

GS1 Healthcare Reference Book
2013/2014



Table of Contents

Opening	
Standardised Data for Safer Healthcare & Acknowledgements.....	3
Introduction	
Leading the Way for Traceability.....	4
Argentina	
ANMAT Marking the Way.....	5
Argentina	
Implementing Drug Traceability at Hospital Alemán in Argentina.....	8
Australia	
Small and Medium Enterprises Lead the Way with GS1 Standards.....	11
Colombia	
Implementing a National Traceability System in Colombia	16
Egypt	
Safemed Keeps Counterfeit Drugs out of the Supply Chain in Egypt.....	19
Germany	
How GLNs Contribute to the Standardisation Efforts at Charité University Hospital.....	23
Ireland	
Safer Surgery Saves Lives	25
Portugal	
Minimising the Risk and Reinforcing Patient Safety for Novartis Products.....	29
Serbia	
Ensuring Traceability of Medicines in Serbia	31
UK	
Complying with New Legislation at Mölnlycke Health Care	35
USA	
Better Immunisation Management for Patient Safety	37



For 40 years GS1 has been bringing industries together to revolutionise the way they do business.

In 1973, industry leaders came together to select a single standard for product identification — the barcode. What started as a way to speed grocery store checkout has become the global language of business — a common way for trading partners around the world to identify, capture, and share information about products, locations, and more.

Today, GS1 is helping diverse industries drive efficiency, safety, and growth through the adoption and use of standards. From retail to healthcare to fresh foods to foodservice to transportation, GS1 Standards continue to transform our lives.

GS1 is a neutral, not-for-profit, global organisation that develops and maintains the most widely-used supply chain standards system in the world.

GS1 standards improve the efficiency, safety, and visibility of supply chains across multiple sectors.

With local Member Organisations in over 110 countries, GS1 engages with communities of trading partners, industry organisations, governments, and technology providers to understand and respond to their business needs through the adoption and implementation of global standards. GS1 is driven by over a million user companies, which execute more than six billion transactions daily in 150 countries using GS1 standards.

Find out more about our history and our future at
www.GS1.org/40thanniversary



Standardised Data for Safer Healthcare

Welcome to the fifth edition of the GS1 Healthcare Reference Book (2013/2014).

In this compendium of case studies you will find a variety of successful stories on how the implementation of GS1 Standards significantly improves patient safety and provides cost savings to the Healthcare supply chain.

We hope it will inspire your initiatives and we extend our appreciation to everyone who contributed to its development.

Acknowledgements

GS1 Healthcare would like to thank the following experts for contributing to this edition of the GS1 Healthcare Reference Book.

- **Dr Alaa Mohamed Affy**, Dr. Alaa Pharmacy Chain (Egypt)
- **Margarida Alves**, Novartis (Portugal)
- **Pauline Biganne**, HSE (Ireland)
- **Rachel Boden**, Orion Laboratories (Australia)
- **Blanca Elvira Acosta Cajigas**, INVIMA (Colombia)
- **Maximiliano Derecho**, ANMAT (Argentina)
- **Ken Gerlach**, NCIRD (US)
- **Jenny Gough**, Mölnlycke (UK)
- **Milorad Komljen**, Galenika company (Serbia)
- **Mohamed Mabrouk**, Utopia Pharmaceuticals (Egypt)
- **Bogdan Pavlović**, Hemofarm (Serbia)
- **María José Sánchez**, ANMAT (Argentina)
- **Ishan Sinha**, Care Essentials (Australia)
- **Simone Wagener**, Link Healthcare (Australia)
- **Muazzez Weiß**, Charité University Hospital (Germany)
- **Warren Williams**, NCIRD (US)
- **Heidi Wimmers**, Hospital Alemán (Argentina)

In addition, we would like to thank the following GS1 Member Organisations for facilitating this process:

- GS1 Argentina (contact: Gabriel Melchior – gmelchior@gs1.org.ar and Mario Abitbol - mabitbol@gs1.org.ar)
- GS1 Australia (contact: Tania Snioch – tania.snioch@gs1au.org)
- GS1 Colombia (contact: Ana Maria Prieto – aprieto@gs1co.org and Leonel Pava - lpava@gs1co.org)
- GS1 Egypt (contact: Ahmed Nassar – ahmed.nassar@gs1eg.org)
- GS1 Germany (contact: Sylvia Reingardt – reingardt@gs1-germany.de)
- GS1 Ireland (contact: Siobhain Duggan – siobhain.duggan@gs1ie.org and Alan Gormley - alan.gormley@gs1ie.org)
- GS1 Portugal (contact: Silvério Paixão – s.paixao@gs1pt.org)
- GS1 Serbia (contact: Miroslav Ilic – miroslav.ilic@gs1yu.org and Branislava Mitic - branislava.mitic@gs1yu.org)
- GS1 UK (contact: Roger Lamb – roger.lamb@gs1uk.org and Chris Doyle - chris.doyle@gs1uk.org)
- GS1 USA (contact: Michael Pheny – mpheney@gs1us.org and Annette Pomponio - apomponio@gs1us.org)



Leading the Way for Traceability

In recent years “Traceability” has become a hot topic in a number of sectors, due in part to notable failures occurring across the supply chain. In the healthcare sector, the increase in counterfeit pharmaceuticals entering the legitimate supply chain, as well as the lack of robust identification of medical device products, have made adverse events reporting difficult and hindered efficient product recalls (e.g. PIP Breast Implants ¹ or Metal-on-Metal Hip Implants ²).

As a response to this Public Health concern, there has been an increasing number of traceability pilots undertaken and several regulations emerging around the world, for both Pharmaceuticals and Medical Devices, aimed at minimising failures and ultimately improving patient safety.

The case studies that follow demonstrate the wide range of efforts taking place around the world by different stakeholders - all intended to achieving visibility in the healthcare supply chain by implementing Traceability systems and solutions based on GS1 Global Standards. Although they may have different drivers, they all ultimately have the same goal: **improve patient safety.**

Visibility can provide Traceability for medications and medical devices, but in order to achieve visibility along the entire supply chain all the way to the patient it is essential for all stakeholders, including healthcare providers, to also implement traceability systems.

To this end, GS1 Healthcare introduced the Best Provider Implementation Case Study Award, a formal process for identifying, recording, sharing and rewarding such implementation activities.

Frédérique Frémont, Organisation Engineer at the Centre Hospitalier Intercommunal (CHI) Robert Ballanger, Aulnay-sous-Bois, France is the first individual to receive the Provider

Recognition Award for her long standing involvement in the promotion and implementation of GS1 Standards. She has been instrumental in numerous and on-going implementations of GS1 Standards in the Centre Hospitalier Intercommunal Robert Ballanger and she continues to drive implementation initiatives that have been proven to benefit patient safety and to control costs, namely in the field of traceability within hospitals.

More information about GS1’s Best Provider Implementation Case Study Award can be found at: <http://www.gs1.org/healthcare>

40 years of GS1’s Global Standards

This edition of the Reference Book is being published in the year of GS1’s 40th anniversary, making it even more special.

From the first bar code scanned until today, over 5 billion products are scanned every day. From local to global use, the GS1 System of Standards includes a variety of solutions that apply to many different sectors.

GS1 Global Healthcare was built upon local GS1 foundations with the industry’s commitment to improving the lives of patients. Today, we have GS1 Member Organisations in 110 countries and Healthcare User Groups (or HUGs) organised in 33 countries.

In 2012, the McKinsey & Company Report “Strength in Unity - The promise of global standards in healthcare”³, pointed out significant patient safety benefits and cost savings by implementing one single global standard in Healthcare.

Over 40 leading Healthcare stakeholders from around the world called for that standard to be the GS1 System of Standards for Healthcare ⁴, and that number continues to grow.

With this 40th Anniversary in mind, we look ahead to the next 40 years aiming to improve patient safety all over the world.

GS1 Healthcare is committed to bringing together hospitals, pharmaceutical companies, medical device manufacturers, transporters and others to increase patient safety and care through reduced medication errors and improved product traceability.

¹ <http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Product-specificinformationandadvice/Product-specificinformationandadvice-A-F/Breastimplants/PIPbreastimplants/BackgroundinformationonPIPimplants/index.htm>

² <http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Product-specificinformationandadvice/Product-specificinformationandadvice%E2%80%930%93M%E2%80%933T/Metal-on-metalhipimplants/>

³ <http://www.gs1.org/healthcare/mckinsey>

⁴ http://www.gs1.org/healthcare/news_events/news#announcements



Argentina

ANMAT Marking the Way

A new contribution to the security of drugs in Argentina

ABSTRACT

In 2011, Argentina introduced a catalogue of drugs covered by its national drug traceability scheme, listing more than 3.000 medicines that require the placing of unique serial numbers and tamper-evident features on the secondary packaging. The drugs listed are recorded in real-time in a central database managed by the National Administration of Drugs, Foods and Medical Devices of Argentina (ANMAT), which uses Global Location Numbers (GLNs) to identify the various actors in the supply chain. Last February the government of Argentina added another 11 substances to the catalogue. The purpose of this programme is to actively limit the use of illegal drugs. Today, ANMAT has shown that the implementation of the system has delivered more than favourable results.



by **Maximiliano Derecho** and **María José Sánchez**

When reality exceeds fiction

In the legendary tale by the Grimm brothers, knowing that their parents will try to abandon them in the forest, Hansel and Gretel try to “trace” a way back home, first with pebbles and later with breadcrumbs which will unfortunately be eaten by birds. Could we ever have imagined that the authors of these children’s stories were in fact the intellectual precursors of the initiatives of traceability that have been implemented in different industries around the world? Surely not, but Hansel’s idea was not so different from the ideas of those who today try to apply traceability to different production and logistic processes. Of course, the scientific and technological evolution provides many and better prospects, optimising the means to fulfil the objective.

The progress of science and the possibilities offered by different technologies have allowed us to achieve things that were unthinkable years before. Likewise, the traceability of medicines has been the object of a broad and fruitful evolution, resulting in the National Medicines Traceability System at the end of 2011 and representing a change in the paradigm for the national market of medicines.

Traceability as a tool to assure the quality of drugs

One of the principal obligations of the Health Authorities, indicated by the World Health Organisation and its regional offices, consists of assuring that people have access to quality, secure and efficient drugs:

- First, it must be assured that the drugs are legitimate, registered and manufactured by the authorised drug makers
- Second, Good Manufacturing Practices (GMP) must be applied to all products manufactured at a national level
- Third, it must be assured that these conditions are maintained along the entire supply chain, and comply with the Good Distribution Practices (GDP) in the country
- Lastly, it is necessary to apply a post-marketing surveillance to control products in the field and provide reports on any lack of efficacy or adverse events that could happen after their use or clinical application

Since its creation in 1992 by the Government Resolution Nº 1490/92, ANMAT has adapted and improved its role, which has positioned it as one of the leading authorities in the region. In 1997, ANMAT has moved forward with the implementation of the National Programme to Search Illegitimate Drugs (today the National Programme for the Control of Drugs and Medical Devices Market).

The main objective of this Programme is the surveillance and control of drug distribution processes in order to identify illegal drugs and prevent risk of usage. The Programme, supported by field controls undertaken by highly qualified inspectors, presented an innovative model which significantly reduced the presence of illegal drugs in the medicine distribution chain. The Programme reached such a success that it has become an international reference model, and inspired many Latin American countries who had not implemented any model yet.

ANMAT Marking the Way - A new contribution to the security of drugs in Argentina

In 2003, the National Institute of Medicines was given the National Award in Quality. In addition, following a strict external audit, ANMAT joined the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (known together as "PIC/S") in 2008. These two international instruments, implemented between the countries and the pharmaceutical inspection authorities, favour an active and constructive cooperation in the field of the GMP.

Moreover, in December 2009, ANMAT was named the First Authority of Reference in America following an extensive

audit by the Pan American Health Organisation (PAHO).

In this context, the implementation of the National Drug Traceability System places ANMAT as one of the world's leading authorities actively working on this subject. As Dr. Carlos Chiale, Director of the ANMAT, states: "It represents one more step in strengthening the institutional policy of quality of ANMAT, by which we improve the security of patients concerning the legitimacy, quality and efficacy of the drugs they consume".



The National Traceability System

The system requires the individual and unambiguous identification of each pharmaceutical product to allow its traceability all along the distribution chain (pharmaceutical companies, logistic operators, drug wholesalers, pharmacies, healthcare institutions and patients). At each step of the process, the product data is confirmed in real-time through a central database managed by ANMAT. As each container has an inviolable and incorruptible code, the security and authenticity of the drug is therefore ensured and guarantees that the product has never abandoned the legal trail of production and distribution.

In order to allow a scaled implementation scheme, the system takes into account the different categories of drug products and the means and technological systems available, whilst reducing any obstacles that the patient may face. Today the National Traceability System has already been applied to a wide list of costly critical drugs used to treat conditions such as cancer, AIDS, haemophilia, rheumatoid arthritis and cystic fibrosis. It has also been applied to drugs treating illnesses such as asthma, acromegaly, wet macular degeneration and anaemia associated to the chronic renal disease. In addition, it is applied to various sedative drugs, antihypertensive and cough medicines, and analgesics for central action, psychoactive drugs and other substances which can cause addiction. The scheme will then be extended to all new drugs registered and launched in the market. It is worth mentioning that it applies both to local-produced and imported products.

The National Traceability System imposes that all drugs be serialised through the application of an unambiguous code,

according to the recommendations of the GS1 Standards. Each drug should contain the Commercial Product Code, the Global Trade Item Number (GTIN) and a unique Serial Number placed on the secondary packaging. This information can be integrated into any type of data carrier, provided that it complies with the standards mentioned above, allowing each owner to choose the most appropriate data carrier for their products (whether it is a linear bar code, GS1 DataMatrix, EPC/RFID tag or any other). Notwithstanding the data carrier of choice, the information must always be placed in human readable format so the patient may read it.

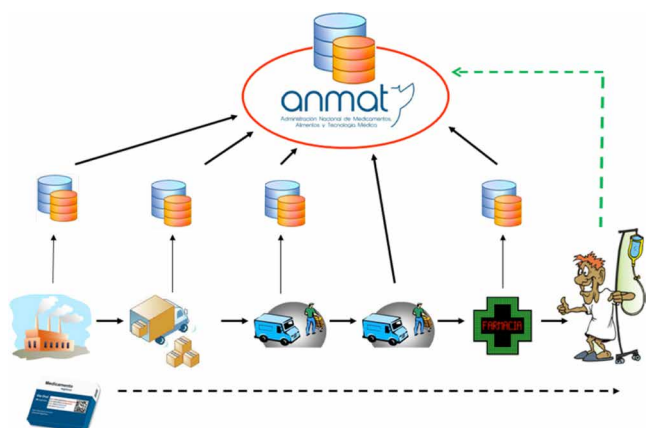
Argentina does not impose the data carrier and the choice is left to the manufacturer. Nevertheless, the rule highlights that: "The data carrier cannot be removed without leaving an evident mark on the packaging. A drug that shows signs of label tampering or that cannot be read by an electronic reader shall be considered adulterated ..."



Objectives of the system

With the implementation of the National Traceability System, the following objectives should be achieved:

- Regularise the distribution of drugs at a federal level
- Prevent the diversion of products and the distribution of falsified drugs
- Detect product code duplication
- Improve efficiency and reduce the costs of the healthcare systems
- Provide patients with quality, security and efficacy of the drugs they consume
- Minimise wrong supply of products
- Discourage theft and adulteration of products
- Facilitate effective product recalls from the market
- Evaluate in real time the consumption of each type of drug
- Encourage the rational use of drugs



Results and future developments

When we talk about the implementation of a National Drug Traceability System this includes access to medicines of the highest quality, and therefore access to a higher level of healthcare for everyone. The implementation of the new National Traceability System established in Argentina represents an important change in the surveillance of drug distribution on a federal level. This represents considerable challenges for the different stakeholders involved, which are accepted due to the important advantages that the System brings.

The implementation of the Traceability System has begun successfully, with a large number of agents already incorporated into the System and interacting within it. **From December 2011 until today this includes more than 111 million logistic events, which correspond to more than 25 million individual units of medicine (GTIN + Serial Number).** This reflects the commitment of the different agents

in Argentina to comply with the Traceability rules issued by the Health Authorities.

GTINs registered in the National Traceability System

2,974 products

Agents in the System

Laboratories:	221
Distributors:	11
Logistic Operators:	10
Wholesalers:	577
Pharmacies:	8,685
Healthcare Institutions:	405
Public Establishments:	172
Lab. of Intravenous Mixtures:	1
TOTAL:	10,082

These results confirm that the Traceability System is on the right track and ready to broaden the scope of traceability to new drugs and other products regulated by ANMAT, such as medical devices and pharmaceutical raw materials.

As Minister Ramón Carrillo stated, "The scientific breakthroughs in healthcare are useful only if they are accessible to all people". Time and history will tell us if the implemented initiative will allow us to reach our objectives or if we are only tracing the trail with breadcrumbs that birds will eat. In the meantime, the programme will continue marking the way...

About the authors

Maximiliano Derecho is a Lawyer who graduated from the University of Buenos Aires with an honorary degree. In 2002 he joined ANMAT as a Legal Advisor for the National Programme fighting against counterfeit drugs, and in January 2008, he was appointed Alternate Coordinator for the programme. He is also the legal advisor of the National Program for the Control of Drugs and Medical Devices Market since its implementation in April 2011.

María José Sánchez is a Pharmacist graduated from the University of Buenos Aires. In 2001 she joined the ANMAT as an inspector in charge of controlling the different steps of the distribution channel of medicines. Since January 2008 she is the Coordinator of the National Programme in Search of Illegitimate Drugs and since April 2011 she has become the General Coordinator of the National Program for the Control of Drugs and Medical Devices Market.



Argentina

Implementing Drug Traceability at Hospital Alemán in Argentina

ABSTRACT

In order to reduce the serious risks presented by the proliferation of counterfeit medicines, Hospital Alemán (HA) implemented a traceability system complying with the new legislation introduced by the National Administration of Drugs, Foods and Medical Devices of Argentina (ANMAT) in late 2011.

The primary objective of the programme is to counteract the distribution and supply of illegitimate drugs to guarantee patient safety. It is based on the unambiguous identification of products through IT systems and through the use of the global and harmonised language of GS1 Standards. All drug movements are recorded in real-time in a central database managed by ANMAT using Global Location Numbers (GLNs) to identify the various agents involved in the supply chain.



by Heidi Wimmers

Introduction

Counterfeit drugs present a major growing concern for public health. Although there is not a universally accepted definition for “counterfeit medicines”, the World Health Organisation defines the term counterfeit drugs as “medicines that are deliberately and fraudulently mislabelled with respect to identity and/or source”¹

The most common factors increasing the occurrence of counterfeit drugs are considered to be:

- Lack of legislation prohibiting counterfeiting of drugs
- Weak penal sanctions
- Weak or absent national drug regulatory authorities
- Weak enforcement of drug laws
- Shortage and/or erratic supply of drugs
- Lack of control of drugs for export
- Trade involving several intermediaries and free trade zones
- Corruption and conflict of interest²

Although it is difficult to know the exact counterfeit drug rate, estimates range from 2-4% to 5-10% globally, with significant variations across countries. Many experts estimate the rates at 1% or less in developed countries and anywhere from 10 to 30% in developing countries.³

What is drug traceability?

We are living in a world of global markets where there are few - if any - borders between sectors, countries and continents. The Healthcare supply chain is becoming much more complex with its increase in the variety of suppliers, products and buyers, and rise of large-scale productions in emerging economies like Brazil, Russia, India, and China, making it increasingly difficult to trace a product from the point-of-production to the point-of-use, or from pill to patient.

Although traceability has become a necessity, global supply chains need more complex business processes and information systems to achieve it. They need standards for identifying, capturing and sharing information, and this is where GS1 Standards can help.

In GS1 terms, Traceability is the ability to track forward the movement through specified stage(s) of the extended supply chain and trace backward the history, application or location of that which is under consideration.

¹ WHO, Fact sheet N°275, May 2012: www.who.int/mediacentre/factsheets/fs275/en/
² Guidelines for the development of measures to combat counterfeit medicines, WHO/EDM/QSM/99.1 consulted 30-MAY-2013: http://whqlibdoc.who.int/hq/1999/WHO_EDM_QSM_99.1.pdf

³ McKinsey & Company “Strength in unity: The promise of global standards in healthcare, October 2012”

Traceability means patient safety

The progress of technology has allowed us to implement systems that were unthinkable years ago.

When the National Administration of Drugs, Foods and Medical Devices of Argentina (ANMAT) implemented the provisions of their National Medicines Traceability System, Hospital Alemán put in place an internal system not only to comply with the rule, but also to ensure full traceability of single unit doses of products when fractioning, reconstituting or repackaging the products, thus making the five patients' rights (right patient, right medication, right dose, right time and right route) a reality.

When evaluating the entire cycle of drugs' use, the Hospital focused on patient safety and set the goal to obtain the certification from the Joint Commission Accreditation on Healthcare Organisations (JCAHO).

How was traceability implemented at Hospital Alemán?

In the hospital, the traceability system involves three specific steps:

1. Hospital reception of traceable drugs
2. Single dose fractioning at the pharmacy with the commercial code and serial number of the drug in each unit dose
3. Administration to the patient

The traceability process begins when the hospital receives the drugs and starts capturing the data. GS1 Standards used include:

- Global Trade Item Number (GTIN)
- Global Location Number of the supplier
- Serial Number
- Expiration Date associated with the receiving GLN

All the suppliers were previously audited as part of a quality assurance programme, which ensures that products are consistently produced and controlled according to the quality standards appropriate to their intended use and as required by the marketing authorisation/product license (Good Manufacturing Practices - GMP).

The suppliers must also provide properly identified packages in accordance to the national traceability regulation. It is imperative that full identification using one of the three GS1 compliant Data Carriers are placed on secondary packaging:

- Linear bar code
- DataMatrix
- RFID

GS1-128 Concatenated data



GS1 DataMatrix



(01)10857674002017
(17)141120
(10)1234AB

GS1 EPC/RFID

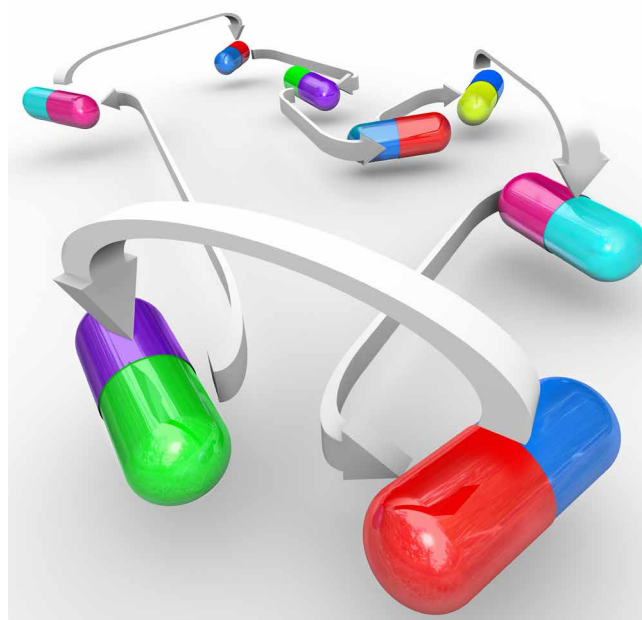


(01)10857674002017(17)141120(0)1234AB

Data carriers for illustration only, not to scale and not in proportional size to one another.

Figure 1: Examples of Data Carriers used

Once the drug is received, ANMAT is informed and an ID is obtained. The traceability of the drug is confirmed on ANMAT's website using the transaction ID, from the GLN of origin to the GLN of destination (Hospital Alemán as informant agent).



The traceable drug is fractioned in unit doses at the pharmacy in the inpatient ward. These medicines are re-labelled in all types of presentations and dosage forms using a printed GS1 DataMatrix linking to all the original information from the marked secondary packaging.

Implementing Drug Traceability at Hospital Alemán in Argentina

The unit dose re-packaging is done through an aseptic process where the original blister packs are cut and each unit doses individually overwrapped. A programme of preventive maintenance is implemented in order to control the machine,

the printers and the labels. The work of the technician is under the close surveillance of a pharmacist⁴.

4 Cina J, et al. Medication errors in pharmacy-based bar-code-repackaging center. *Am J Health-Syst Pharm* 2006; 63(2):165-168

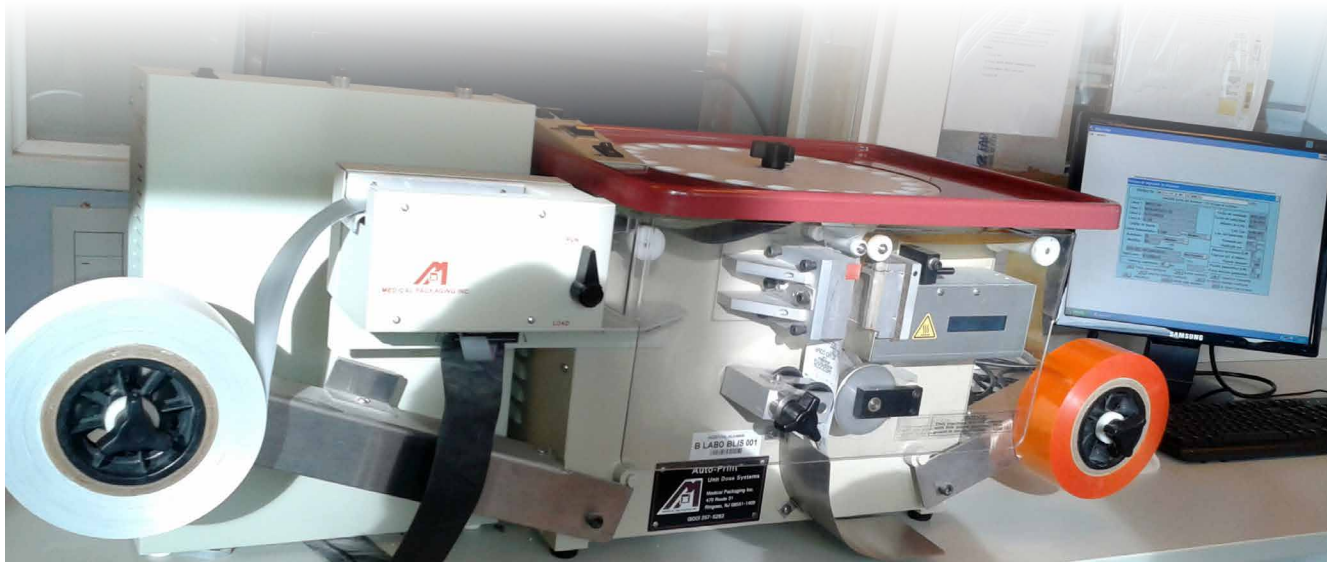


Figure 2: Machine for unit dose repackaging in the HA-Pharmacy

The role of the nurse in the traceability process

Nurses are an essential link in the supply chain. Not only do the standards help increase patient safety, but they also allow to save time. A survey conducted by the Nursing Times in the UK showed that “more than a third of nurses waste up to two hours a shift searching for missing medical items”⁵.

The work of nurses is fundamental in the Hospital Alemán programme. Prior to administering the medication to a patient, which is one of the critical stages of treatment, nurses read the bar code of the medicine dispensed by the pharmacy, confirming usage of the drug in the electronic system.

Findings

Quality and safety are more important than ever. The medicine traceability process is very important for the safety of our patients, especially in the treatment of older patients who are polymedicated.

To continue improving the traceability process in the hospital, Hospital Alemán developed a comprehensive quality management system in compliance with the ISO 9001 norm⁶. One of the key findings of the implementation of a

full traceability system is that it is essential to constantly train the staff, while involving internal members aligned in cross-functional teams.

Hospital Alemán targets continuous improvement and allows medicine-confidence for the patients, the medical professionals and the management, ensuring that the drugs administered fulfil the specified quality requirements.

About the author

Heidi Wimmers is Chief of Pharmacy and President of the Independent Ethics Committee in Clinical Trials of the Hospital Alemán. Ms. Wimmers has a Masters Degree in Clinical and Pharmacological Investigations from Universidad Austral. She is a member of the Standardisation Sub-Committee IRAM for Good Pharmacy Practices.

About Hospital Alemán



Hospital Alemán is a university hospital located in Buenos Aires, Argentina, with more than 700 professional doctors providing care in all specialties. The Hospital has 240 beds in individual rooms, 11 Operating Theaters, a Coronary Unit, adult and pediatric Intensive Care Units, Burn Area Care and Transplant Area.

5 <http://news.bbc.co.uk/2/hi/health/7881807.stm>

6 Norm UNE-EN-ISO 9001/2008

<http://www.quality-works.com/download/the-perfect-manual.pdf>



Australia

Small and Medium Enterprises Lead the Way with GS1 Standards

ABSTRACT

Small and Medium Enterprises (SMEs) in the healthcare industry compete with the big players in innovation, agility, and efficiency. As well as ensuring competitiveness, SMEs need to meet the same industry and trading regulations as their larger competitors. GS1 Australia's support teams help SMEs to leverage the GS1 Standards in order to meet their trading partners' requirements, enabling them to compete with large multinationals on a level playing field.

This case study overviews three SME organisations, all leveraging the GS1 Standards including use of Global Trade Item Numbers (GTINs), GS1 Bar Codes, and GS1's Global Data Synchronisation Network (GDSN) for different applications. All of which are realising outcomes and benefits from their implementations.

The healthcare industry is characterised by research, innovation, and product development, as well as strong competition. While big, multinational companies dominate many of the sector's segments, Small and Medium Enterprises have an important role to play. Much of the innovation in healthcare originates from SMEs and, to successfully compete in this industry, these companies must bring their innovations to market quickly and efficiently.

The Importance of a standardised approach

Complex pharmaceutical and medical products, many of which are highly regulated, must be efficiently and accurately identified throughout the supply chain. In addition, product master data about these products must be communicated between suppliers, distributors, regulators, and end users. Inaccuracies can have life-threatening consequences and will, at the very least, cause manufacturers and distributors the loss of goodwill and business.

GS1 Standards are designed as a multi-industry solution for companies of any size. Using the GS1 System, a company's products may be unequivocally identified and marked with that identifier (as well as with associated production information such as Batch or Lot Number, Serial Number, or Expiration Date). In addition, through use of GS1 Standards for the Global Data Synchronisation Network (GDSN), organisations may share their product and price master data with key trading partners via a secure network.

Since October 2012, key industry position statements have

been released, which clearly articulate the healthcare market's direction towards implementation of GS1 Standards for product identification, marking (bar coding or radio frequency identification) and data synchronisation.

Issued in October 2012, the *National E-Health Transition Authority (NEHTA) Communiqué on GTIN Use Best Practice in Australian Healthcare* explains the need for GTIN allocation and use in line with global standards and states, "NEHTA therefore recommends that Australian Healthcare suppliers adopt GTIN Best Practice and avoid GTIN re-use for Regulated Healthcare Trade Items."

Likewise, the *NEHTA Supply Chain Reference Group Communiqué on Bar Coding and Radio Frequency Identification (RFID) in Australian Healthcare* issued in December 2012 recommends that "Australian and international healthcare brand owners reference and adopt the guidelines contained

within the GS1 Automatic Identification and Data Capture (AIDC) Healthcare Implementation Guide v 1.1 (or subsequent updates) available from the GS1 Australia website."

The National Product Catalogue (NPC), a NEHTA initiative hosted on GS1 Australia's GDSN compliant data pool,

Today 95% packages dispensed at retail pharmacy carry a GS1 GTIN in a GS1 Bar Code

Australia - Small and Medium Enterprises Lead the Way with GS1 Standards

GS1net, has been operational in the healthcare sector since 2006. There are currently nearly 300,000 GTINs in the NPC being relied upon by greater than 400 healthcare suppliers, wholesalers, distributors, and public and private healthcare institutions seeking to deliver improved patient safety and realise significant efficiency gains.

Today GS1 Australia continues to support SMEs to ensure they are meeting their trading partner requirements for data alignment, product identification and marking.

To access the documents referenced in this section, please go to the Healthcare Industry page on the GS1 Australia web site at www.gs1au.org

Quality Affordable Healthcare Products™

By **Rachel Boden**, Commercial Director, Orion Laboratories



Orion Laboratories was founded in 1985 by two young chemists, David Stacy and Paul Rowney, who provided small-scale manufacturing services in the chemical, cosmetic, and pharmaceutical industries.

Based at Balcatta in Western Australia, today Orion offers contract manufacturing services specialising in cream and liquid fills. Orion also manufactures and markets an extensive range of its own Orion branded products, including therapeutic pharmaceuticals, over the counter medicines, formulated devices, antiseptics, and disinfectants.

In March 2010, Perrigo's acquisition of Orion Laboratories expanded the company's global presence and product portfolio making GS1 Standards even more of a focus for the company. Use of global standards for product identification, bar coding and the NPC were essential elements in the company's drive for improved sales and efficiency.

Orion first began implementation of GS1 Standards in 2005, as the SME representative on a Victorian Government funded project called 'eCommerce in the Hospital Pharmaceutical Supply Chain' (Monash Project). At this time, the prevalence of GS1 GTINs in bar codes in the pharmaceutical sector was substantial, however not to the levels seen today where 95% of the packages dispensed at retail pharmacy carry a GS1 GTIN in a GS1 Bar Code.

Orion found that 14 of the top 15 products ordered by Monash Medical Centre Pharmacy Department carried GS1 Bar Codes at unit level, but none were compliant at inner or carton level. To cater for identification and bar coding at carton and inner level, Orion re-designed the adhesive labels applied to these levels of packaging in line with the Orion corporate label and selected the GS1-128 Bar Code, which can encode information additional to the GTIN such as Batch Number and Expiration Date – attributes necessary for traceability in the pharmaceutical sector. Internal processes were put in place for printing and 'in process' verification of the bar codes produced, as well as reviews made of labelling requirements to ensure that applying bar codes to previously non-bar coded packaging did not contravene any regulatory requirements.



Australia - Small and Medium Enterprises Lead the Way with GS1 Standards

At the conclusion of the project, the decision to broaden the scope of use of GS1 Bar Codes was simple as there are significant benefits associated with the ability to improve efficiencies in the supply chain through bar code scanning. Most of the Orion customers require bar codes in order to transact with Orion. It is therefore seen as a necessity and a benefit to ensure that Orion is seen as a supplier of choice.

The next step for Orion in the implementation of GS1 Standards was the National Product Catalogue (NPC). The NPC is the future of the supply chain, with most medium to large companies already utilising it. In order for Orion to tender into health departments and private hospitals, it was necessary to populate the NPC with all of the Orion product information to comply with this tender process. Data upload and maintenance need not be complicated, nor consume excessive resources. The implementation programme provided by GS1 Australia took the pain out of the process.

The greatest challenge when using the NPC was collating information from existing sources into the catalogue. This was a challenging step in the process for Orion, and so a third-party company certified by GS1 was used.

The Orion team found the NPC upload process provided an opportunity to re-examine and improve the company's internal systems and processes.

Data upload to the NPC was initially done quite manually, as all of the data was not stored centrally and was only available from varying sources in different formats. To ensure that all information is now entered only once and is correct and

complete, Orion is in the process of implementing all of the data in SAP and uploading this SAP data into a third-party program supplied by Bizcaps Software, a GS1net Certified Product Partner.

One significant learning during the implementation was the importance of ensuring that all of the data is captured and maintained in one database and that business processes are implemented to support the initial capturing of the data and timely updates as part of change control. It is also important to note that whilst populating to the NPC is the end result, having accurate data about all the products in a single, centralised place will only benefit the organisation.

The next step in this journey will be to implement GS1 Standards and bar code scanning in all Orion warehouses, using the bar coded information to drive efficiencies and reduce errors associated with manual checking within the warehouses.

Use of global standards for product identification, bar coding and the NPC were essential elements in our company's drive for improved sales and efficiency.

About the author



With over 24 years in the Healthcare sector predominantly within the hospital ethical area Rachel Boden has developed an understanding of market dynamics and strategies for new product development. Prior to joining Perrigo, Rachel had significant sales management/marketing experience obtained in previous roles with AstraZeneca and Obagi. Rachel originally trained as a midwife and child health nurse.

Medicine that Matters



By **Simone Wagener**, Business Manager, Link Healthcare

Link Healthcare is a privately owned Australian specialist Pharmaceutical and Medical Technology business. Link's mission is to strive for excellence in the marketing of vitally important and unique specialist products that enhance the well-being of thousands of people in the region.

At first, Link Healthcare joined GS1net because it was required under a number of state-based tenders to be a GS1 Australia

member and have the tendered products uploaded. After getting involved with the NPC, Link Healthcare found a number of additional reasons for utilising the NPC, such as

making the ordering process for customers simpler, or being able to check the data used in the NPC against its own system, ensuring the information matched and was up-to-date.

Since Link Healthcare product information and pricing does not change all that often, maintaining the database is more about the addition of new products as they come in,

or setting up pricing relationships with new customers or organisational partners. The work is centralised and carried out

Link Healthcare was keen to get on board with the National Product Catalogue to realise the benefits it offered in opening doors to new business opportunities, as well as in business efficiencies.

Australia - Small and Medium Enterprises Lead the Way with GS1 Standards

by one who is responsible for adding in new data once it has been approved by the brand manager or business manager.

Having consistently accurate data will lead to significant business efficiencies

Link Healthcare is still at the early stages of NPC usage, however, each time new data is input, it is a much quicker process as the user can duplicate a number of records and easily change the information required.

It is also worth noting that while one central person may be responsible for data upload, it is imperative that multiple people in the company understand the system and can assist when required.

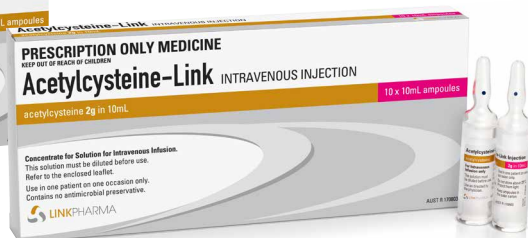
In the future, Link Healthcare will be looking at data-mapping the NPC information to complement its accounting/ordering systems making the process of placing orders, dispatching, through to payment a more simple and accurate process.

This will help to avoid any delay in the sales and payment processes and ensure accurate pricing to the right customers when you are dealing with a large number of customers all at varying pricing levels.

About the author



Simone Wagener is the Business Manager for Link Medical Technologies – a division of the Link Healthcare Group. With Bachelor of Nursing Science & Applied Science (Biomedical) degrees, she worked clinically as a Vascular Nurse for a number of years in Queensland before moving into a more commercial role in Sales & Marketing in the Healthcare industry in New South Wales. A major interest and passion has always been in the area of wound management and she has worked closely with a number of companies who specialise in unique solutions for wound healing.



Essentials for Warming

By **Ishan Sinha**, Director, Care Essentials



Care Essentials has specialised in patient warming since its establishment in 1996 and has set a benchmark for excellence. The development of the Care Essentials Micro Pore system for the delivery of air gives a constant air flow, thereby giving a uniform distribution of warm air across the patient. Care Essentials named its products Cocons, as when they are used they give a warm, cocooning effect for the patient.

Care Essentials is an Australian company which conducts all its research and development in-house and sources all materials locally, manufacturing its products at their factory in Geelong, Victoria.

In 2011, Care Essentials entered a tender put out by Health Purchasing Victoria. One of the tender requirements was that suppliers be GS1 compliant and NPC ready. Since then, it has found that being GS1 compliant is an advantage for many, if not all, tenders and purchasing contracts.

Initially, the process involved significant research and data collection for Care Essentials, but GS1 Australia provided a very helpful, dedicated account manager to assist along the way, helping the team to complete the process.

"We only have around 30 products and others, and not many changes, so the exercise to get the data together to complete the GS1 Browser Template and load the NPC has been worthwhile. Especially since with most tenders it is a requirement, or at least preference will be given, to NPC compliant suppliers," states Care Essentials.

Australia - Small and Medium Enterprises Lead the Way with GS1 Standards

In addition, the company recently made a submission to a tender issued from Northern Territory Health where the required tender data was NPC data, and the format that needed to be submitted a spread sheet generated from the browser template. The other states and territories are also requesting this same format, providing additional benefit from a consistent tender approach across Australia. This will result in a further reduction of work effort.

“In such a competitive industry as healthcare, being GS1 compliant (having GS1 GTINs allocated to products) and having products listed in the NPC are essential requirements. Meeting these requirements identifies Care Essentials as an organisation that is continuing to be innovative and embracing new developments”.

Having made a significant investment in getting Care Essentials data loaded to the NPC, the company is now seeing the possibilities for use of this data in other areas and will continue to explore opportunities where quality data and use of GS1 Standards will distinguish their business from competitors. This may be by use of GS1 GTINs encoded in GS1 Bar Codes on products, or perhaps by a further promotion of NPC status. One thing is certain, Care Essentials will continue to innovate.



About the author



Ishan Sinha is Director of Care Essentials Pty Ltd, the leading Australian company in patient warming. Ishan is involved in filing tenders, which often requires him to use the GS1 platform. Ishan holds a Bachelors degree in Commerce and a Masters degree in Applied Finance.





Implementing a National Traceability System in Colombia

ABSTRACT

The illegal trade of products of any nature is one of the many issues faced by Colombia. When it involves food or medications the risk for people is magnified. The ingestion of an altered, counterfeit, expired or contraband food or drug can lead to a person's death. In 2007, to address the problem in the healthcare sector, the Congress of the Republic enacted Law 1122, bringing some changes to the Social Security System in Health. It was stated that "INVIMA (the government entity that exercises duties in Inspection, Oversight and Control over food, medications, and medical devices in Colombia) has the duty to ensure the identification of medications in any part of the distribution chain, from production up to the final patient, by means of labelling technology for the purpose of avoiding counterfeiting, altering, expiry, and contraband."



by Blanca Elvira Acosta Cajigas

Pilot project: GS1 Colombia & INVIMA

To research the appropriate model and technology for a National Traceability System for Pharmaceutical Products, leading to the enforcement of the law, INVIMA established an agreement with the "Universidad Nacional de Colombia" (National University of Colombia).

Prior to the end of the first semester of 2012, the university recommended the use of technologies supported by GS1 Standards. From there, INVIMA, with the support of GS1 Colombia, led a pilot project to test GS1's technology in the field to ensure compliance with all legal regulations.

Eleven pharmaceutical companies (multinational and local) were voluntary participants in the large-scale pilot project and determined the players with whom they would participate: IPS (Healthcare Provider Institutions), and their wholesale distributors with their respective drugstores.

The goal was to develop a pilot for a Traceability System for Pharmaceutical Products with players from the commercialisation chain in the health and social security sectors, backed by international standards (GS1). This would allow INVIMA and all other players in the healthcare sector's supply

chain to learn the requirements that would serve as the basis to generate a proposal for regulations on medication traceability that would be further submitted to the Ministry of Health and Social Protection.

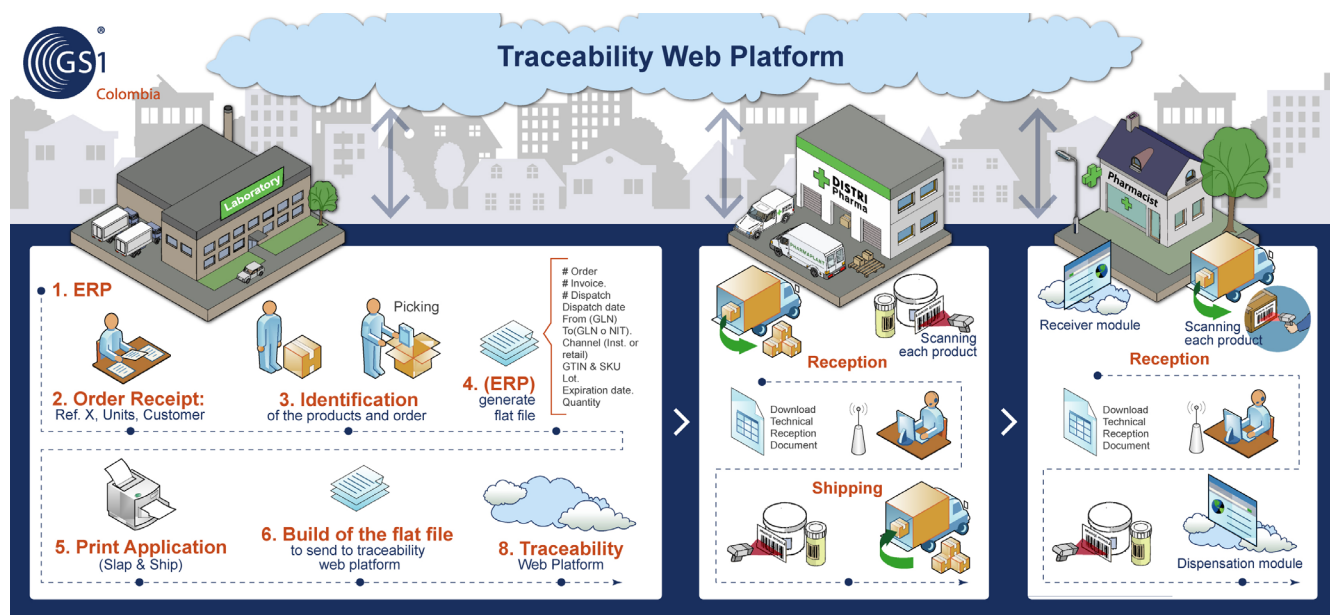
The most important consensus between the parties was to base the National Traceability System for Pharmaceutical Products on GS1 Standards, which guarantee to all players in the healthcare sector and to their patients that any medication leaving a pharmaceutical manufacturer and running through the various points in the value chain until reaching the final patient is legal and of good quality.

In addition to the conclusive recommendation in regard to using GS1 Standards for the National Traceability System for Pharmaceutical Products, the university determined certain geographical parameters, as well as product types, actors and channels, for the pilot project test. Seven cities in the country were chosen, determined by three criteria: border cities (2), difficulty to reach the area (1), and densely populated area (4).

The Pilot Project began once the ground rules were established.

- **Period of execution:** from October 2012 to February 2013
- **205 shipments made** by pharmaceutical manufacturers to clients
- **31,788 units reported** to the platform (92% Commercial - 8% Institutional)
- **25 pharmaceutical presentations** for 12 active ingredients

The process & model



Relevant figures

The following indicators were measured during the period of execution of the pilot:

- **Indicator 1** - Effectiveness of Receipt process and forwarding of information to the traceability web platform - Distributor: 94%
- **Indicator 2** - Effectiveness of Receipt process and forwarding of information to the traceability web platform – IPS (Healthcare Provider Institution) : 100%
- **Indicator 3** - Effectiveness of Receipt process and forwarding of information to the traceability web platform - Drugstores: 84%
- **Indicator 4** - Medications traced by channel: 92% Commercial and 8% Institutional
- **Indicator 5** - Queries to Inspection, Oversight, and Control Process: 100%

Conclusions

Undoubtedly, everything that allows to get information on the movement of a medication through the supply chain, from its production to its sale and/or its administration to a patient, translates into safer and more efficient processes, which will benefit the legal pharmaceutical supply chain and national public health every time a medication is needed or prescribed.

For the previous reasons, the participating companies concluded:

- The identification and the marking of medications with GS1 DataMatrix, including the GTIN (Global Trade Item Number), Batch or Lot Number, Expiration Date, and Serial Number, ensure the traceability and tracking of medications throughout the commercialisation chain
- Serial Numbers on medications become an additional tool for identifying and combatting problems with counterfeiting, contraband, and alteration. For this reason, there is value in implementing the system immediately with high-cost medications that are sensible to these issues
- The implementation of the suggested traceability system facilitates and optimises processes in regard to inspection, oversight, and control through the use of information and communications technologies
- Although the framework of this pilot project did not consider obtaining traceability information up to identification of the patient to whom the medication is delivered or administered, it is important to consider this process in subsequent phases

Moving forward

From the results, conclusions, and final document regarding the Medication Traceability Pilot Project, INVIMA will report the information to the Ministry of Health, which will in turn seek for the initiative's approval with the Office of the President of the Republic. Expectations are high that the National Government will vet the implementation of the National Medication Traceability System over the short term given that the benefits are fully demonstrated.

Implementing a National Traceability System in Colombia

There will eventually be collaborative work groups with participation of all players in the health sector (both public and private) whose purpose shall be to continue developing more and better practices for the sustainability of the traceability system and efficiency in the commercialisation chain.

The implementation of a National Medication Traceability System in Colombia, using international GS1 Standards, will facilitate the harmonisation with models implemented in other countries in the region. In this manner, it will achieve the possibility of extending coverage to control imports and exports (legal and illegal) of medications.

The execution of this system is expected to generate an environment of greater safety and peace of mind for Colombians who are users of the healthcare system. Consequently, it is to hope that criminal activities derived from the trade of illegal medications will dramatically drop in the future.

About the author

Blanca Elvira Acosta Cajigas is an industrial engineer with studies in Financial Management, Quality Systems Implementation and Social Protection Management.

"The leadership of health surveillance is exercised by INVIMA with commitment to quality and public service, supported in new technologies".

Blanca Elvira Acosta Cajigas,
General Director, National Institute of Food and Drug Monitoring, INVIMA

During her career she has served as Advisor to the Health System, Quality General Director of Social Protection Ministry and Deputy Minister of Health and Welfare. She also served as Chair and member of several boards of state enterprises and President of the National Health and Social Security Advisory.

About the co-author

Leonel Pava is Communities Development Manager at GS1 Colombia. He joined the organisation in 2002 and previously served as Project Consultant. In recent years, Leonel has worked in the Healthcare industry promoting the implementation of GS1 standards and traceability systems. He has led projects with private sector actors, and more lately the "National Traceability System Pilot for Pharmaceutical Product", along with INVIMA.





Egypt

Safemed Keeps Counterfeit Drugs out of the Supply Chain in Egypt

ABSTRACT

The desire to introduce or regulate standards-based traceability¹ in healthcare systems around the world has increased significantly in recent years. One important driver of these regulations is the issue of counterfeit pharmaceuticals. Regulators are introducing various safety measures to prevent counterfeit pharmaceuticals, or “falsified medicinal products”, from entering the supply chain and reaching patients. These include traceability systems, but also other tools such as tamper-evident seals or holograms.



By **Dr Alaa Mohamed Afify** and **Dr Mohamed Mabrouk**



The European Union (EU) defines ‘falsified medicinal product’ as “any medicinal product with a false representation of:

- (a) Its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients;
- (b) Its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or
- (c) Its history, including the records and documents relating to the distribution channels used.

This definition does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights.”²

All supply chain stakeholders (manufacturers, distributors, hospitals and retail pharmacies) in Egypt are facing major challenges when trying to ensure the right drug reaches the final point of dispense. These include low security systems, supply chain penetrations and developed counterfeit techniques.

Did you know? It is estimated that the value of counterfeit drugs in Egypt has reached \$200 million. (Egyptian Drug Authority – 2010)

“Safemed” is a standard-based pharmaceutical traceability solution, introduced by GS1 Egypt, that enables pharmaceutical stakeholders to capture and share defined product information between trading partners, increasing the security of the extended supply chain.

Completed in March 2013, the Safemed pilot was the first standard-based pharmaceutical traceability project undertaken in Egypt.

Pilot participants

Pilot participants included actors of the healthcare supply chain, as **Utopia Pharmaceuticals** (S.A.E) supplying the pilot with *Blokaten*, a mid-high level cardiovascular product recommended for hypertensive treatment and **Dr. Alaa Pharmacy** testing the system at the Point-of-Sale, verifying the authenticity of the product by connecting to the Safemed system before supplying it to the patient.

Objective

The principal objective of the Safemed pilot was to implement a comprehensive, standards-based traceability solution across the pharmaceutical supply chain, from manufacturer to pharmacy, that strengthened known weak points in the legitimate supply chain making it more difficult for counterfeits to enter.

¹ “Traceability is the ability to track forward the movement through specified stage(s) of the extended supply chain and trace backward the history, application or location of that which is under consideration” GS1 Global Traceability Standard For Healthcare www.gs1.org/docs/gsmpt/traceability/Global_Traceability_Standard_Healthcare.pdf

² http://ec.europa.eu/health/human-use/falsified_medicines/index_en.htm

Safemed Keeps Counterfeit Drugs Out of the Supply Chain in Egypt



Figure 1: The GS1 System of Standards

GS1 Standards in action

GS1 Egypt supported all participants with the implementation of GS1 Standards (Figure 1), in particular the Auto Identification and Data Capture (AIDC) and healthcare traceability standards, whilst complying with the local regulatory requirements.

GS1 DataMatrix was the key data carrier adopted for the pilot. It was chosen as it is emerging across the world as the preferred data carrier in healthcare, due to the fact that it can hold the same amount of data as a linear data carrier (e.g. GS1-128) but takes up less space (Figure 2) whilst providing error detection and correction capabilities. This approach is aligned with developments in other parts of the world (e.g. Turkey, Korea, Argentina, Europe).

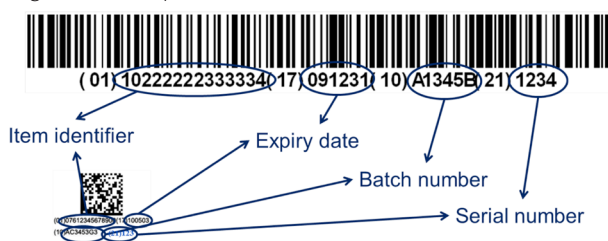
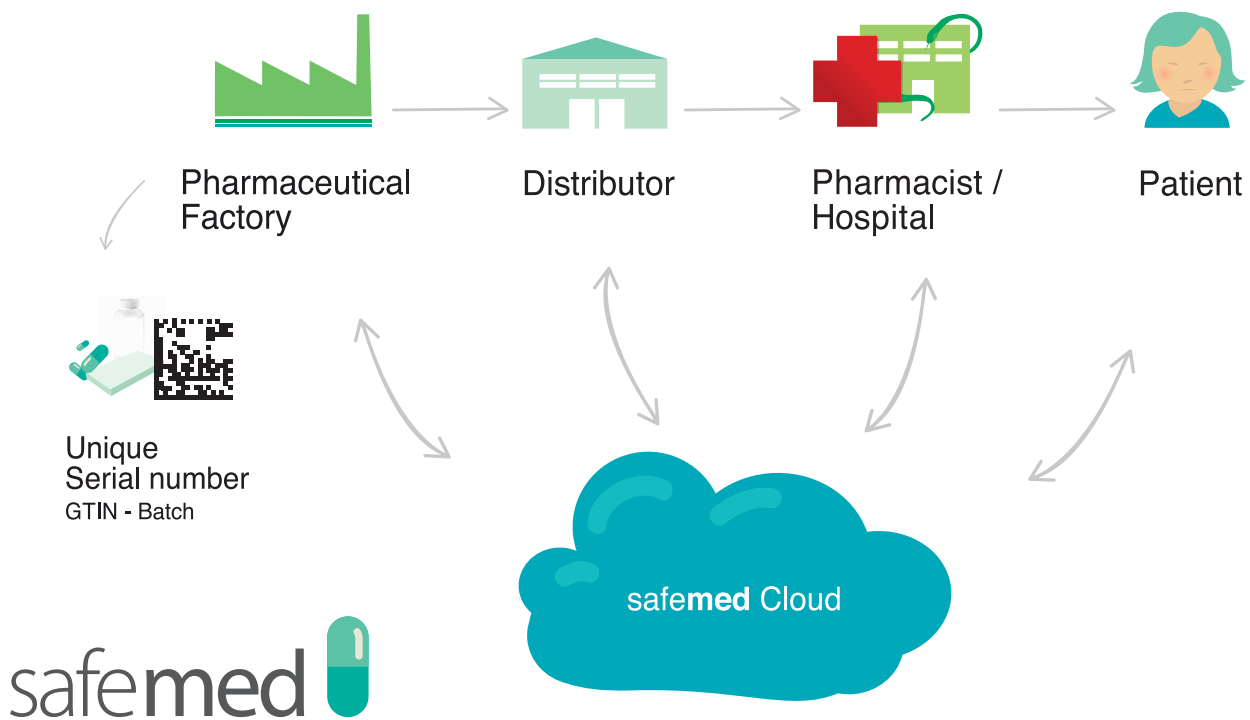


Figure 2: GS1-128 and DataMatrix

For this pilot the GS1 DataMatrix was structured to carry four data element strings with related application identifiers (AIs), as follows:

- GTIN (Global Trade Item Number) AI (01) - unique identification for the manufactured drug Bokatens and Utopia Pharmaceuticals
- Expiration Date AI (17) – as determined by the manufacturer
- Batch Number AI (10) – the product control number
- Random Serial Number AI (21) – randomised, non-sequential event serialisation for every single pack

Safemed Keeps Counterfeit Drugs Out of the Supply Chain in Egypt



Process description

- In the production phase, the manufacturer's production line Enterprise Resource Planning (ERP) system was programmed to print the GS1 DataMatrix bar code symbols on the product packaging and upload the 4 data elements (GTIN, Expiration Date, Batch No. and Serial No.) and related information (e.g. active ingredient and/or drug specifications) to the Safemed platform
- When product cartons and/or pallets were dispatched from the manufacturer (to a distributor for example) all related information about that consignment was shared and accessed by trading partners registered to use Safemed
- The distributor then accepted the received consignment after checking them on Safemed by scanning the GS1 DataMatrix bar code symbols on the cartons/pallets
- After that, the distributor performed various internal operations (e.g. Mixing/Separating/Dividing boxes as per order), while uploading all modified data to Safemed. Safemed generated another authenticity confirmation so that the products could be shipped. The modified data was then shared with trading partners downstream (e.g. sub-distributors and/or retail pharmacies)
- Finally, the pharmacy received cartons/packages from the distributor and checked the Serial Numbers on Safemed. The bar code was scanned once more when the medicine was sold to the patient. This dispatched Serial Number was then marked as "Sold" in Safemed to overcome the problem of returns facing the pharmacy and the distributor

Pilot counterfeit scenario

A total of 60 packages of Blokaten supplied by Utopia Pharmaceuticals were included in the pilot.

- 50 packages were aggregated into two cartons and their data uploaded to Safemed
- The remaining 10 packages acted as "counterfeits" to test Safemed and its traceability process and their data were not uploaded to Safemed

The "counterfeit" packages were brought back to the pharmacy by a made-up "distributor". As the pharmacist could not authenticate the packages scanned into Safemed, it rejected the delivery.

Outcomes, concerns and recommendations

The implementation of the Safemed solution, utilising GS1 DataMatrix, enabled traceability. Each participant was able to record, share data and track the movement of the drugs in a timely manner, in and out of their custody directly via Safemed.

The pilot also demonstrated that such standard-based traceability solutions could enable future recall processes, inventory management and financial reconciliation, which will generate further process efficiencies.

Safemed Keeps Counterfeit Drugs Out of the Supply Chain in Egypt

Some concerns were raised during the pilot, such as the complexity of coding and printing on the production line, the space required to print the GS1 DataMatrix symbol directly on the packages, and the inexperience of the staff. All these concerns were overcome enabling the Egyptian pharmaceutical stakeholders to realise the positive impact of improving patient safety whilst reducing the plague of counterfeit drugs.

The Egyptian pharmaceutical sector needs to implement essential standard based solutions and supportive track and trace technologies as soon as possible. This is especially true today as counterfeit drugs are spreading on both a local basis and across borders.

About the authors

Dr Alaa Mohamed Affy is a pharmacist and now owner of Dr. Alaa Pharmacy Chain, which counts 3 retail pharmacies in Egypt. Dr Alaa Mohamed Affy is an experienced healthcare executive and has been a medical representative since 2008.

Dr Mohamed Mabrouk has a degree in Veterinary Medicine and an MMBA from Missouri State University. Before joining Utopia Pharmaceuticals Egypt in 2007, he started his career as a medical representative at Lilly Egypt, then worked his way up to become the Business Development Manager at Utopia and since 2011, their Business Development Director.

About Dr. Alaa Pharmacy

The pharmacy is one of the local retail pharmacy chains in Cairo. Dr. Alaa Affy, owner of the chain, is extremely concerned about the counterfeit problem in Egypt and is working to help overcome this challenge through enhancing transactions' efficiency and security along the chain.

About Utopia Pharmaceuticals (S.A.E)

The company was established in 2008 as a specialised company in the field of pharmaceuticals manufacture and health care. Utopia Pharmaceuticals produces more than 40 pharmaceutical products, which are available on the Egyptian market and Kingdom of Saudi Arabia. Such a regional supply chain has pushed Utopia Pharmaceuticals towards searching among newly adopted pharma best practices and concepts, especially those related to counterfeit of drugs.





How GLNs Contribute to the Standardisation Efforts at Charité University Hospital

ABSTRACT

The basic information in the healthcare supply chain needs to be accurate, up to date, and synchronised. Even though today information and data are more easily accessible than ever before, the healthcare system is still an immature and expensive system with significant barriers to efficiency. Poor data impacts patient safety when the supply chain fails to deliver the right product, to the right patient, at the right time. Common standards are required to effectively control both cost and quality in healthcare.



By **Muazzez Weiß**



Realising the importance of identifying the location as accurately and precisely as possible, Charité University Hospital decided to implement GS1 Global Location Numbers (GLNs) for accounts/locations as an essential step in its efforts to fully support the adoption of healthcare supply chain standards.

Charité mission statement: play an active role

The GLN is used to uniquely identify locations and legal entities from manufacturers, distributors, and hospitals, all the way down to nursing stations. Transaction errors are then reduced while ensuring that the right product, procedure, and/or treatment are delivered to the right location.

“It is important that organisations take ownership of their data. We did not want to rely on a third party identifying a shipping location. We believe in global, accepted standards, and the efficiencies that can be gained across the supply chain by implementing GS1 Standards.”

“Only we can be responsible for knowing who we are”

The Charité situation was considered challenging due to its geographical split, with four sites throughout Berlin:

- Campus Berlin Buch (CBB), located in the north of Berlin
- Campus Virchow-Klinikum (CVK), located in the center of Berlin

- Campus Benjamin Franklin (CBF), located in the south of Berlin
- Charité Management as well as Charité Campus Mitte (CCM) situated in a 4th location in Berlin

In addition, each location may also have several additional delivery addresses. In total, more than 15,000 addresses need to be maintained.

Project steps

The project stakeholders agreed to the following project phases:

- Validate the address information¹ and reconcile any discrepancies
- Assign a GLN to all active shipping addresses
- Upload the assigned GLNs to GEPIR (www.gepir.org) in order to make the GLNs visible to all trading partners
 - Verify the process by using the GLN throughout the whole transaction cycle and demonstrate end-to-end success
 - Establish a process in order to maintain and update the GLN registry in GEPIR on a daily basis. The process can be initiated by the functional department and be fully supported by an automated web-based solution including a final approval step.

¹ GLNs must have proper alignment with the daily operations and the application they are used for; therefore, it is recommended to determine which locations truly need to be identified with a GLN.

How GLNs Contribute to the Standardisation Efforts at Charité University Hospital

Project outcomes using GLNs

The use of GLN brought important improvements to the healthcare supply chain:

- Clean data on delivery locations and therefore reduced error rate (by considering the correct internal and external delivery address)
- More accurate purchase orders and invoicing processes
- Real-time access to GLNs – always up-to-date using GEPIR and the recommended processes

Overall benefits

The project was very successful and resulted in diverse benefits that not only increase patient safety but also improve the hospital's efficiency and information accuracy.

- Improved infrastructure and data accuracy set the stage for process optimisation and patient safety initiatives
- Use of GLNs within healthcare facilities promotes reliable identification of precise locations within the facility. This supports caregivers' efforts to ensure that the right product, procedure, and/or treatment are delivered to the right location
- Real-time encoding of product usage and consumption allows an efficient documentation and account billing
- GLNs facilitate a streamlined product recall process by precisely identifying specific locations where recalled items were received, stored, and/or used

Greater transparency, safety, and quality

Charité also initiated an additional project consisting on the implementation of standardised bar coding in order to improve the time-consuming cost unit billing by Diagnosis-Related

Groups (DRG calculation). Scanner systems were introduced. By scanning the GS1 bar codes on the consumed products, materials are allocated directly to the patients through the IT-system.

This optimised stock management process provides up-to-date figures of the article in stock, as the entire ordering process can be automated. With the transparency created, products can also be easily traced within the hospital, contributing to increased efficiency and enhanced patient safety.

About the author

Mrs Muazzez Weiß is Senior Application Manager SAP Logistics. She has been with the Information Technology (IT) Division at Charité since 2003, where she has managed several IT projects (e.g., the implementation of SAP® Supplier Relationship Management (SRM)).

About Charité



Charité is one of the largest university hospitals in Europe. Thirty-eight hundred doctors and scientists provide care, do research, and teach at the top international level. More than half of the German Nobel Prize winners in medicine and physiology come from Charité, among

them Emil von Behring, Robert Koch, and Paul Ehrlich. Charité also has an international reputation for excellence in training. It extends over four campuses with more than 100 clinics and institutes bundled under 17 Charité Centers. With 13,000 employees, Charité generates about 1.2 billion euro in sales per year and is one of the largest employers in Berlin.





Safer Surgery Saves Lives

GS1 Identification and bar code standards deployed in the Irish Health Service Executive's (HSE) Central Decontamination Units (CDUs)

ABSTRACT

The Health Service Executive (HSE) is the government agency responsible for the provision of public healthcare services for everyone living in Ireland. The HSE now requires that all surgical instrument trays are identified using GS1 Standards to enable stakeholders to track and trace them throughout the supply chain. The system currently being rolled out is designed to create a collaborative, interoperable, and nationwide traceability solution for Central Decontamination Units.



by **Pauline Biggane**

Introduction

There is well documented evidence highlighting the importance of effective decontamination processes to prevent the spread of infections. The Medical Devices Directive (93/42/EEC) specifies the minimum standards in relation to decontamination of Reusable Invasive Medical Devices. Hospital acquired infections are a concern for all hospitals and their patients as Surgical Site Infections (SSIs) can have an impact on both patient safety (e.g., development of a serious illness) and hospital costs (e.g., additional cost of treatment for the patient).

The importance of a robust track and trace system that complies with regional, national and international best practices for the decontamination of surgical instrument sets is recognised as an integral part of all Central Decontamination Units (CDUs). Under the current economic and budgetary pressures that are faced by most health services across the globe, including Ireland, there is often a need to share important hospital resources such as surgical instrument sets. There is also a significant market for manufacturers to loan instrument sets to hospitals for specific procedures because it is not cost effective for a hospital to purchase them.

Proof of Concept

A Proof of Concept (POC) began in 2011. The objective was clear: could the use of GS1 Standards help realise the requirement of the HSE to increase Patient Safety by introducing an interoperable traceability system for the Irish National Health Service?

St. James's Hospital volunteered to demonstrate the feasibility of the project. St. James's is a leading, major acute and academic teaching hospital. The hospital caters for over 14,000 surgically invasive procedures every year. With 30,000 surgical trays, including over 300 shared loan sets being reprocessed by St. James's CDU every year, the POC was needed to reflect the complex nature of implementing a national traceability solution.

The POC showed that by implementing GS1 Standards the CDU moved away from manual processes, and at the same time, effectively managed a 17% increase in workload with less staff members.

Sharing reusable surgical instrument sets has obvious benefits, but can challenge proprietary track and trace systems. Having multiple proprietary systems in each hospital can result in a break in the traceability chain when an item leaves a hospital, as there is no guarantee that the identification of that item is unique. Recognising this challenge, the Health Service Executive (HSE) in Ireland implemented a solution using GS1 Standards.

Ireland - Safer Surgery Saves Lives

Following the successful pilot at St. James's Hospital, the HSE made the decision to roll out the system in seven additional HSE and HSE-funded acute hospitals throughout Ireland in 2012:

- Beaumont Hospital
- Kerry General Hospital
- Mullingar General Hospital
- Portlaoise General Hospital
- Adelaide and Meath Hospital, incorporating the National Children's Hospital
- Tullamore General Hospital
- Waterford Regional Hospital

A simple solution to a complex problem

The supply and demand chains for surgical instrument sets are complex. There are two distribution channels needed to get the product to the end user: a surgeon or another medical professional. Firstly there is the macro supply chain; when an instrument set is loaned between hospitals or when it is loaned or consigned to a hospital from a commercial loan set provider. Secondly there is the micro distribution channel; the decontamination process that occurs within the four walls of the CDU. Importantly, continuity of traceability between these two supply chains is a key factor in ensuring patient safety.



Figure 1: The Decontamination Cycle

Using GS1 Standards for Identification

GS1 Standards and a new electronic traceability system was introduced in eight hospitals initially. A GS1 Global Individual Asset Identifier (GIAI) was assigned to each instrument tray owned by the hospital. As the tray moves through the decontamination process, its unique identity is enhanced. Batch numbers identify the relevant autoclave cycle, expiration dates help ensure the surgical instruments are decontaminated when necessary and Global Location Numbers (GLN) are used to identify the location of the CDU that has decontaminated the surgical instrument set and its contents. Each

step of the process is time and date stamped when the GS1 bar code is scanned. Technicians working in the CDU scan their ID badges to complete the "who, what, where and when" of the traceability process.

The Traceability process

The track and trace software system application is provided by FingerPrint Medical Ltd. The system helps users monitor all control points in the decontamination supply chain, from using an autoclave to decontaminate the instruments in the CDU to linking a particular instrument set to a patient in theatre, by scanning the GS1 bar code at each of the control points. In addition to providing the checks and balances that help create the assurances needed for patient safety, the software helps its users to drive efficiencies in their departments.

An Independent Monitoring System (IMS), which monitors the Autoclaves (Temperature & Water Pressure) and Washer-Disinfectors (Temperature, Dose Levels & Conductivity), is also required by the HSE. The IMS functionality was provided by Irish Power and Process and interfaced seamlessly with the track and trace application, adding an additional layer of quality assurance. Significantly, if any cycle fails to reach the required decontamination parameters this is immediately communicated to the track and trace system. When the bar code is scanned at the relevant control point, the user is notified if there was a failure in the autoclave process, thus requiring the instruments to begin the decontamination process again.

Sláinte Healthcare provided the shadow Patient Master Index (PMI) for this project. The shadow PMI enables theatre staff to ensure the correct patient is in the operating theatre and to record the exact instruments used for the patient's procedure. This is done by reading feeds of demographic data from the hospital administration system and making the information available to the track and trace software. The instrument tray is scanned against the patient's procedure and the data is recorded accordingly.

Finally, hospitals and commercial loan set providers can share the transactional data needed for their business processes by using the cloud based Medical Standards 1 (MS1) software, which is also integrated with the track and trace software. Up-to-date data on the contents of the instrument trays is accessed when the bar code is scanned on the instrument set. The system enables hospitals to download up-to-date instruments tray contents, decontamination certificates and instructional photographs to streamline processes.



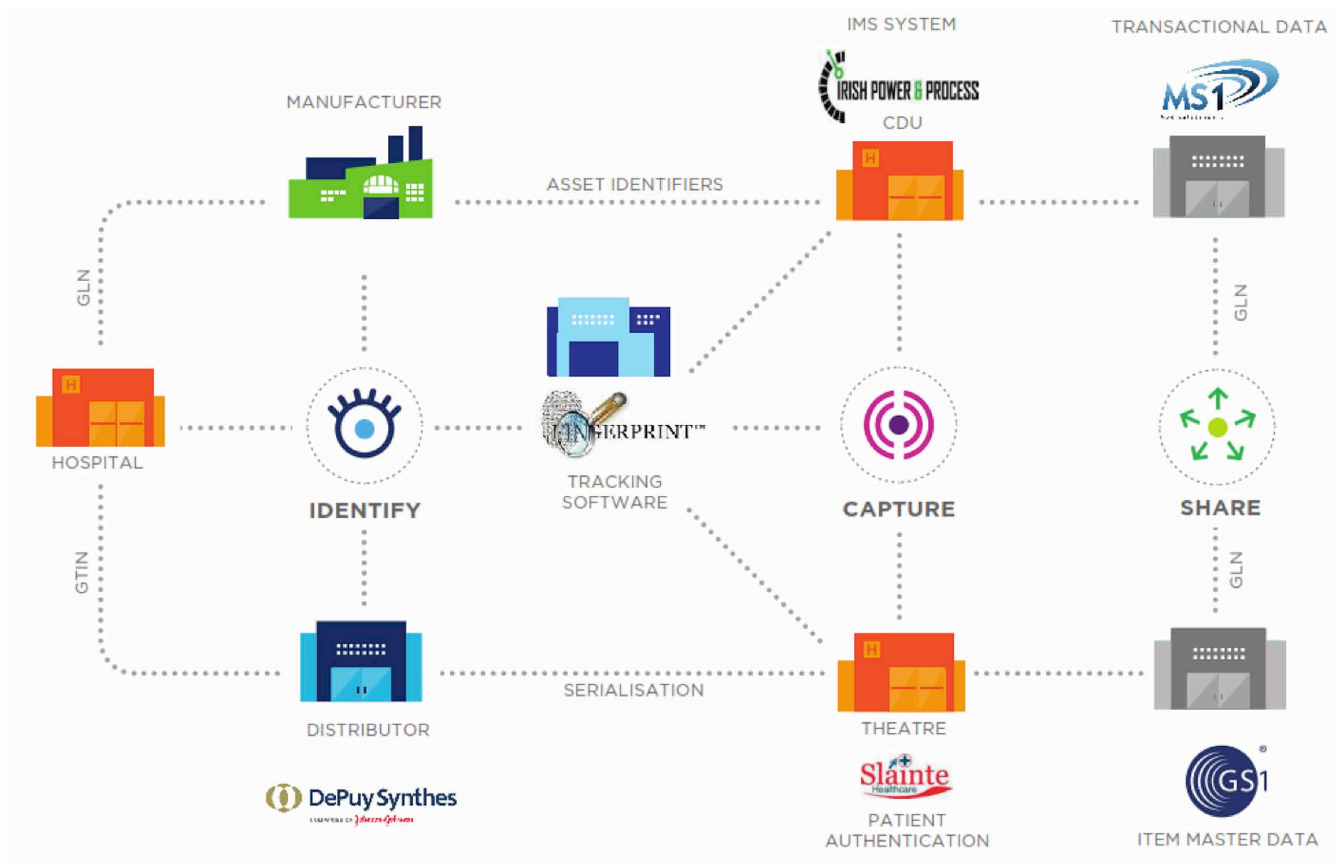


Figure 2: The Use of GS1 Standards in Surgical Instrument Traceability Systems

The traceability chain is also maintained when an instrument tray is loaned between hospitals using the track and trace system. When a hospital borrows an instrument set, they simply scan the GS1 bar code which acts as the key to access the relevant information. The details associated with each particular instrument set can then be downloaded to the local systems, maintaining traceability data and ensuring accurate data on the contents of the set. Prior to the adoption of GS1 Standards this was a paper-based, error prone, and labour intensive process.

The HSE has published three documents that explicitly recommend the use of GS1 Standards to help them realise their exacting standards. These documents describe a set of standards which define the structures and processes needed to identify, assess and manage specified risks in relation to the decontamination process.

Nothing succeeds like success

The HSE has steered this project with great success. The natural next step for the project was to extend GS1 coding to ridged and flexible endoscopes. The risk involved, both to patient and provider, in the use and maintenance of these instruments is well documented and GS1 Identification Standards are now being rolled out in Endoscope Reprocessing Units (ERUs).

The use of GS1 Standards is viewed as a means by which assurances about the integrity of the HSE's standards can be automatically captured and shared amongst all stakeholders, thereby helping to streamline ERUs in the same way that the HSE has accomplished with instrument tray management in CDUs.

Benefits and outcomes

The objectives of the project (to reduce manual labour, increase efficiency and create assurances that an effective decontamination process has occurred) have all been achieved through the track and trace solution. For both patients and internal customers of the CDU, the implementation of the traceability solution and the adoption of GS1 Standards have exceeded expectations and many unanticipated benefits have also been achieved.

Indeed, one of the biggest benefits identified is the ability to loan instruments seamlessly between the eight hospitals currently participating in the initiative.

Ultimately the full benefit will be fulfilled when manufacturers apply the GS1 Identifier at the point of manufacture. In this regard, DePuy Synthes is the first manufacturer to mark their loaned tray sets at source, to guarantee traceability from manufacturing site right through to the patient record.

Ireland - Safer Surgery Saves Lives

Prior to the implementation of the traceability system, using loan sets for a specific procedure could involve the reprocessing of between 10 to 15 individual sets of instruments before and after the procedure. The contents of the loan set also had to be manually entered into the track and trace software, sometimes taking staff an additional 3 to 4 hours to complete the task. DePuy Synthes' use of GS1 Standards has delivered a significant reduction in the manual work that hospitals encounter when receiving and processing instrument trays.

The success of the project, the benefits delivered and the willingness of DePuy Synthes to foster a collaborative traceability solution with the HSE has not gone unnoticed. The HSE is now in communication with the majority of commercial loan set providers in Ireland and hopes to work closely with them. Encouragingly, the commercial loan set providers engaged in the project recognise both the business and the patient safety benefits that using GS1 Standards can enable.

The reality is that managing inventory is a difficult task for hospitals, instrument manufacturers and distributors alike. It is a cumbersome, resource intensive process that is complicated by the fact that an instrument tray's visibility is critical to patient safety and the efficiency of a CDU. Independent research conducted by Trinity College Dublin identified some compelling benefits of implementing a collaborative interoperable solution:

Patient safety benefits:

- Robust traceability of instrument sets with audit trails for quality assurance are electronically accessible
- Instrument sets can be located quickly in emergency situations
- Warnings are provided if a step is skipped in the decontamination process
- Links between patients, instrument sets and the decontamination process are established

Efficiency benefits:

- Ability to analyse staff productivity to improve processes
- Ease of reporting both during and post event
- Automated validation and streamlined processes
- Inventory visibility available in real time
- Automatic generation of set lists when the GS1 code is scanned, reducing administrative work
- Improved communication between CDU and theatre staff, ensuring sets are ready where and when needed

The independent research also found that the potential savings in economic terms are twofold. Firstly, if 30%¹ of Hospital Acquired Infections (HAI) is caused by Surgical Site Infections (SSI), and if an estimated 10%¹ of these are attributable to contaminated surgical instruments, the potential cost savings from implementing the

By applying GS1 Identifiers at the point of manufacturer, hospital staff was able to save 3 to 4 hours of manual work by task.

traceability system means the system would pay for itself in the first year. It was also established that by reducing SSIs hospitals may have more beds available for patients that need them. Perhaps most importantly, the impact of stress, longer hospital stays and adverse events on the health of patients can also be reduced.

The future

The success of implementing GS1 Standards for tracing instrument trays between and within Irish hospitals has highlighted that a combination of effective processes, the application of GS1 Standards and use of scanning technologies have measurable benefits for all Healthcare stakeholders. The instrument track and trace solution incorporating GS1 Standards is currently being rolled out to an additional 31 Hospitals.

The scope of the current phase of the project now includes endoscope reprocessing sites, which will bring further benefits by virtue of scale and patient safety. Further phases will involve single instrument marking, helping to ensure a level of traceability and reporting that would not have been previously possible with a manual or proprietary system of identification.

About the author

Pauline Biggane is a project analyst with the ICT Directorate of the HSE. Currently one of the projects Pauline is managing is the National Reusable Invasive Medical Devices (RIMD) / Endoscope Track and Trace Project. Working with clinicians and other healthcare professionals, Pauline has procured and implemented clinical IT solutions across acute hospitals in the HSE South East region for the benefit of patient safety and the improvement of service delivery.

Pauline is trained as a Nurse and specialised in Midwifery. She holds a degree in Healthcare Management with the Institute of Public Administration. Through both her academic and practical experience, Pauline has developed expertise in change management, Project planning, implementation and business process modelling.

About the co-author

Alan Gormley is a Technical Expert in the Automatic Identification and Data Capture (AIDC) aspects of the GS1 System® and also responsible for the development and delivery of training, at GS1 Ireland.

Collaborating with solution providers nationally and globally, Alan works in numerous industries such as healthcare, aerospace and retail to help implement GS1 Standards for traceability, patient safety and efficiency solutions. Alan holds diplomas in both process and polymer engineering, in addition to a Bachelor's Degree in Economics and Law from University College, Galway (NUIG) and a Master's Degree from Trinity College, Dublin.

¹ "The potential benefits of a traceability solution for surgical trays in the Irish Health Service", Alana McMahon.



Portugal

Minimising the Risk and Reinforcing Patient Safety for Novartis Products

ABSTRACT

In 2010, Novartis Pharma in Portugal developed and implemented a traceability programme using GS1 2D DataMatrix. This programme allows to track the product, from the warehouse to the patient, including all the moves in the hospital from the pharmacy to the operating theatre. It also enables online status checks in the case of an adverse event or any investigations due to quality aspects. The programme is set up to include other products and is being adopted by other countries.



by Margarida Alves

With patient safety as the focus, in 2010 Novartis Portugal developed and implemented a traceability programme for one of its medicines, which is now available in five Portuguese public hospitals. From September to December 2012, around 2000 units of the concerned medicine have been tracked.



What is the programme?

The programme consists of implementing a tracking system based on GS1 2D DataMatrix, which allows registering the course of the medicine from the Novartis warehouse to the hospital where the patient receives treatment, and ultimately to the patient to whom the product is administered. This includes the date and time of each of the various steps.

How does it work?

Pre-printed labels containing a GS1 DataMatrix, including the Global Trade Item Number (GTIN) and a Serial Number, are applied onto the secondary packaging. The inclusion of a serial number allows the individual identification of each pack of product, which can then be linked with the patient to whom the product was given.



When the product leaves Novartis' warehouse, each pack is individually scanned. This step ensures that the unique identifier on the product is registered in a database available to the hospitals.

Front-end hospital

To allow the registration of the course of the product once in the hospital, Novartis has also developed a tracking programme with an access provided to the hospitals who have adopted the tracking system. Due to the great variability of systems used by the different hospitals, easy access was very important. Therefore, a web-based application was designed (www.trace.novartis.com).

Each hospital has an account and as many users as necessary to meet internal dispensing procedures.

In the hospital, once doctors prescribe the product, the pharmacist scans the packs to be dispensed, and the information is again stored in the same database. Scanning allows confirmation that the product was supplied by Novartis with an online verification of batch and shelf life.

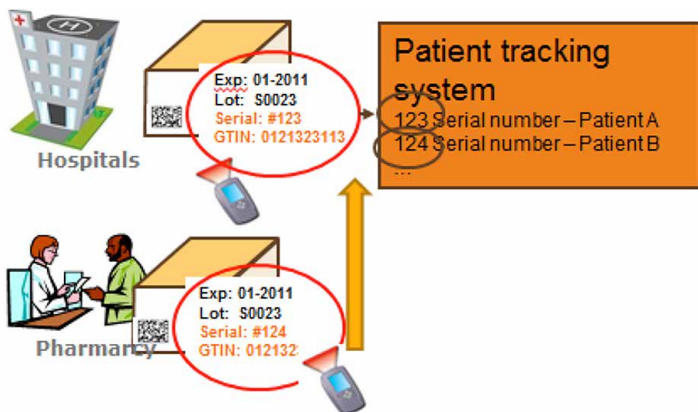
After administration of the product, the patient number is allocated into the database so that the dispensing of each unit to a single patient can be recorded.

This programme allows to perform queries by date of dispensing/scanning, date of treatment, and by patient

Minimising the Risk and Reinforcing Patient Safety for Novartis Products

number, thus allowing a fast identification of the status of each individual pack if necessary.

Confidentiality



The system is based on an auto-identification solution in which the patient data remains confidential (except to the hospital pharmacist) during the entire process through an encryption system. When the patient number is introduced, it is automatically hashed with an alpha numeric key. Furthermore, patient numbers are different from hospital to hospital, which contributes to the security of the information.

Conclusion

Although the technology is complex, the system itself is very simple to use. The traceability programme is effective and has the advantage of offering a user-friendly and low-maintenance system.

Additionally, it supports the process of dispensing and tracking inside the hospital, from pharmacy to the operating theatre, reducing then the risk of exchanging drugs and supporting the management of stocks. It enables online status check in case of

an adverse event or any investigations due to quality aspects, both at the hospital or at Novartis.

The project has great potential and is to be expanded to other products, including into areas where a more restricted control over medication is needed, such as oncology as well as to other countries where it is already under evaluation for adoption.

Fully designed and developed at Novartis Portugal, this programme has anticipated the changes which will be introduced in the European Union following the publication of the EU Directive on Falsified Medicines.

About the author

Margarida Alves has worked in the pharmaceutical industry since 1990. She started in a Portuguese Animal Health company and joined in 1992 the Health Division of Ciba-Geigy which became Novartis following a merger with Sandoz. She has served as a Logistics Manager and Regulatory Affairs Manager at the company and has been involved in several projects both in Animal Health and Pharma Divisions at Novartis.

About Novartis

Novartis provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, over-the-counter and animal health products. Novartis is the only global company with leading positions in these areas. For more information, please visit <http://www.novartis.com>.

Novartis Portugal – Oeiras - Portugal



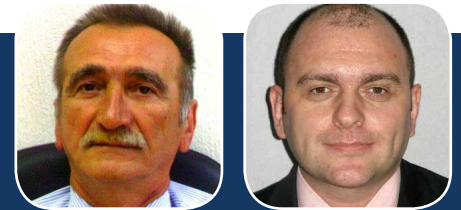


Serbia

Ensuring Traceability of Medicines in Serbia

ABSTRACT

Pharmaceutical supply chains across the world are often very complex and non-transparent. Such complexity, as well as the occurrence of falsified medicines in the market, seriously threatens the security of patients. Serbian stakeholders joined forces and initiated a traceability pilot project aimed at creating a medicines traceability system from production to patient. In addition to ensuring traceability and reinforcing the fight against the occurrence of falsified medicines, the pilot also wanted to prove the importance of automating the work processes to meet European regulations.



by Milorad Komljen and Bogdan Pavlović

Project objectives

The project goal was to demonstrate that it is possible to provide visibility across the healthcare supply chain, from manufacturer to patient, using GS1 Standards. A key element of the project was also to implement the GS1 DataMatrix carrier and item serialisation. Standards used included Automatic Identification and Data Capture (AIDC) technologies and Business-to-Business electronic messaging (eCom). Such a traceability system was set to demonstrate the possibility of tracking medicines at any chosen point across the distribution chain and provide key data about the product (e.g. the batch or lot number and expiration date), connecting the medicine to the patient.

In addition, the project was intended to demonstrate that a documented recall of specific batches or lots of medicines from the market could be achieved in a relatively short time.

Lastly, the project participants were motivated to expand the scope to demonstrate that the use of GS1 Standards could increase the security of the supply chain and strengthen the fight against the growing threat of falsified products penetrating the market.

Participants and sponsors

The system tracked two domestic medicines that are reimbursed by the Government Healthcare Fund and included 11 companies representing the whole healthcare supply chain up to the retail pharmacy, of which:

Domestic Medicine Manufacturers

Galenika a.d.
Hemofarm Stada a.d.

Medicine Wholesalers

Farmalogist a.d.
Phoenix Pharma a.d.
Velefarm a.d.

Pharmacies

Apoteka Beograd with its 54 Pharmacies and about 150 dispensing points.

Solution Providers

Metadata for designing of a specific central data base.
Panteon Group® for the message exchange.



Apoteka Beograd



Ensuring Traceability of Medicines in Serbia

The Ministry of Health of Serbia and the Medicines and Medical Devices Agency of Serbia supported the project and approved the use of GS1 DataMatrix to be applied to the medicines secondary packaging.

588,163 packs of medicines from 32 batches were marked with GS1 DataMatrix, amongst which 524,066 carried serial numbers. 8,528 individual packs of medicines were issued to patients.

GS1 Serbia provided education and understanding of the regulations, standards and guidelines and provided complete support and guidance to all project stakeholders whilst also managing the central data base. The GS1 Healthcare Team of GS1 Serbia also acted as the project Coordinator.

Application of GS1 Standards

As the Serbian Drugs Law of 1993 already mandates the use of GTINs to identify products, the use of a GS1 DataMatrix data carrier to encode the GTIN was seen as a continuation of the standardisation process.

GS1 Standards applied in the project included:

- GS1 DataMatrix placed on the medicines secondary packaging holding the GTIN, Batch or Lot Number, Expiration Date and Serial Number
- GS1 Serialised Shipping Container Code (SSCC) also known as a Logistics Label
- Global Location Numbers (GLN) for the unique identification of the trading partners and their operational premises (e.g. warehouse, pharmacy)
- GS1 eCom Despatch Advice (DESADV; XML version 2.5)
- A database modeled on the GS1 Global Data Synchronisation Network (GDSN) standard, holding the master data of each medicine (GTIN) and trading partners (GLN)

The database included all the transactions related to the medicines, which enabled visibility of medicines along the supply chain. Data and reports were only available to the project participants. According to regulatory requirements, patient data was available only to pharmacy institutions.

The process

The manufacturers selected the prescription products to be included in the project and got trained to the use and application of GS1 Standards, ie. how to apply the GS1 DataMatrix carrier to the secondary packaging (Figure 1), how to implement the logistics label (SSCC) and how to generate and exchange electronic (eCom) messages.

Accordingly, the wholesalers developed the ability to improve the warehousing processes by monitoring the products GTIN, Batch or Lot Number and Expiration Date.



Figure 1: Marked products with GS1 Standards

In parallel to the movement of the medicines across the supply chain downstream, from manufacturer to wholesaler to pharmacy, a DESADV message was sent. A copy of each message, together with all the information about the sender, dispatched goods and receiving parties were registered in the GS1 Serbia database. This process enabled to centralise the information on each medicine, its Lot Number and quantity transacted in the supply chain (Figure 2).

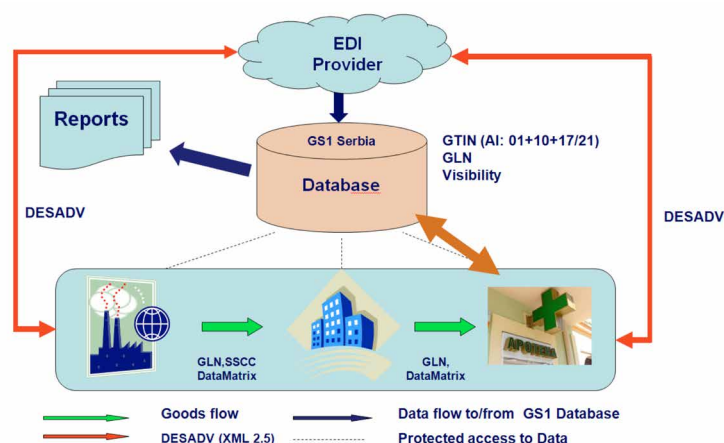


Figure 2: Goods and information flow

During the project the pharmacies needed to ensure they could accept and store the medicines in line with GS1 Standards. Every pharmacy was thus equipped with an image scanner at the dispensing point terminal, which could read DataMatrix carriers (see Figure 3).

In addition, every prescription of medicine carried a GS1 DataMatrix encoded with the patient's name, address and the national product code of the prescribed medicine used for reimbursement purposes. So, when a patient came to the pharmacy, the pharmacist would scan the GS1 DataMatrix on the prescription and, at the point of dispense, scan the GS1 DataMatrix on the medicine's packaging.

This process allowed to link the patient's information to the medicine dispensed. In order to secure patients information, their data was kept in the pharmacy's database while the identification number of each transaction, prescription and the

GTIN number, Batch or Lot Number, Expiration Date and Serial Number on the medicine were held in GS1 Serbia's Data Base. The visibility obtained by linking the data about the medicine dispensed to the receiving patient provided the possibility of recalling medicines directly from the patient.

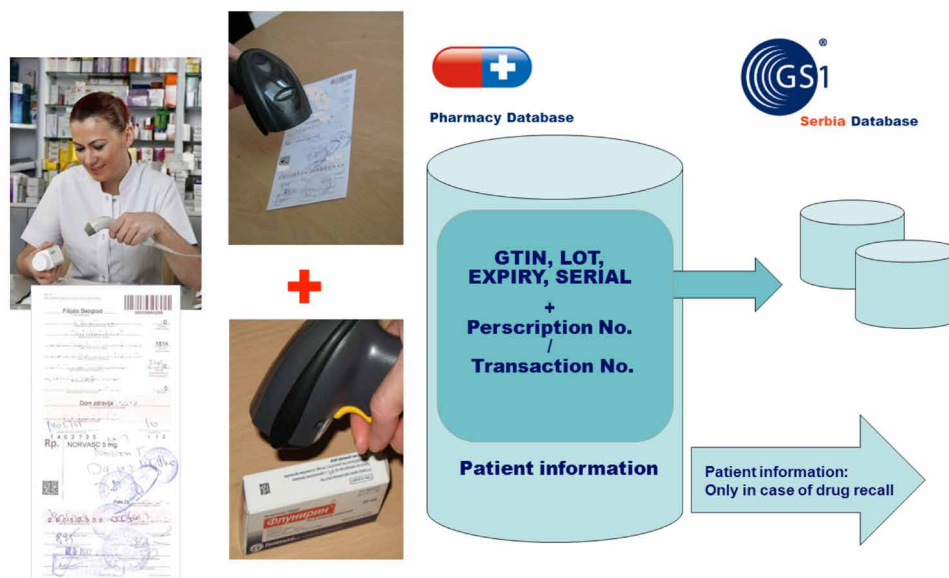


Figure 3: Pharmacist reading a DataMatrix carrier at the point of dispensing

A first test was undertaken to **prove the authenticity of the medicines**. 118 scans of Serial Numbers were conducted on inventory held at the wholesalers and pharmacy locations (Figure 4), as well as at the dispensing point in pharmacies. The manufacturers verified the Serial Numbers and confirmed that no duplicates had been found at the points of dispensing.



Figure 4: Serial numbers being checked

Two additional drug recall tests were undertaken on specific batches. In less than an hour, the packs from these batches were located - whether at the manufacturer, wholesaler, pharmacy or patient.

Findings

The operational part of the project lasted one year and the direct costs amounted to less than €10,000. The project was based on already existing IT equipment purchased by manufacturers for printing and scanning GS1 DataMatrix carriers. Pharmacies were already equipped with image scanners to read GS1 DataMatrix carriers on prescriptions. The changes to Pharmacy software was financed by GS1 Serbia, while the funds tied to eCom providers' solutions were very limited.

It was demonstrated during this project that the efficiency and accuracy of data, as well as the efficiency of all the logistical processes can be improved whilst minimising operational errors and manual activities.

The implementation of GS1 DataMatrix placed on the medicines' packaging holding the GTIN, Batch or Lot Number, Expiration Date and Serial Number proved to be fundamental to:

- Enable medicine traceability
- Strengthen the fight against falsified products
- Increase the visibility of medicines across the supply chain
- Improve the efficiency of the medicine recall process
- Increase the protection of patients from falsified, expired or recalled medicines

Ensuring Traceability of Medicines in Serbia

About the authors

Milorad Komljen, BSc. econ, is the ICT Executive Manager at the Galenika company. He has gained 35 years of experience in informatics while working in different companies from Economics Institute Belgrade to Galenika where he was actively involved in different IT projects.

Bogdan Pavlović, BSc IT, is the Head of IT Development in Hemofarm. He has been with Hemofarm since 2002, starting as an Application Developer. Currently as Head of IT Development, he has worked on a number of projects which included several cycles of alignment with logistic standards. He is proud to have been aligning Hemofarm logistics with GS1 Standards.

About the co-authors

Miroslav Ilic is CEO of GS1 Serbia and has 34 years of working experience. Miroslav has been engaged in pharmaceutical industry in IT sector and management for the past 25 years. He was previously employed by the oldest pharmaceutical company in the Balkans, starting in IT and becoming the general manager for the company. He was the President of the Medicine Wholesalers Group within the Serbian Chamber of Commerce.

Branislava Mitic is the Team Leader for GS1 Identification at GS1 Serbia and has been in the Association for the past 19 years. In addition to leading the team engaged with identification standards labelling and coding, she is also engaged in Traceability initiatives in various sectors and supports Healthcare at GS1. She is the President of the Serbian Institute for Standardisation Board - KSI 1/SC 31 for Automatic Identification and Data Capture, and the member of the mentioned Institute Board KSI / TC 215 - Health informatics.

About the participants

Hemofarm A.D. is one of the leading generic pharmaceutical manufacturers in Serbia and the region. Founded in 1960, the primary activity of Hemofarm is the production of high-quality, safe, and effective generic pharmaceutical products. In 2006 the company became part of the STADA Group. It has about 2,500 employees and operates in the markets of more than 30 countries.

Galenika A.D. was founded in 1945 and is the oldest Serbian manufacturer. Its assortment includes over 250 products in different forms, which covers almost all groups of drugs, dietary supplements, medical devices, dental products and equipment for general use. It has 2,500 employees. Beside domestic production, it also operates in Serbia as well as in the European, Asian and African markets.

Phoenix Pharma Co. was established in Belgrade in 1991 under the name Pharmanova. Starting as wholesaler, incorporating pharmacies, it quickly started to produce its own products. In 2009 it became a member of The Phoenix Group and now operates as part of this famous wholesaler under a new name, PHOENIX Pharma Ltd.

Farmalogist Co., a domestic wholesaler, was founded in 2002. Thanks to ongoing investment in the modernisation of business centres, business process development and integration of all aspects of sales including online ordering, this company was ranked amongst the leading wholesalers in the domestic market.

Velefarm A.D., is a long-standing wholesaler in the country founded in 1979. For more than 30 years it has expanded its network of business centres outside the country, with the modern concept of operations and high-shelf warehouses built on the latest international standards.

Apoteka Beograd was formed immediately after the Second World War as a system of state pharmacies in Belgrade. The company has a network of 123 pharmacies in the territory of Belgrade's 17 municipalities. With 1,200 employees, Pharmacy "Belgrade" is a leader in size and number of employees and a renowned medical institution in the Balkans and South-Eastern Europe in general.

Panteon Group® offers services in the field of inter-organisational e-business, primarily between companies (business to business - B2B) and between businesses and public institutions (Business to Government - B2G). It offers to customers all the necessary services and complete solutions for the restructuring of classical business processes with e-business services.

MetaData, founded in 1991, is engaged in research and development, design, construction, implementation and maintenance of management information systems, as well as with study of information systems development (BSP study), business process re-engineering, computer network projects, and project management.

Implementing a medicine traceability system along the supply chain, from manufacturer to the patient, can improve the security of the supply chain. Linking the physical product flow with the information flow assists in identify when falsified product enter the legitimate supply chain and, if necessary, can assist in the quick location and therefore removal of recalled products from the market.



United Kingdom

Complying with New Legislation at Mölnlycke Health Care

ABSTRACT

Mölnlycke, one of the world's leading providers of wound care and single-used surgical products and services to the healthcare sector, has gone through several mergers and acquisitions over the years, adding to its business various companies with different processes and product ranges. Standardising internal processes was essential, and urged in 2009 when the Andalusian Health Service in Spain mandated GS1 Standards for the coding and symbol requirements for products they were manufacturing and purchasing.



by **Jenny Gough**



Introduction

Mölnlycke was founded in 1849 as a textile company, going through several mergers and acquisitions over the years. During the last decade in particular various companies with different processes and differing product ranges have been incorporated by Mölnlycke.

Today, its products are manufactured in nine countries covering three continents, with marketing and sales offices in thirty countries.

In 2009, whilst trying to standardise internal processes, Mölnlycke was impacted by the Andalusian Health Service in Spain mandating GS1 Standards for the coding and symbol requirements for products they were purchasing.

This demand aimed to maximise the reliability of the identification of a product and its characteristics, and to promote the effective use of automatic product identification systems within the supply chain.

Initial assessment

The company met the tight deadlines set by the Andalusian Health Service in late 2009 by incorporating the relevant bar



codes into the product labelling for this region.

In 2010 the company decided to complete a full assessment of its products against the specifications set by GS1. This research was initially conducted on products distributed within Europe but was then expanded to look at products worldwide.

The results of the assessment showed that, while the products within Mölnlycke were labelled with GS1 bar codes, there were a number of cases where the bar codes did not meet the detailed specifications set out by GS1. This was explained by acquisitions that had not yet been fully integrated, different processes being used within the manufacturing sites and the varying product ranges.

Mölnlycke has about 7,000 employees and manufacturing plants in Belgium, Czech Republic, Finland, France, Malaysia, Thailand, Poland, UK and US.

Applying GS1 Standards

Initially it was thought that to solve the problem the company could use a single label design and update the packaging artworks where required.

After looking into the results in more detail, it was apparent that a single label was not a viable solution due to the different product information required on the labellings (e.g. CE marking, sterilisation methods). Therefore, Mölnlycke decided to design a range of product labels that would satisfy the requirements both internally and externally.

Case Study: Mölnlycke Health Care

Mölnlycke worked closely with GS1 UK on a joint project to ensure that they were working towards a solution that was both compliant with the GS1 Standards and the up-and-coming new regulations covering Unique Device Identification (UDI).

The data within the GS1 bar codes now enables automatic identification of the products at any point in the supply chain. There was also investment in new verification equipment to ensure that all bar codes met not only the GS1 standards but also the print quality standards set out in ISO 15416 for the printing of bar codes.

The labels also needed to be adaptable so that they could be changed to fit local requirements where possible. This meant that new acquisitions could be easily merged into the company in the future.

The benefits of using the GS1 system in the healthcare sector

The benefits of using a single, globally accepted system for positive identification of medical devices included:

- Increased patient safety through identification and traceability
- Continued marketing of products in different countries. In the UK in particular it has helped to meet the new NHS regulations for universal codes on medical products
- Long-term financial benefits through increased efficiency and meeting of requirements
- Much easier product recalls



Figure 1: Product package with GS1 bar code label

Conclusion

Since the initial analysis of the product range in 2010, a significant amount of time and effort has been spent to ensure full compliance with GS1 Standards. Mölnlycke is now in the final stages of completing this initiative.

The global nature of GS1 Standards makes it easier to market the products throughout the world and expand into new markets. As technology is always evolving, it ensured that new developments are addressed by a dedicated specialist resource, and that the GS1 Standards are being met for any new acquisitions, in order to safeguard patient safety through the identification and tracking of products.

About the Author

Jenny Gough has been working with GS1 Standards since 1996. This was mainly in the retail sector working for FMCG

companies but for the last 7 years she has been working in the Healthcare sector for Mölnlycke Health Care. Jenny is also actively involved with GS1 UK and Irish HUGs and Eucomed UDISC Task Force.

About Mölnlycke

Mölnlycke, founded in 1849, is one of the world's leading providers of wound care and single-use surgical products and services to the health care sector. The company has about 7000 employees and manufacturing plants in Belgium, Czech Republic, Finland, France, Malaysia, Thailand, Poland, the UK and the US.



Figure 2: Labelling specification



Better Immunisation Management for Patient Safety

ABSTRACT

The US Government's National Childhood Vaccine Injury Act of 1986 requires that clinicians record specific information about the administered vaccine and Vaccine Information Statement (VIS) in patient medical records. The Centers for Disease Control and Prevention (CDC) launched two projects using GS1 Standards to automate vaccine and VIS information management processes. One pilot is testing how vaccine data – the GS1 Global Trade Item Number (GTIN), Lot Number, and Expiration Date encoded in a GS1 DataMatrix bar code – can be scanned on vaccine vials and syringes for populating electronic medical records (EMRs). The CDC is now adding a GS1 DataMatrix bar code encoded with the GS1 Global Document Type Identifier (GDTI) to each VIS so that providers can automatically capture and record VIS document type and edition date into EMRs. The CDC expects that providers will save time and gain efficiencies in immunisation management, as well as reduce the risk of errors by scanning bar codes versus manually transcribing vaccine and VIS information. This improved accuracy means improved safety for patients.



by **Ken Gerlach** and **Warren Williams**

A recent study conducted by RTI International and published in the June issue of *Vaccine*¹ also found that implementing 2D bar codes on vaccines will increase the probability to locate a patient should a vaccine be recalled. The results also showed that between 2011 and 2023 the net economic benefits from switching vaccines to using 2D bar codes were forecasted to be between \$310 and \$334 million.

From manual to electronic

Vaccines are manufactured and given each year in the US to millions of newborns, children, and adults. Whether part of seasonal immunisations or scheduled vaccinations, or one of the many newer immunologic agents designed to protect against harmful viruses, a vaccine travels through an intricate healthcare supply chain – from its manufacturer to patients – passed from one organisation to another along the way.

Consider that there are more than 650,000 different organisations in the US alone, including manufacturers, distributors, carriers, group purchasing organisations, and hospitals involved in healthcare supply chains². These industry players are quickly transitioning from manual processes to

The net economic benefits from switching vaccines to using 2D bar codes are forecasted to be between \$310 and \$334 million.

automated processes and EMRs. As this movement progresses, information about each vaccine must be shared completely and accurately among these organisations for patient safety and operational efficiencies.

Tools and technologies are becoming more and more usable and mature, spurring an increase in EMR adoption. In turn, EMR implementations are helping to facilitate healthcare initiatives like the CDC's 2D bar coding projects.

Bar coding the vaccine

One project is the CDC's vaccine identification pilot that is testing 2D bar coding on vaccines, specifically the GS1 DataMatrix bar code. Participants include two manufacturers and approximately 220 healthcare providers or immunisers. In the pilot, the Immunization Information Systems Support Branch in the CDC's National Center for Immunization and Respiratory Diseases is testing how bar codes on vaccine vials and syringes can be scanned into patients' electronic medical

¹ RTI International, "Prospective cost-benefit analysis of a two-dimensional barcode for vaccine production, clinical documentation, and public health reporting and tracking", *Vaccine*, Volume 31, Issue 31, 28 June 2013.

² Locklair, Dale L., "Transforming Healthcare Supply Chains Into Healthcare Value Chains." *Supply Chain Strategies and Solutions*. May/June 2012.

Better Immunisation Management for Patient Safety

records, and then used to populate downstream systems such as Immunization Information Systems.

In its part of the CDC, the Immunization Information Systems Support Branch team is interested in exploring how to make providers more efficient when it comes to immunisation management practices. Using technology and standards, the team believes it can help providers enhance patient safety with more accurate and complete vaccine data.

With the GS1 DataMatrix technology, significantly more data can be encoded into the bar code in a much smaller area than with a linear bar code. The NDC (National Drug Code) can be included using a GS1 GTIN, Expiration Date, and Lot Number all in one bar code that is appropriately sized for vaccine vials and syringes.

The decision to use GS1 Standards for vaccine identification in this pilot emerged from multiple meetings between the CDC, the American Academy of Pediatrics (AAP), and GS1 US®. The CDC team wanted to take a standards-based approach to have a broad impact across the diverse healthcare supply chain.

Vaccine Bar Codes

The concept of vaccine bar coding has evolved during the past decade. In 2004, the Food and Drug Administration (FDA) finalised its guidance to industry on bar coding, requiring the use of linear bar codes, like the GS1 Universal Product Code (U.P.C.) or GS1-128 bar code, on vaccines. While the vaccine's Lot Number and Expiration Date are not required by the FDA, the National Childhood Vaccine Injury Act of 1986 requires these attributes, thus necessitating that immunisers manually register them in patient records. However, in August 2011, the FDA released its final guidance to industry on vaccine bar code label requirements, which allowed manufacturers to use alternative symbologies like the 2D bar code. With this expanded direction, the CDC moved quickly to test the 2D bar code, announcing the vaccine identification pilot in the same month.

Bar coding the VIS

The CDC team received feedback from its partners stating that if it were to bar code vaccine vials and syringes, consideration should be given to the VIS. The team agreed that it made a lot of sense to put a bar code on the Vaccine Information Statement. Providers could then scan and record required VIS information in patients' medical records along with vaccine identification information.

"We decided to implement a set of standards that is widely used by industry – here in the US as well as around the world."

Warren Williams, Team Lead, Immunization Information Systems Support Branch, CDC

Produced by the CDC, the Vaccine Information Statement is an information sheet that explains to vaccine recipients, or to their parents or legal representatives, both the benefits and risks associated with a particular vaccine. The National Childhood Vaccine Injury Act requires that the appropriate VIS be provided to the patient each time a vaccine is administered. Certain VIS information must be recorded in the patient's medical record or on a permanent office log, the edition date being the key piece of data. By bar coding the VIS, the CDC team responded to the partner's request, giving them a great way to gain record-keeping efficiencies.

Part of the GS1 System of Standards, the GS1 Global Document Type Identifier uniquely identifies a document by type and may be encoded into a GS1-128 bar code, a GS1 Electronic Product Code™ (EPC)-enabled radio-frequency identification (RFID) tag, or a GS1 DataMatrix bar code. The GDTI can now offer healthcare providers an opportunity to electronically capture the VIS document type, like influenza or MMR, and the VIS edition date.

To implement the GDTI-encoded bar codes on Vaccine Information Statements, the team partnered with the CDC's branch responsible for VIS development. They tested scanning the bar code on different types of papers, in different colours, and with copies of the original VIS document. Many offices, for example, colour-code their VISs by vaccine type. The CDC team wanted to make sure providers could effectively scan the bar code in different situations . . . and it proved they could.

After just six months, the CDC announced the availability of the first Vaccine Information Statements with bar codes.

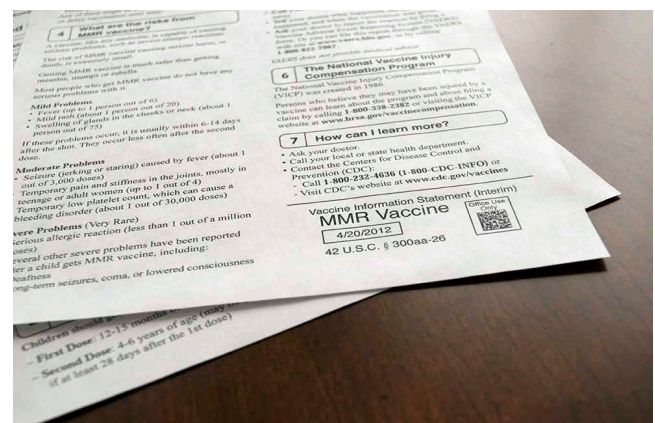


Figure 1: Part of the GS1 System of Standards, the Global Document Type Identifier is encoded in a GS1 DataMatrix bar code on the VIS. Healthcare providers can now scan the bar code to electronically capture the VIS document type, like MMR and VIS edition date.

Using a web-based service, the CDC creates a GDTI for each new and revised VIS. Any healthcare provider can take advantage of the benefits associated with the new bar coded VIS by purchasing a 2D bar code scanner and having its EMR system modified.

Advancing patient safety

Healthcare providers can benefit in multiple ways by using the new bar coded Vaccine Information Statements. Scanning the bar code reduces the time needed to record the VIS information. Providers may gain efficiencies in their immunisation management processes.

Yet, perhaps a more important benefit is reducing the risk of errors when transcribing vaccine information. If someone is manually updating a patient's medical record, there is always the chance for human error.

Near-perfect accuracy can be achieved when a provider scans a bar code to update a patient's medical record, a level of accuracy not attainable from manual methods. And in the future, with vaccine identification bar codes used by more and more manufacturers, healthcare providers can validate vaccines administered against vaccines listed in patients' EMRs, a major advancement in patient safety.

As America's public health agency, the CDC is focused on disease prevention and health preparedness. Yet, the team concludes it is also part of a global community that must be ready for "what is around the corner".

About the authors

Ken Gerlach, MPH, CTR, NCIRD/Immunization Services Division, Health Scientist - Centers for Disease Control and Prevention.

Mr. Gerlach has worked at Centers for Disease Control and Prevention (CDC) since 1998 in the areas of cancer registration and immunisation services. Prior to that time, he worked at Emory University as the Administrator of the Georgia Center for Cancer Statistics (GCCS), a unit of the Rollins School of Public Health. His research interests and expertise lie in the area of disease registration and public health informatics. Currently, Mr. Gerlach serves as the Contracting Officer Representative (COR) for the Implementation Pilot for Two-Dimensional Vaccine Bar Code Utilization project within the Immunization Information Systems Support Branch in the National Center for Immunization and Respiratory Diseases at the CDC.

Warren Williams, MPH, NCIRD/Immunization Services Division, Informatics Team Lead, Immunization Information - Systems Support Branch - Centers for Disease Control and Prevention.

Mr. Williams received his MPH degree from Emory University in 1991. Since 1991, he has been working at the Centers for Disease Control and Prevention. He has experience with maternal and child health programmes, cancer registries, and most recently immunisation registries. His research interests and expertise lie in the development and utilisation of informatics efforts to promote public health programme development. Mr. Williams is involved in programme planning, system evaluation, and technical assistance. Currently, Mr. Williams is the team leader of the informatics unit in the Immunization Information Systems Support Branch in the National Center for Immunization and Respiratory Diseases at the CDC.

"Near-perfect accuracy can be achieved when a provider scans a bar code to update a patient's medical record - a level of accuracy not attainable from manual methods."

Ken Gerlach,
Project Coordinator,
Immunization
Information Systems
Support Branch, CDC







The global language of business

Copyright©2013 GS1 AISBL - GS1 is a registered trademark of GS1 AISBL



GS1 AISBL
Blue Tower
Avenue Louise, 326, b10
B-1050 Brussels, Belgium
T +32 (0)2 788 78 00
F +32 (0)2 788 78 99
contactus@gs1.org

www.gs1.org