http://www.n-economia.com/informes_documentos/pdf/sintesis_documentos/SINTESIS_NE_09-2008.PDF

The four main functions of RFID middleware are:

• Data acquisition: The middleware is responsible for the collection, grouping and filtering data from multiple RFID readers in a complex system.

Without the existence of middleware, information systems companies collapse quickly.

• Routing data. The middleware facilitates the integration of network elements and systems RFID in the systems company. This directs the data to the appropriate system within the business organization.

• Process Management. The middleware can be used for shooting events according to the rules of business organization where it operates, for example, shipments unauthorized downs or losses of stock, etc…

• Management devices. The middleware is also responsible for monitoring and coordinating the RFID readers, as well as to verify their status and operability, and enables its remote management. Many of the middleware developed or developing complies with the standards of EPCglobal, known as Savant. The specification Savant sort of middleware components according to their functions. At present, the development of middleware is far from finished something.

KIND OF SYSTEMS DEPENDING THE FREQUENCY [71] [72] [73]

There are some systems depending the frequency

Low Frequency (125 kHz LF)

The low-frequency RFID systems typically use passive tags. They have few regulatory requirements.

Capacity data

In the usual case of passive tags, the data capacity is low, about 64 bits. If it is active labels, they enable a storage capacity of up to 2 kbits.

Speed and reading time data

The data transfer rates are low, typically between 200 bps and 1 kbps.

For example, a label of 96 bits transmitted at a speed of 200 bps, will need 0.5 seconds to be read, which implies a very slow reading time.

Coverage

The area of coverage is strictly limited to a small area (in production controls). The antennas are using small and complex, but the technology is well developed.

71 http://pdf.directindustry.es/pdf/siemens-rfid-systems/sistemas-de-identificacion-simatic-rf/25688-31590-_2.html
72 http://www.n-economia.com/informes_documentos/pdf/sintesis_documentos/SINTESIS_NE_09-2008.PDF
73 http://es.wikipedia.org/wiki/RFID#Regulaci.C3.B3n_de_frecuencias

The passive tags typically have a small coverage, which reaches as much 0.5 meters, but also depends on the power available on the label.

Active tags can exceed 2 meters, although this range also depends on power, construction, configuration and size of the antenna.

Reading Zone

The penetration of non-conducting materials is good, but do not work well with conductive materials. This problem increases with frequency. They are also very susceptible to electromagnetic interference industrial low frequency.

Cost

They depend largely on the form and the needs of the system. In general, one can say that both active and passive tags that are used in the low-frequency RFID systems are expensive in relation to those that are used in higher frequencies. This is due to the nature of the components used for manufacturing costs are high compared with the tags working at frequencies above. However, the construction of chip packaging and is cheaper. In addition, readers and programmers are simple and their manufacturing cost is lower than those of higher frequencies.

Areas of application

It´s suitable for applications requiring read little amount of data and for small distances. For example, access control, animal identification, asset management, identification of vehicles and containers, and as support to production.

The access control is undoubtedly the most widespread application for this range of frequencies. However, there is the low coverage and small memory capacity of the passive tags, so for such applications may sometimes be necessary to use active tags to expand the reading area and to improve the security encryption information.

The low-frequency tags also appear on the animal identification in order to: manage livestock, identify and control the protected species or identify pets.

High Frequency (HF 13.56 MHz)

Most systems working to 13.56 MHz using passive RFID tags and its basic working principle is the same as at low frequencies.

Capacity data

Tags (passive) often possess capacities ranging from typical 512-bit (often carry a number unequivocal identification industrial 64-bit) until 8 kbits divided into segments or blocks that allow direct data.

Speed and reading time data

Typically the data rate is usually about 25 Kbps. Devices are also available with higher rates of 100 Kbps.

The RFID systems in this frequency are able to read about 40 tags per second. For example conveying 512-bit to 25 Kbps takes approximately 0.02 seconds.

So at 40 read labels, will use 1 second.

Coverage

Typically, passive tags have a coverage radius of about 1 meter.

Reading Zone

It has a good penetration into non-conducting materials and liquids. However, it does not work well when there are metallic materials in the area of reading, since they produce reflections in the signal. His immunity to noise by electromagnetic interference industrial low-frequency is better than for the Low Frequency systems.

The orientation of the label may be another problem as the distance increases. This effect can be countered through the use of antennas transmission more complex.

Costs

It depends mainly on how to label and its implementation.

The design of the antenna of the tag is easy, so their cost is lower than in LF.

The RFID systems that use smart cards are the cheapest in the category of high frequency.

Areas of application

As in LF, HF systems are suitable for applications requiring read little amount of data and small distances. This applies to the management of luggage in airports, libraries and rental services, package tracking and logistics applications in the supply chain. This is frequently used in hospitals (identification of patients), access control, documents, traceability, animals, etc...

Ultra High Frequency (UHF 860-960 MHz).

The RFID systems that work to Ultra High Frequency base their operation in the spread of electromagnetic waves to communicate data and to feed the label if it is passive.

Capacity data

They are available active and passive tags with capacities from the typical 32-bit (often carry a number of unequivocal identification) until 4 Kbits, typically divided into pages of 128 bits to allow direct data.

Speed and reading time data

The data transfer rate is typically about 28 kbps but also higher speeds are available. It enables the reading of approximately 100 tags per second. For example 32-bit transmitted to 28 Kbps take 0,001 seconds. So read at 100 labels will be used 0.1 seconds.

Coverage

The UHF passive tags can achieve a coverage of 3 or 4 meters. Working with active labels and the lowest frequency, 433 MHz, coverage can reach 10 meters.

However, coverage is significantly influenced by the regulations of different countries for the amount of power permitted, which is lower in Europe than in the United States. Standardization is inadequate and little technology matures.

Without going any further, in Europe, where the maximum power emitted by the reader is 0.5 Watts, the scope of the system can be reduced to 33 centimeters. It is expected that this value will increase to 2 meters, where the maximum allowable power increase to 2 Watts.

Reading Zone

It has a good penetration into non-conductive materials and drivers, but presents difficulties in the presence of liquid (water). His immunity to noise by electromagnetic interference industrial low-frequency is better than for low-frequency systems, but must be considered the influence of other UHF systems operating in the vicinity.

The orientation of the tag can also be a problem at this frequency, because the characteristics vector of electromagnetic fields. This effect can be countered through the use of satellite transmission more complex.

Costs

The costs depend mainly on the way. Smart cards have a reasonable cost, representing the cheapest option within the category of systems RFID UHF. In large quantities, these tags to UHF can be cheaper than those of lower frequencies.

Areas of application

The main applications are: control of assets, access control, inventory management, parking, pharmaceutical industry, laboratories, exhibitions, tracking of containers and pallets, traceability of items, logistics supply chain, etc...

Microwave (MW 2.45 GHz).

Capacity data

They are available systems of active and passive tags, with capacities ranging typically from 128 bits to 512 Kbits devices, which can be divided into segments or blocks to allow direct data.

Speed and reading time data

It´s depends on the design of the label, but is usually high. The typical speed is below 100 kbps, although some devices may reach 1 Mbps. For example 32 Kbits transmitted to 100 kbps takes 0.3 seconds. If you are measuring 128-bit blocks, 40 tags were used 0.05 seconds.

Coverage

Good work range, covering regions of between 1 and 2 meters for passive devices and up to 15 meters or more, for active devices.

Reading Zone

It has a good penetration into non-conducting materials, but not in liquids that contain water, where the absorption coefficient is important. This is reflected by metals and other conductive surfaces. It is susceptible to noise. This is a shared band work.

Costs

The costs depend mainly on the shape and method of feeding (active or passive).

Areas of application

It is suitable for applications requiring high coverage and high transmission speeds. For example: automation in manufacturing, access control, toll roads, and logistics supply chain and logistics military applications.

SAFETY ASPECTS[74]:

Despite the potential benefits arising from the implantation of RFID systems, there an increasing flow against this technology, because anyone with an appropriate reader can read the information bearing labels. In this regard, RFID entire system must be protected to a greater or lesser extent:

* Read / write unwanted, in order to obtain information or modify data by deceit.

*The existence of false labels inside a restricted area, seeking to circumvent security system accessing or receiving unauthorized places certain services without payment.

*Listens illegal to copy the data and counterfeit labels.

Security is a particularly important aspect. Often embrace new technologies without unduly worrying about the safety. We can think of computers (with the emergence of viruses), Internet (with the emergence of various types of attacks on networked computers, etc.). RFID is an emerging technology and uses very promising, and if not provided with adequate security, will undoubtedly

74 http://www.n-economia.com/informes_documentos/pdf/sintesis_documentos/SINTESIS_NE_09-2008.PDF

trouble serving, theft of personal data and confidential, etc.. In fact, RFID is beginning to be used in many applications without too much concern in the security aspects.

Despite being a young technology, have already appeared cases of security commitments in RFID systems. For example, in January 2005 a group of students managed to break the encryption system outlets RFID ExxonMobil.

In February 2006, Adi Shamir, a professor at the Wiezmann Institute showed that it was possible to monitor power levels of RFID tags using a directional antenna and an oscilloscope. The patterns that appear in power levels can be used to determine if the password is accepted or not by the RFID device. Using this information and a mobile phone could commit the information is transmitted via RFID.

The simplest form of attack on a RFID system is to prevent communication between the reader and the tag. This can be done as simple as shielded metal.

There are other more sophisticated forms of attack, whose targets are in radio communications. *The most important can be classified into four types: Spoofing, Insertion, Replay and Denial of Service.*

Spoofing

This type of attack is to provide false information that seems valid and that is accepted by the system. For example, one could send an electronic product code (EPC) false, when the system expects a correct.

Insertion

This type of attack inserted commands system where data is usually expected.

Replay

In this type of attack is a signal intercepts RFID and recorded data.

It was subsequently relayed to the system, which accepts as valid.

Denial of Service (DOS)

in such attacks, the system collapses food with more data than it can handle. There is a variant known as RF jamming in which nullifies the RF communication broadcasts noise sufficiently powerful. Of course, it is also possible to attack the information contained on the label. If this information out, for example, a price, the attacker could get a substantial discount.

Security measures for labels

One obvious way to avoid changing the information on labels is to use labels read-only, or not write data directly on the labels, but include only those labels in a code, and move all the other information to a base data, higher than the label.

Security measures for the reader

To prevent counterfeit IDs reader, thereby obtaining access to labels, can be used to validate authentication methods of communication between tag and reader.

APPLICATIONS[75]:

We can cite some of the current uses of RFID:

• Dealers.

• Automatic Identification Systems vehicle.

• Control access to buildings or sites in the interior of buildings.

• Identification of farm animals and livestock.

• Tracking assets.

• Identification of pets.

• Logistics and management at warehouse (Example, Kimberly Clark).

• Monitoring product supply chain (e.g. tracking pallets, Wal-Mart, DoD, Target, Tesco, Metro Group).

• Security products.

• Monitoring movement of materials at the factory.

• Implementation of traceability.

• Systems payment of tolls.

• Entering and leaving books in libraries (Vatican Library, Berkeley, University of Connecticut).

• Tracking baggage at airports (e.g. at the airport from Hong Kong, or Delta Airlines, or Globalbagtag).

• Startup car (Toyota, Renault, Lexus and Audi).

• Sports (application in monitoring athletes in the Marathon).

• Tickets (for example, use in the Tennis Masters Cup in 2005 or the Canon Expo 2005 in Paris).

• Tracking people (in medical applications or as a security measure, for example, to identify newborns in hospitals).

• Pharmaceutical applications.

In addition to these industrial applications mentioned, there are other areas where RFID devices are highly promising as an option. One is that of border security systems. In this context, the role of biometric identification systems with capacities of tracing and identification of RFID devices is having

75 http://www.rfidc.com/docs/introductiontorfid_technology.htm

very positive results. They can apply to:

• Identification of vehicles, drivers, passengers and staff at border posts.

• Systems vehicle registration.

• Access Control of vehicles in protected sites.

• Traceability of imported goods, and security in imports.

• Monitoring and identification of containers.

• Control of passengers, baggage and cargo air transport.

Another aspect in which RFID can be useful is the improvement in police and judicial efficiency. The areas where RFID technology can help are:

• Improvement of police efficiency. In this area we can highlight:

Management and security in the police evidence storage.

Location in police stations.

• Improved security police. In this area we can highlight:

Protection of firearms.

Monitoring patrols.

• Fight crime. In this area we can highlight:

Protection of property.

License plates of cars.

Meat and driving licences.

SWOT ANALYSIS

The analysis Weaknesses, Threats, Opportunities and Strengths (SWOT), but does not allow direct decision-making, it provides some guidance to companies in the sense of providing a summary of the positive and negative factors of a given technology, project or venture, with the aim of providing an overview to take an initial idea about the wisdom of undertaking its realization. Then we devised a simple SWOT analysis on the implementation of RFID technology in applications related to health.

Strengths:

• Allows improve the efficiency of healthcare processes, improve inventory management and reduce errors arising from their manipulation.

• Success tested in the deployment of other logistics applications.

• The characteristics of the technology: remote reading, possibility of programming, compact, rugged, and low power consumption.

• The versatility of the technology: labels in a variety of shapes, sizes, scopes, consumption, etc... Allow you to easily adapt to the changing requirements of the procedures and the various characteristics of the equipment.

• Movement clears towards the adoption of standards that facilitate the interoperability of equipment. Although this is still in process, it seems clear that in the end one or two standards will be those that dominate the market.

• The technology appears to be reaching a degree of maturity.

• Reducing the price determined of equipment: tags, readers and software (particularly passive systems), reason for the growing supply on the market of RFID.

• No need for food labels passive and low prices from them.

• The same technology that is used for the identification may also be used for locating and tracking.

Weaknesses:

• Limitations of the technology. It does not work well in the presence of metals or elements rich in water. There are also limitations spread depending on the frequency used, which have been previously considered.

• Limitations coverage passive RFID technology. In many cases, this scope is less than the meter, which hinders the operation at distances greater.

• Issues of privacy and confidentiality. Although it is possible to provide security to the RFID transmissions the public still perceives it as a potentially invasive technology of their privacy.

• Frequency of operation. Depending on the band work, there may be potential for interference.

• Lack of unanimity on what will be the standard that will prevail, although it is working on it. Not only requires a certification of current systems, but also requires interoperability between them.

• While declining price, the cost of active systems is still high.

Opportunities:

• RFID not only improves existing processes but generates new business opportunities with applications that until now could not be developed with other technologies (eg, location in real time).

• The labeling of patients actually provides the individual with more freedom, since it means reducing the number of outstanding professionals in their state.

• Immediate implementation in the fight against counterfeit medicines.

Threats:

• The costs of transition from systems based on other technologies can be high or at least the return of the short-term economic benefits, which can cause a degree of resistance to the adoption of RFID-based systems.

• An improper sizing of the needs or expectations of erroneous functionality may not cause the expected benefits.

• Emergence of new technologies (or variants thereof) that improve their performance.

• The various existing regulations, for example, in the USA and the European Union issued on the powers, scope, etc... In some of the frequency bands may pose a threat to the standardization worldwide.

STANDARDISATION[76]

The standards for RFID address four key areas:

Protocol on the air interface: specifies the way in which RFID tags and readers communicate using radio waves.

Content of data: specifies the format and semantics of data that are communicated between tags and readers.

Certification: evidence that products must meet to ensure that they meet the standards and can interoperate with other devices from different manufacturers.

Implementation: use of RFID systems.

As in other areas of technology, standardization in the field of RFID is characterized by the existence of several groups competing specifications. On the one hand are ISO and other Auto-ID Centre (since October 2003 known as EPCglobal, 8 EPC Electronic Product Code). Both share the goal of achieving low-cost labels that operate on UHF.

The standards for EPC labels are of two kinds:

Class 1: simple label, passive, read-only memory with a non-volatile programmable only once. Class 2: read-only tag that is programmed at the time of manufacture of the chip (not reprogrammable later).

Classes are not interoperable and are incompatible with the standards of ISO. Although EPCglobal is developing a new generation of standards is EPC (commonly known as Gen2), with the aim of achieving interoperability with ISO standards, is still in discussion about the AEF (Application Family Identifier) 8-bit.

76 http://es.wikipedia.org/wiki/RFID#Estandarizaci.C3.B3n

For its part, has developed ISO standards for RFID automatic identification and management of objects. There are several related standards such as ISO 10536, ISO 14443 and ISO 15693, but the series of standards strictly related to RFID and the frequencies used in these systems is the number 18000.

Gen 2

EPC Gen2 is short for EPCglobal UHF Class 1 Generation 2.

An organization called EPCglobal is working on an international standard for the use of RFID and EPC in the identification of any item in the supply chain for companies in any industry, anywhere in the world. The Board of Governors of the organization includes representatives from EAN International, Uniform Code Council, The Gillette Company, Procter & Gamble, Wal-Mart, Hewlett-Packard, Johnson & Johnson, sat and Auto-ID Labs. Some RFID systems use alternative standards based on ISO 18000-6 classification.

Mails information

Here the mails (with dates and names) that the companies send us for give us additionally information.

Finn Zoega, DTI

dear David
The flow chart looks okay.
The difference between HF and NFC is the standardisation. At this moment there are no wide standard for NFC. It is suspected that the NFC protocol will be changed in the near future.
HF has several standards. At this moment EPC are working on a general standard for HF communication, similar to the standard used with UHF.

Med venlig hilsen / Best Regards

Finn Zoëga, Sektionsleder, eMBA

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Fra: David Sossna [mailto:david_sossna@yahoo.dk]
Sendt: 26. maj 2008 15:07
Til: Finn Olesen Zoega
Emne: urgent
We made a process description of the use of rfid within a manufacturing company. We would like your approval or suggestions for changes. See attached.

1. Incoming products from supplier have HF tags on item and box level and an UHF tag on the pallet. The pallet belongs to the supplier and will be returned after delivery. The UHF tag on the pallet is read by the first UHF RFID gate and gives information about the boxes on it. The Data is stored in an internal database.
2. The boxes are stored in the stock.
3. When a new drug is manufactured, a new batch number is created in the database and every ingredient will be scanned by a HF handheld scanner and stored in the database belonging to the batch.
4. When the drug is completed, an HF tag is placed on the bottle. This tag includes the batch number, lot number, epc product code, expiry date and production date.
5. A number of e.g. bottles are packed into cases and a HF tag is placed on the case, including the epc case code
6. The cases are put into boxes where a new HF tag including the epc carton code is attached.
7. Several boxes are placed on a pallet with an UHF tag including the epc pallet code. This pallet is placed in the finished goods storage.
8. When the products have to be distributed, they pass an UHF gate where the UHF tag on the pallet is scanned.

BUT we still don't really understand why manufacturer rather would use HF compared to NFC.

Kind regards

David Sossna

Helle Jacobsgaard, Apotekerforeningen

Kære David Sossna

Det vil passe mig fint hvis I kommer den 9. april kl. 10.30. Jeg regner med et møde af max. 1 times varighed.

I kan henvende Jer i receptionen og spørge efter mig. Adressen er: Danmarks Apotekerforening, Bredagde 54, København K (lige ved Marmorkirken (Frederikskirken) og Amalienborg.

Jeg skal venligst bede om en liste med navne på dem der deltager i mødet samt hvor I kommer fra.

Venlig hilsen
Helle Jacobsgaard
Specialkonsulent, cand. pharm.
Danmarks Apotekerforening
hj@apotekerforeningen.dk
tlf. + 45 33 76 76 60 (direkte)

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david_sossna@yahoo.dk]
Sendt: to 27-03-2008 15:04
Til: Helle Jacobsgaard
Emne: AW: Møde med Danmarks Apotekerforening om forfalskede lægemidler

Hej Helle,

Tak for at vi kann mødes med jer for at tale om vores projekt.
Vi har aftalt at den bedste dag for os ville være den 9. April, da vi skal give en lille projekt præsentation den 10.
Vi håber at det også passer ind i jeres skema. Vi har tid hele dagen.

Mvh
David Sossna

Ole Wulff, NNE Pharmaplan / NovoNordisk

Hej David,
Jeg ved ikke hvor meget forhistorie Carsten har givet jer, men ellers kommer det her i korte træk.
For ca. 12-13 år siden begyndte man i Novo Nordisk at indføre stregkoder i produktionen.
Det startede i det små, men for at det ikke skulle udvikle sig i alle mulige retninger så udarbejdede man en stregkode standard, som i detaljer beskrev hvordan og hvor man skulle anvende stregkoder.
Standarden er baseret på EAN128 koden, og de oplysninger som skrives i koden spænder bredt, men er typisk batch, varenummer, løbenummer, udløbsdato, kvalitetsstatus osv.
Som tiden er gået har implementeringen af stregkoder bredt sig i vandet og efter en periode på 6-7 år (fra start) var de implementeret overalt i Novo Nordisk produktion, og understøttet af de bagved liggende systemer: Både MES systemer i produktionen, samt globale ERP systemer.

Jeg har været indblandet i mange af disse implementeringer, og har siden starten haft ansvaret for at følge stregkode eller mere generelt AutoID teknologien til dørs for Novo Nordisk (jeg har arbejdet med AutoID i alle aspekter siden 1990). Vi har derfor også løbenden holdt øje med RFID for at se i hvilken retning det udviklede sig i.

I kraft af, at vi havde valgt EAN128 som stregkode standard havde vi set vigtigheden i at vælge en standard og ikke blot lave en proporitær løsning. Med EAN128 koden kan vi genbruge data i stregkoden, mellem systemer selvom systemerne ikke datamæssig er budet sammen (når en vare modtages i Warehouse systemet og forsynes med en stregkode, kan f.eks. batch data anvendes direkte af de underliggende produktionssystemer selvom der ikke er forbindelse til disse, og efterfølgende kan ny data fødes direkte ind i de overordnede ERP systemer via stregkoden).

Som sagt, så har vi holdt øje med RFID i mange år, og for 4-5 år siden EPC begyndte at melde at en ny standard for UHF tags snart vil være på trapperne, og samtidig hermed at WallMart i USA vil stille krav til deres leverandører omkring opmærkning, betød at vi vil gøre lidt mere end blot at holde øje

(en af den basale grunde til, at vi ikke har kastet os over RFID, er at vi har en næsten 100% implementering af stregkoder, og en cost/bennefit analyse ikke faldt ud til RFID's fordel).

Vi besluttede for ca. 3 år siden at vi ville sætte et pilot projekt op, hvor vi kunne teste mulighederne i RFID i vores eget miljø (og havde den gang også kontakt til Teknologisk Institut, som var på tegnebordet med deres testmiljø) og tog kontakt til en række leverandører (Siemens, Intermec, IBM) af RFID for at købe udstyr og tags.
Det store problem var, at både udstyr og tags til EPC (Gen1 tags) var prototyper, og i så lille antal at vi ikke kunne købe det, men vi fik lavet nogle indledende forsøg.
Det afslørede at vi ville få problemer med at læse tags i vores miljø (vi vil læse tags som sad på nogle præparat kasser, hvori der var flere hundrede hætteglas eller karpuler fyldt med insulinvæske. Og ydermere var disse kasser stablet i 2x44 styk). Det satte det hele i stå, og vi ventede på Generation2 af EPC tag'en, men midt i det hele trådte RoHs directivet i kraft i EU, og det udstyr som var liiiige på trapperne udgik, hvorefter vi måtte vente på nye produkter (primært læsere).

Sidste sommer kom der imidlertid skred i det, og læsere var nu tilgænglig ligesom tags (nu i Generation2). Hurtige tests viste at nogle af de problemer som vi havde oplevet med Gen1 og det gamle udstyr var fjernet, og vi besluttede derfor at starte vores pilot projekt projekt op igen. Intermec som vi tidligere havde arbejdet sammen med, ændrede struktur, og det var ikke længere det rette valg. Vi søgte derfor efter nye samarbejds partnere og forhandler i dag med IDZone. Vores valg af tags bliver fra TagSYS. Vi har samtidig valgt at vi både vil prøve UHF EPC Gen2 tags - i kraft af den standard som findes - samt HF tags (13.56 MHz) da vi med dem kan komme ned og mærke de enkelte hætteglas/karpuler. Dette med Counterfeit for øje, men også da det sandsynligvis vil være vejen frem i forbindelse med pedigree i USA, hvis dette skal ske med RFID tags.

Tidsrammen for vores pilot er derfor sat til en gang til sommer, og resultatet vil være en generel vurdering af hvad Novo Nordisk kan anvende RFID til, samt et udgangspunkt for kommende projekter som overvejer RFID.

Dette var den korte version. Har I behov for mere viden, må I sige til. Min kalender en lidt fyldt pt., men vi kan nok finde et hul i starten af maj, hvis vi skal mødes og snakke videre (eller mail mig, det er i altid velkommen til).

mvh.

Ole Wulff

From: David Sossna [mailto:david_sossna@yahoo.dk]
Sent: 21. april 2008 11:17
To: OW (Ole Wulff)
Subject: rfid projekt til ingeniørhøjskolen

kære Ole Wulff,

vi er en gruppe på 5 internationale ingeniørstuderende fra ingeniørhøjskolen i kbh. I sammenarbejde med danmarks teknologiske institut laver vi en markedsundersøgelse med temaet "automation and system integration" med fokus på pharmaindustrien.

Projektet går ud på at undersøge i hvilken grad RFID (radio frequency ID) teknologi vil gavne det danske medicinal marked. I denne sammenhæng fokuseres der på i hvor hvidt denne teknologi kan stoppe counterfeiting problemet (ulovlige kopiprodukter).

Vi prøver at kontakte flere medicinalvirksomheder, også dem som ikke bruger RFID, for at få et overblik over det hidtidlige situation.

Vi har fået din kontakt fra Carsten Holm Pedersen som vi har mødt tidligere i vores projekt forløb.

Vi har hørt at NovoNordisk har bygget et rfid test anlæg og at du er ansvarlig for dette centre.

Vi håber at i kan finde tid til os, da det ville være en stor hjælp for projektet.

Med venlig hilsen David Sossna

Hej igen,

Glemte lige de sidste spørgsmål.

Vi har valgt at se på HF og UHF som separate dele. Vi er som sagt i en pilot fase, og vi har alt for mange gange set, at teknologien ikke var moden nok. Derfor har vi besluttet, at det som undersøges er produkter som er tilgængelig som lagervarer.

Vi holder øje med markedet, og hvis piloten viser et positivt udfald og vi senere skal lave en business case, så vil vi alligevel genoverveje hele tag/læser forløbet igen og vælge det som på det tidspunkt tegner til at blive en standard.

Husk en vigtig parameter er prisen pr. tag. Hvis vi snakker et forbrug på 500 millioner tag pr. år, så betyder nogle få ekstra cents en masse.

mvh.

Ole

From: David Sossna [mailto:david_sossna@yahoo.dk]
Sent: 19. maj 2008 13:49
To: OW (Ole Wulff)
Subject: rfid projekt, ihk

Hej Ole,

nu har vi set lidt på de der slides du sendte og vi bliver ikke helt kloge på dem. Vi mangler stadigvæk transaktionsomkostninger. Og ud fra slidene kan vi ikke helt se hvor og hvor mange scanner der skal installeres i en fabrik.

Noget helt andet: Du nævnte at i overvejer at bruge HF og UHF reader og tags. Hvorfor HF og ikke NFC? Vi har talt med DTI og de mener at fordelen ved NFC er at det er de samme tags der kan bruges til NFC og UHF.

Mvh David

Steen Winther, Leo Pharma

Hej David

Har har ca 1400 varenumre i sortimentet som sælges heraf produceres de ca 800 i Ballerup - resten i Irland eller Frankrig.

Mvh

Steen

"David Sossna" <david_sossna@yahoo.dk>

"David Sossna" <david_sossna@yahoo.dk> 02-05-2008 16:05	To	<steen.winther@leo-pharma.com>
	cc	
	Subject	rfid projekt, ingeniørhøjskolen

Kære Steen Winther,
Kan du fortælle os hvor mange produkter i sælger pr. år?
Mvh David Sossna

Hej igen

Det er jo noget andet :-)

De ca 1400 varenumre sælger tilsammen 98792276 pakninger per år.

Mvh

Steen

"David Sossna" <david_sossna@yahoo.dk>

"David Sossna" <david_sossna@yahoo.dk> 05-05-2008 11:58	To	<steen.winther@leo-pharma.com>
	cc	
	Subject	AW: rfid projekt, ingeniørhøjskolen

Hej Stehen,
de der varenummer på ca. 1400 kunne vi også læse os frem til, men vi vil gerne vide styktallet af jeres producerede hhv solgte produkter.

Mvh David

Hej David

Vi modtager ca 10 paller/time/mand incl alt, dvs varemodtagelse registering via stregkode, opmærkning af alle enheder på pallen, prøveudtagning til QC og indlagring på lagret.

Håber informationerne svarer til det du søger.

Mvh

Steen

"David Sossna" <david_sossna@yahoo.dk>

"David Sossna" <david_sossna@yahoo.dk> To <steen.winther@leo-pharma.com>
28-05-2008 19:48

cc

Subject rfid projekt, scanning af stregkoder

Hej Steen,
vi er næsten færdig med vores projekt men hænger lidt fast i at beregne nogle priser. Har du måske nogle oplysninger om hvor meget tid det gennemsnitligt tager for at scanne en palle (almindelige stregkoder) med et given antal produkter?

Mvh David Sossna

Ash Patel, Biogen Idec

Hi David,
Unfortunately I am travelling every week to the UK at the moment and I am not sure when I can meet with you. I also want to stress that Biogen Idec does not use RFID and does not have any plans on using this because of the evaluation that we have done. We have a requirement to use Matrix coding and that is the direction that we are moving in at the moment.
Hope you can find someone else that Todd can suggest.
with regrets
Ash

"David Sossna" <david_sossna@yahoo.dk>

06-May-2008 12:18 PM

Message Size: **7.2 KB**

To <Ash.Patel@biogenidec.com>
cc
Subject rfid project meeting

Dear Ash Patel,

If you returned from your trip to the UK already, could it maybe be possible to meet with us this or next week and talk about RFID within Biogen Idec? We are slowly running out of time for our project as we have to hand it in June 4th.

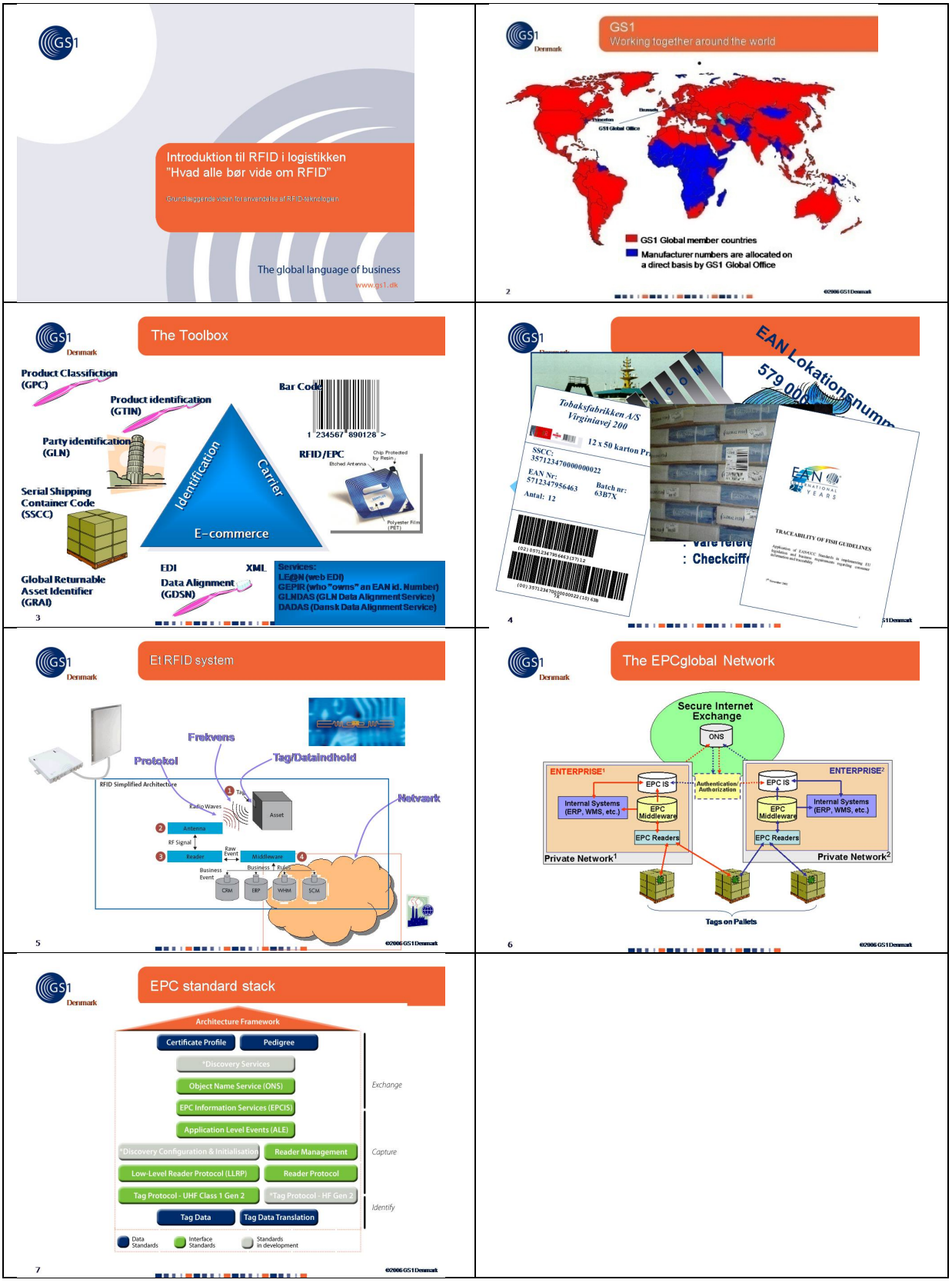
Kind Regards

David Sossna

David Sossna
Terrasserne 18, st86
2700 Brønshøj
Denmark
Mobile: +45 31772759

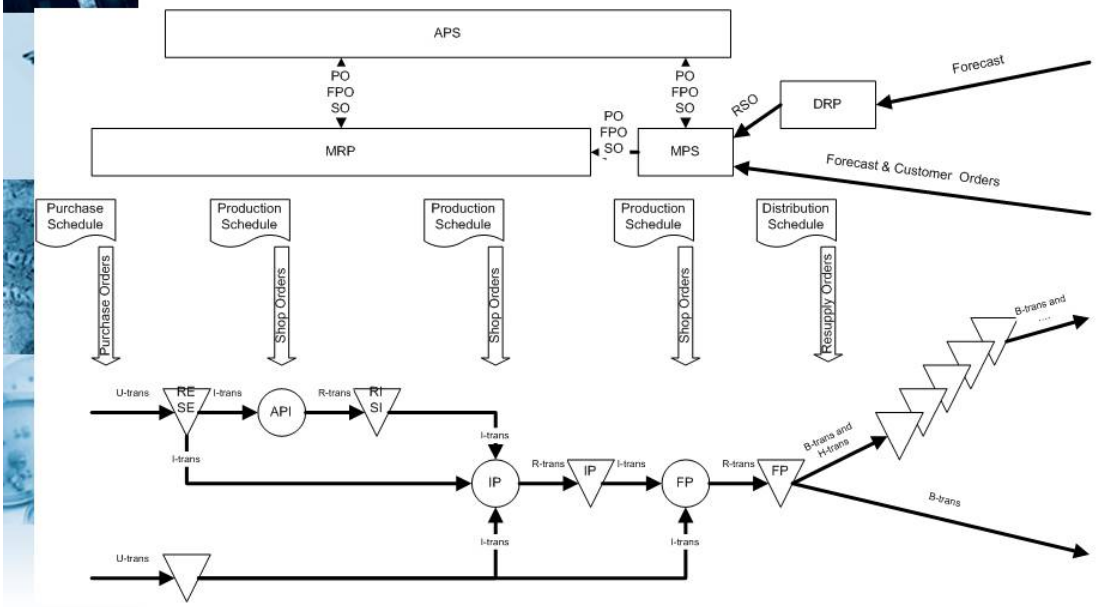
Power Point Presentations

GS1



Steen Winther, Leo Pharma

Supply Chain Model



research based, people driven

ACTIVITY DATA

Number of finished good items (FP)	~ 800
Number of intermediate items (IP)	~ 100
Number of raw material items	~ 200
Number of packaging components	~ 2000
Number of packaging orders per year	~ 3000
Number of production orders per year	~ 1800
Number of purchase orders per year	~ 5000
Number of sales orders per year	~ 4000
Number of orderlines shared services per year	~ 25000+
Number of courier shipments per year	~ 7000
Number of inventory transactions per year	~ 200000+

research based, people driven

Questions for companies meetings

Interview guidelines:

- How is the process from receiving the products to the end consumer?
- Is there any serialization standards?
- What ID technologies do you use?
- Are you using RFID for some applications?
- If not, are you thinking about it?
- What are the advantages and disadvantages of RFID technology to you?
- What would be the impact on your company if drug manufacturers use different ID technologies?
- Do you think about upgrading your inventory management?
- Are you considering the problem of counterfeiting and patient safety?
- Are you considering the different future possible law regulations (e.g. e-pedigree)?
- How do you deal with the products from the parallel-trade association?

Guidelines for the international study

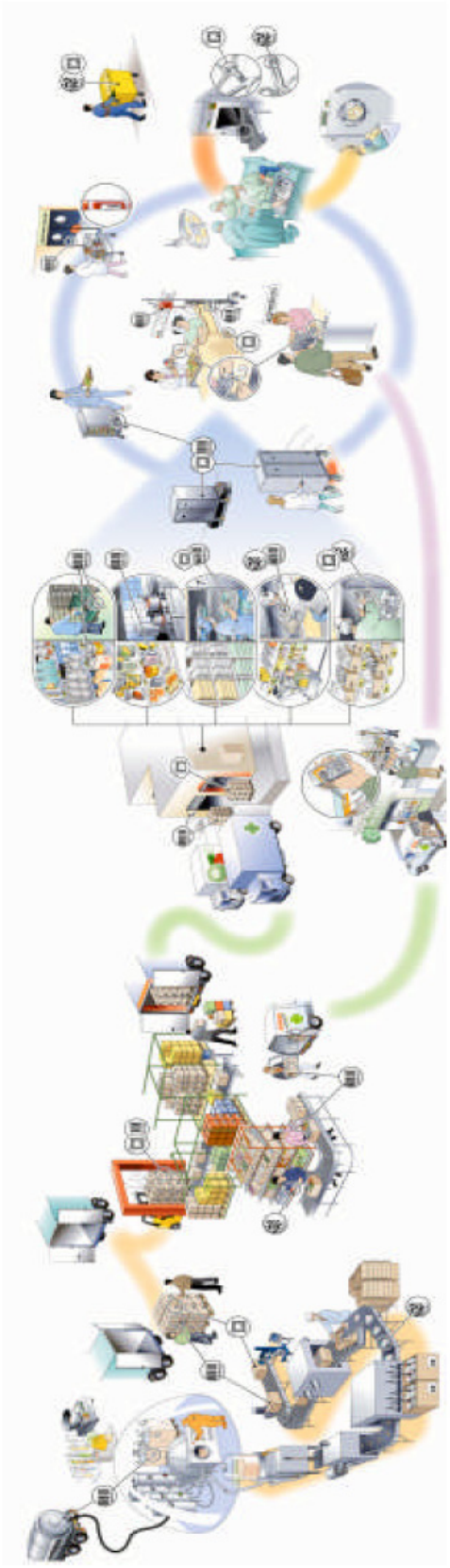
Companies which are using RFID:

- When did you implement RFID technology?
- Is it used for just a part of your production?
- If yes, what other ID technologies do you use?
- Do you use RFID internally or do you belong to the Electronic Product Code Global Network?
- Why did you decide to implement it?
- What are the benefits of this technology?
- Is RFID useful for the prevention against counterfeiting, for example caused by the virtual selling in the Internet?
- What kind of problems did you have to deal with so far because of this technology?
- Could you give us a general cost calculation of the implementation of RFID technology within your supply chain?
- Could you give us some other contacts which could be helpful for our study?

Companies which are not using RFID:

- What ID technology do you use for your products?
- Do you belong to a common network with other companies of your working environment?
- Have you ever considered implementing RFID technology?
- If yes, why did you decide not to implement it and did you make a cost calculation?
- How do you prevent the market from counterfeiting?
- Is the virtual pharmaceutical market (i.e. Online Pharmacies) a problem for your company?
- Do you think that this technology will be mandatory in the future?
- Do you know some other companies which are using RFID?

GS1 France



DTI

Danish Technological Institute is an independent, not-for-profit institution approved by the Danish authorities to provide technological services to businesses and the community.

The Institute employs experts in hundreds of different fields at 34 centers organized under the auspices of the 5 organizational units that define the main parameters for their work:

- Building Technology
- Industry and Energy
- Business Development
- Materials
- Productivity and Logistics

The Institute adopts an interdisciplinary approach to innovation and to the task of improving the ability of small and medium-sized companies to exploit new technologies and management tools.

The Danish Technological Institute researches and develops new knowledge – in line with universities and other research institutions – and makes this knowledge available to the Danish business community on a commercial basis.
Knowledge is one of Denmark's most important resources and provides the cornerstone for Danish commercial competitiveness in the global market. The Danish Technological Institute is a key player in the knowledge system.

We have done this project with the cooperation and help of DTI. Our contacts in DTI have been Finn Zoega Olesen and Morten Pedersen. Finn is a head master of the production and transportation sector and Morten is a senior consultant .In the first visit, they explained us an introduction about RFID, and they showed us good points for our project and how we could start and how we could focus it.

They spoke about Danish market and the current situation of RFID. They also showed us the laboratory, when the tests are made. They did a demonstration for us, and explain us the operation step by step. It was a good experience because we saw all the components acting. We had the opportunity to combine both the theoretical and the practical part, which gave us a clear idea and

we resolved several doubts, like where to put the antennas, the kinds of materials or components of the same size , the speed or how fast can a RFID tag be read (it is not the same seeing that read).

We contacted DTI several times more, either via mail or visit them again, because as we moved in our study the technical uncertainties arising.

In our first meeting Finn and Morten plan us some questions. It can be interpreted as a way to focus or move us towards the correct path. These are the question that we can answer now:

- How could RFID technology help in securing safe and genuine products?
- How can Danish Pharmaceutical companies cope with the FDA mandate on product pedigree in USA?
- How could technologies like WIFI and NFC influence the industry?
- What is the status in the Danish Healthcare and Pharmaceutical industry today – using or planning to use RFID?

Case implementation companies providing goods medical / pharmaceutical

We have already commented on the problem of counterfeit medicines worldwide, and particularly in the USA, and the election by the FDA of RFID technology for the labeling of certain drugs more relevant, aware of the positive aspects that can make to the pharmaceutical industry. This decision has been pushing the regulation of RFID within this sector, which should ensure traceability of the drug, from its manufacture to its arrival in pharmacies.

In Europe, the use of RFID by the European pharmaceutical industry will continue to be driven by the increase in the counterfeiting of products in the market. These fakes are mainly due to deficiencies in the supply chain and parallel trade legalized drugs among the various Member States of the European Union. According to a study by Frost & Sullivan European markets for RFID in the pharmaceutical sector had revenues of around 14 million Euros in 2005 and are estimated to reach 350 million Euros for 2012.

Despite the high potential for the use of RFID in the monitoring and management of the products in the pharmaceutical industry, the lack of interoperability and harmonization of standards remains a key issue. The EU Member States will have to reach a consensus and, at the same time, vendors of RFID technology must be kept abreast of the regulations and the technological requirements of different countries and work together with government agencies to ensure a smooth transition from bar codes to RFID technology.

Until now, only large giants distribution such as Wal Mart, Metro (Germany), Marks and Spencer (UK), Boekhandels Group (Netherlands), Maruetsu (Japan), have achieved that labeling their products RFID is profitable. The obligation to the FDA in the pharmaceutical market will increasingly become more vendors offering systems with the deployment of RFID technology, which will reduce the price of them and encourage the rest of distributors and logistics companies to implement these systems. Therefore it seems that the massive deployment of RFID will be led from the market of logistics and distribution.

Here are some first successful cases of application of RFID technology to the pharmaceutical industry, and then continue with other examples of application in companies that provide active physicians to hospitals or medical centers (blood bags, orthopedic implants, etc...).

• AmerixourceBergen, American wholesaler, uses IBM Websphere middleware, and software authentication VeriSign, for the monitoring of pharmaceutical products throughout the supply chain.

• Cardinal Health, a provider of technology products and services in health deployed by the end of 2006 a pilot to tag and track pharmaceuticals throughout the supply chain (end to end). Despite

confirm improvements in efficiency and prevent counterfeiting, those responsible for the pilot extracted the conclusion that barriers still exist on issues relating to global standardization and privacy issues.

• Mallinckrodt Pharmaceuticals, a manufacturer of generic drugs, implemented in 2005 a system based on RFID in order to maintain surveillance on drugs along the supply chain. The manufacturer uses technology from ADT Security Services and OAT Systems.

• Sun Microsystems has developed an RFID solution for the authentication of medicines that provides traceability at every stage of the supply chain.

• Pfizer has a pilot in this area, with the use of RFID to prevent forgeries of the Viagra pill.
• Intelligentz Corporation has developed a system to eliminate counterfeit drugs using RFID technology. A database generates a uniform code for each pill, code that is sent to manufacturers through.

• Zimmer multinational distributor of orthopedic surgery products has installed RFID readers Maguellan Technology through its operational centers in New Zealand, Australia, Japan and Thailand. The individual orthopedic implants are part of a more comprehensive kit that is supplied to hospitals and scenarios operations. The creation of the kits is conducted with 100% precision, ensuring that all items are readily visible to provide quality pre-shipment and post-reception. When these kits are returned for updating, cleaning and conditioning annually, it is necessary to revise them one by one, where only 3% of its content is often used. The losses of time and costs were significant until the labeling of items through RFID has accelerated further that such verification accuracy in the records of inventories has improved dramatically.

• Purdue Pharma integrates RFID label of Impinj Gen 2 in their lines of high-speed pharmaceutical packaging with the aim of improving the efficiency and security of the pharmaceutical supply chain. The solution used is based on the UHF RFID GrandPrixTN, comprising SpeedwayTM readers, the tags with chips and antennas MonzaTM readers with a specific application Near field.

• A German company specializing in pharmaceutical labels will begin testing tags with temperature sensor Montalbano Technology (Italy), which has created a family of RFID tags HF semi passives keeping record of environmental conditions such as light, temperature and humidity. The pharmaceutical industry is very interested in testing with the use of these RFID tags with temperature sensor, and that certain drugs can be very expensive because of inadequate conditions spoil in storage. The tags allow add additional functionality such as additional memory or sensors.

Moreover, they are programmable, allowing users to define their own criteria for recording data from the sensors as the interval between steps, for example, measures only outside of a predetermined threshold, etc.

They are equipped with small batteries to activate the sensor gain and temperature, while sending signal is captured with the power of readers.

• In Malaysia, three medical institutions (University Malaya Medical Centre, Penang Adventist Hospital and the National Blood Bank) are testing an RFID system to improve the monitoring of blood bags and reduce errors by blood incompatibility, among other advances. This solution RFID recently development, called BloodBank Manager, has been developed jointly by the Siemens Malaysia Sdn Bhd and Intel MSC Sdn Bhd. The solution will ensure the transparency and accountability of records, labeling and tracking of blood products; it may create profiles of patients and generate historical donations and transfusions as well as profiles of donors and patients.

• The San Raffaele Hospital in Milan has developed three projects RFID.

Comment one of them, focused on reducing errors in blood transfusions. According to statistics, the error rate is 1 in transfusions transfusion erroneous 12,000 each. About 80% of errors in transfusion were caused by labeling, and of them, most are due to human error, caused by overburdened medical personnel.

The project was aimed at ensuring the donations themselves, namely a patient is extracted donated blood for himself. Its main objectives were:

Remove errors or labelling.

Eliminate or as far as possible the paper forms.

Or provide traceability of blood bags in the whole process.

HF labels were used, applied to a band on the wrist of the patient and blood bags. The band wrist stored patient information, including a photograph of it. This information is copied into a label that is fixed to the bag of blood. The project collaborated Intel, and Autentica Cisco Systems, providing computers, RFID tags and wireless network to be used in the project.

Lastly, we will cite a couple of technological solutions for the management of the supply chain, which could particularize is perfectly to the asset management health and therefore collect here:
• Microsoft launched at the 2006 RFID BizTalk Server 2006 that enables companies to better manage its supply chain by integrating their management software with data from RFID systems. In addition

Microsoft has partnered with hardware manufacturers like Alien Technology Corp., Intermec Inc. And Paxar Corp.

• RF SAW Inc. marketed a new type of RF system based on surface acoustic wave devices (SAW) technology and commentary. The company has successfully developed and patented this new system, whose core is called "Global SAW Tag." This system provides solutions in competitive markets such as the supply chain, asset management and resources and monitoring instrumentation.

We have seen therefore that the application that is having better reception in the field of health, and that surely will lead the market for RFID tags, serving as a tractor for the rest of applications, is the labeling and tracking drugs and assets, in order to preserve the traceability of products throughout the supply chain and thus avoid counterfeits of the same while also preventing errors in their administration and management. In this area, there are numerous cases, both hospitals and pharmaceutical distributors, which have successfully deployed RFID pilots to that goal. Despite the success of the initiatives and clear benefits, manufacturers and distributors of generic drugs have a problem financing of the deployment, and that the cost of implementing this system is high, and part of those costs cannot be reversed in customers, as in the case of non-generic drugs.

The frequencies of operation are most often used both UHF and HF. In particular, companies often try to label individually HF and UHF medicines for crates or pallets, as is done in the rest of logistics services.

Logbook (Agenda)

Agenda meeting Thursday, the 6th of March

Time: 11:00
Place: A2.02a
Project: EPS group 9: "Automation & system integration, B2B & B2C"

Chairman: Nadia Khaji

Secretary: Sara Zayed

Team members: Miguel Oscar Lozano, Monika Polak, David Sossna

Supervisors: Poul Kosel

1. Approval of the agenda and minutes
2. Companies
3. Gantt Chart
4. Project Review, comments
5. DTI questions
6. Interim report
7. Any other business
8. Date and time of the next meeting

Agenda meeting Thursday, the 13th of March

Time: 11:00
Place: A2.02a
Project: EPS group 9: "Automation & system integration, B2B & B2C"

Chairman: Monika Polak

Secretary: Nadia Khaji

Team members: Miguel Oscar Lozano, Sara Zayed, David Sossna

Supervisors: Poul Kosel

1. Approval of the agenda and minutes
2. Preparation for the meeting with NNE
3. Any other business
4. Date and time of the next meeting

Agenda meeting Thursday, the 27th of March

Time: 11:00
Place: A2.02a
Project: EPS group 9: "Automation & system integration, B2B & B2C"

Chairman: Ray David Sossna

Secretary: Miguel Oscar Lozano

Team members: Sara Zayed, Monika Polak, Nadia Khaji

Supervisors: Poul Kosel, Karin Siegumfeldt.

1. Approval of the agenda and minutes.
2. Interim report.
3. Talk about the Novo Nordisk Engineer meeting and next meetings with other companies.
4. Date and specifications about GPW 2 (Group Project Review 2).
5. Actual situation about our project (new meetings).
6. Any other business.
7. Date and time of the next meeting.

Agenda meeting Thursday, the 3rd of April

Time: 11:00
Place: A2.02a
Project: EPS group 9: "Automation & system integration, B2B & B2C"

Chairman: Miguel Oscar Lozano

Secretary: David Ray Sossna

Team members: Monika Polak, Sara Zayed, Nadia Khaji

Supervisors: Poul Kosel, Karin Siegumfeldt

1. Approval of the agenda and minutes
2. Interim Report
3. Company contacts
4. Project Review 2
5. Any other business
6. Date and time of the next meeting

Agenda meeting Thursday, the 17th of April

Time: 11:00
Place: A2.02a
Project: EPS group 9: "Automation & system integration, B2B & B2C"

Chairman: Sara Zayed

Secretary: Nadia Khaji

Team members: Monika Polak, David Sossna, Miguel Lozano Martin.

Supervisors: Poul Kosel, Karin Siegumfeldt.

1. Approval of the agenda and minutes.
2. Project review 2.
3. Our international study, the list of the companies we want to call.
4. Questions we want to ask them.
5. How we can use the study of the international market?
6. Our meeting with DTI.
7. Any other business.
8. Date and time of the next meeting.

Agenda meeting Thursday, the 8th of May.

Time: 11:00
Place: A2.02a
Project: EPS group 9: "Automation & system integration, B2B & B2C"

Chairman: Nadia Khaji

Secretary: Monika Polak

Team members: Sara Zayed, David Sossna, Miguel Lozano Martin.

Supervisors: Poul Kosel, Karin Siegumfeldt.

1. Approval of the agenda and minutes.
2. Structure of our report.
3. Advice for our final report.
4. Advice for the calculation, how we should do?
5. Any other business.
6. Date and time of the next meeting.

Agenda meeting Tuesday, the 20th of May

Time: 11:00
Place: A2.02a
Project: EPS group 9: "Automation & system integration, B2B & B2C"

Chairman: Sara Zayed

Secretary: Nadia Khaji

Team members: Monika Polak, David Sossna, Miguel Lozano Martin.

Supervisors: Poul Kosel, Karin Siegumfeldt.

1. Approval of the agenda and minutes.
2. Our last meetings (DTI and NNE).
3. Cost estimate plan.
4. Questions for GS1.
5. General appendix questions.
6. GS1 conference in Copenhagen the 12th of June.
7. Any other business.
8. Date and time of the next meeting.

Agenda meeting Thursday, the 29th of May

Time: 11:00
Place: A2.02a
Project: EPS group 9: "Automation & system integration, B2B & B2C"

Chairman: David Sossna

Secretary: Sara Zayed

Team members: Miguel Oscar Lozano, Monika Polak, Nadia Khaji

Supervisors: Poul Kosel, Karin Siegumfeldt

1. Approval of the agenda and minutes
2. Table of content
3. Our Recommendations
4. Final report basics
5. Number of copies, cheap place for printing?
6. Process report, Gantt chart?
7. Date and time of the next meeting

Current coding status in UK pharmaceutical industry

Coding[77]

The 92% of pharmaceutical drug packs contain an EAN.UCC barcode (EAN 13) on the product pack.

The current gaps include clinical trials, specials, hospital own manufactured items and parallel imports. The EAN 13 code contains fixed information (Country, Company, Product and a check digit), which means it can be produced and printed when the product pack artwork is commissioned. From a manufacturer's perspective the effort to adopt EAN13 would be relatively straight forward as most already apply this coding standard.

As the codes used are based on the global, open standards of EAN.UCC they are globally unique, ensuring product identification integrity that is critical to supply chain efficiency and patient safety.

Supply chain processes

Downstream from the manufacturer there are different routes to the patient that are less transparent in terms of capturing product identification (e.g. named patient, homecare and clinical trials). By the adoption of one standard method for product identification there is an opportunity to reduce medication errors and streamline the supply chain, but for these benefits to be realised there needs to be consistency of application.

Speed and error are the main pressures in the wholesaler with systems picking up to 10 items a second. Full line wholesalers make 235,000 deliveries per week in the UK to dispensing GP's, hospitals and community pharmacies (a British Association Pharmaceutical Wholesaler statistic).

Therefore an automated process of data capture will improve accuracy and speed.

In the community pharmacy another system is generally employed for ordering and receipting of goods using the PIP code. This system is manually orientated (non machine readable). Some pharmacies use the EAN code for EPOS (Electronic Point of Sale) benefits.

The downside is that deliveries need to be checked manually where the EAN codes are not used.

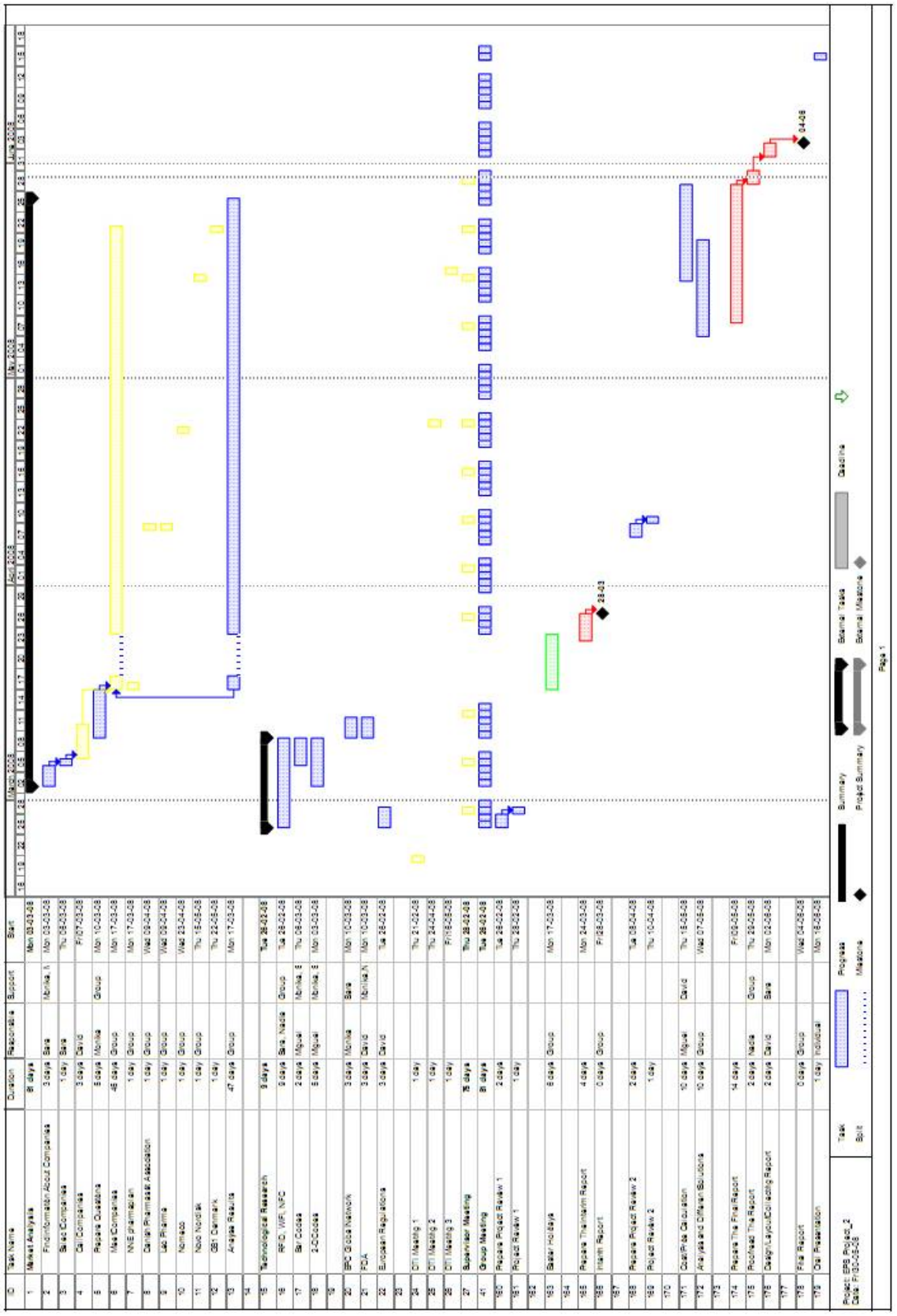
Current processes in hospital pharmacy can be manual and labour intensive. In some of the more technologically advanced pharmacies, goods are ordered via bespoke and individual pharmacy systems with some electronic transfer of orders and invoices, and even in these cases, the systems require manual checking. Goods are often ordered generically but supplied by brand, which can give

77 Recommendations and Guidelines for product coding within the UK Pharmaceutical Supply Chain Developed

rise to confusion. If the use and transference of EAN.UCC codes were employed this issue would be greatly reduced.

Traditional distribution systems in hospitals are manual and lead to an unacceptably high level of transcription picking, ordering and invoicing errors that take time to sort out and are potentially harmful to patients. However there is increasing investment in electronic systems, automated picking and administration systems being adopted. The huge investment in IT systems being delivered by NPfIT will accelerate this process. Hospitals are starting to refuse packs without a Machine-readable product identifier.

Gantt chart



More reference

• NFC Forum

http://www.nfc-forum.org/aboutnfc/

• RFIDHealthcare.com

http://www.rfidhealthcare.com/

• European Comision website

http://ec.europa.eu/information_society/policy/rfid/index_en.htm

• RFID Consultation Website

http://www.rfidconsultation.eu/

• RFID security &Privacy

http://www.avoine.net/rfid/

• The Independent European Centre for RFID, Wireless and Mobility

http://www.rfidc.com/docs/about.htm

• IDTrack – Sure Identifiation & Traceability

http://www.idtrack.org/IDtrack/

• Gartner Consulting

http://www.gartner.com/

• RFID in Action

http://www.rfidinaction.net/

• Technology information

http://www.btglobalservices.com/business/es/es/about_us/index.html

•List of pharmaceutical companies

http://en.wikipedia.org/wiki/List_of_pharmaceutical_companies

• RFID progress

http://www.microsoft.com/mexico/empresas/businessvalue/rfidinvestment.mspx

• Medical webside

http://www.saludymedicina.com.mx/nota.asp?id=2157