Future in Pharmaceuticals

The countdown to Serialisation and the benefits of implementing GS1 Standards

GS1 Ireland Healthcare – 26th February 2014
New McKinsey & Company report on benefits of a single global standard

New McKinsey report “Strength in unity: The promise of global standards in healthcare”

Highlights the cost savings and patient safety benefits of adopting a single global supply chain standard in healthcare

Available at: http://www.gs1ie.org/healthcare
New McKinsey & Company report on benefits of a single global standard

‘…we estimate an overall potential obsolescence reduction of $19-27 billion across the entire supply chain.’

Source: http://www.mckinsey.com
Agenda

- Why are Global Standards needed?
- Examples from Irish Healthcare
- The Falsified Medicines Directive
- Traceability - the how
- The Future

How GS1 Standards enable Patient Safety, Traceability, efficiency & collaboration
The healthcare supply chain needs global standards

- **Medication errors** result in additional treatments, disabilities and even loss of life
- **Counterfeiting** is an increasing global threat
- **Traceability** from manufacturer to patient is problematic
- **Product recalls** can be difficult to manage, in particular for healthcare providers
- **Manual interventions** in the healthcare supply chain decrease its efficiency and accuracy
In the news

“Fake pharmaceuticals:  Bad medicine”
--Economist, October 13, 2012

“U.S. has drug recall problem”
--ABC News, June 4, 2012

“17,000 die from medical errors”
--Deutsches Arzteblatt International, March 5, 2010

“Medical error is expensive for life”
--In2EastAfrica, January 22, 2012
Counterfeit Drugs Lab

Eg: Rat Poison, Talcum powder, Highway paint, Sugar…
The end product
Counterfeit Drugs and the threat to Patient Safety

Top Medicines affected by Counterfeit
1. Weight Loss
2. Erectile dysfunction
3. Anabolic Steroids
Examples from Irish Healthcare
### GS1 Standards help save €7 million worth of stock at St. James’s Hospital since 2005

#### Issue(s)
- Infected medication remained in the supply chain after recall in 2001-leading to subsequent infection and over 80 deaths
- Lack of standardised bar codes on haemophilia medication and ineffective traceability

#### Solution
- Deployment of **multi-location Electronic Patient Record system**
- Deployment of **medication delivery traceability system**
- Implementation of GS1 Standards, including GTIN, GLN, GS1 DataMatrix

#### Results
- Over €7 million worth of medication stock has been removed from the supply chain
- Savings due to stock rotation (between hospitals) in 2011 of over €600,000; Initial cost in 2005 €90k (ROI 1 year)
- Visibility of patient usage via scanning in the home (Smartphone App) lead to over €70,000 savings in first 3 months after implementation (2010)
- Mock recall identified location of all (100%) medication within 10 minutes
### GS1 Standards help enable traceability of surgical instruments at St James’s Hospital (as part of National HSE programme)

#### Issue(s)
- Ineffective traceability of surgical instruments from theatre through to hospital sterilisation process
- Time wasted on manual processes (searching for instruments, documentation etc.)

#### Solution
- Implementation of an integrated tracking and **traceability system**
- Identification of Instrument Trays using GS1 numbers
- Implementation of GS1 Standards, including GTIN, GLN and Global Traceability Standard

#### Results
**Effective traceability of surgical instruments during sterilization process**
- Reduced manual effort and increased efficiency due to automation
- Increased inventory management | better stock visibility
- Increased traceability from theatre through sterilisation
- Improved workflow through automation/scanning
- Process to share loan sets much more efficient and effective

**Cost:** Setup cost: €47k, Ongoing maintenance: €7.5k p.a.
**Return:** 17% increase in workload with less staff
‘…Track and Trace provides a level of visibility on the journey of a vial which we currently don’t have. The information it can provide in the event of a recall is invaluable…’
Conclusions

- Serialised vaccine doses provide accurate records of all stock movement and usage – leading to better stock tracking and tracing.

- Serialised bar coding linked to an IT system allows for automatic replenishment of stock based on vaccine depletion.

- Vaccine administration recording is more timely and accurate.
GS1 Standards help save €106 million in Dutch hospitals (2011)

### Issue(s)
- Increased pressure to improve patient safety and save costs in hospitals
- Suboptimal management of inventory of medical devices for OR
- Manual processes for ordering, billing, recall

### Solution
- Implementation of effective IT infrastructure to track and trace products throughout the supply chain
- Implementation of GS1 Standards, including GTIN, GLN and Global Traceability Standard

### Results
**Medical device inventory mgmt for OR - potential savings across 100 Dutch hospitals: €106 million (conservative estimate)**
- Estimated cost to implement system per hospital: €173k (non-recurring) and €218k (annually recurring)
- Estimated ROI per hospital in **year 1**: €668k; **year 3**: €2.5m
- Reducing inventory levels by approx. 20%
- Decreasing obsolete stock by approx. 80%
- Reducing handling expenses for stock replenishment by 25%
- Accelerating recall procedures
- Increasing effective use of consignment goods

- **UMC Nijmegen** - a 953-bed university hospital
- **UMC Utrecht** - a 1,042-bed university hospital
- **Ziekenhuisgroep Twente** - a 1,085-bed hospital group
- **St. Antonius hospital** - a 880-bed hospital group
The Falsified Medicines Directive
The Countdown to 2017 for Pharmaceuticals!!

What will you be doing in 2017?

» China plans to launch an unmanned sample-return mission to the moon

» In-car internet access will become the norm, with wireless computing systems built into almost every new car

» EU Falsified Medicines Directive estimated to take effect – are you ready?
EU Falsified Medicines Directive
Delegated Act on Safety Features

1. Characteristics and specifications of the unique identifier
2. Verification of the safety features by manufacturers, wholesalers and pharmacists
3. Establishment, management and accessibility of the repository system
4. Lists containing the medicinal products which shall/ shall not bear the safety features
5. Procedures for the notification of medicinal product at risk of falsification to the Commission
Typical Data Structure
Proposed Standardisation for EU Serialisation

1. GS1 Data Matrix: 2D bar code type: ECC200

2. Product Code: Turkey: GTIN 14 digits

3. Batch/Lot Number

4. Expiry

5. Unique Serial Number
Scanning & Application Identifiers (AIs) in action...

GTIN: 09012345670016
BATCH/LOT: 123456

ERP Entries

SERIAL: 123456
20 Nov 2014
NYFUL01 192837
EU Directive on Counterfeiting medicinal products - Timeline

July 2011
Publication in Official EU Journal

Jan 2012
Public Consultation on Concept Paper

Jan 2013
Transposition of Directive into national law

Q4 2013
Q1 2014 (tbc)
EC draft Delegated Act submitted to the EP and Council

Q4 2014 (tbc)
EU Commission Delegated Acts

Q4 2016
Implementation in Member States without pre-existing measures

June 2014 EU elections

Q4 2017
Compliance to directive expected to take effect
**Driver:** To address counterfeiting: many actors in the supply chain, legitimate/illegal blurred
- Numerous US States have enacted laws, e.g. Nevada, Florida
- California specifies an ePedigree Model
- Desire to identify and prosecute perpetrators
- Enforcement date continuously pushed out, currently starts 2015
- Now possibly federal regulation?

NEW GS1 Healthcare US guideline available
http://www.gs1us.org/industries/healthcare/tools-and-resources/implementation-resources/2015-readiness
**Pharma □ Different emerging models □ Turkey**

**Driver:** Reimbursement Fraud; pharmacists claiming more than once for dispensed product

- Government developed and controlled, Centralised Track & Trace system (iTS)
- Enforcement date 2010, live 2+ years *(only fully implemented system globally!)*
  - Phase 1: Manufacturers published data to MoH central database (2010)
  - Phase 2: Distributors (2012)
  - Future phases: ePrescriptions, Patient access

ROI in ONE YEAR!

- Reimbursement fraud eliminated
- Examples of counterfeits being detected entering legitimate supply chain
- Prosecutions

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![Diagram](image-url)
**Pharma ▶ Different emerging models ▶ EU (1)**

**Driver:** To address counterfeit/falsified medicines, prevent them reaching the patient

**EFPIA / GIRP / PGEU / EAEPC**  
**European Stakeholder Model (ESM)**
- A pan-European end-to-end system enabling medicines to be verified at point of dispensing
- Developed by the stakeholders who will use it on a day-to-day basis
- Run on a non-profit basis; Costs to be borne by Manufacturing Authorisation Holders
- Effective system expected in 2017
**Driver:** To address counterfeiting (falsified medicines), prevent them reaching the patient

Two emerging (competing?) models: EDQM & EFPIA:

European Directorate for the Quality of Medicines & HealthCare (EDQM) eTACT

» Part of the Council of Europe; EDQM members 37 European countries, bigger than EU

» Traceability from manufacture to the patient, ultimately given also patients access to authenticate product

» Developed by EDQM
Traceability
The How
Global standards enable compliance with regulations, effective and efficient implementation of traceability systems in Healthcare.

Such as:

Track & Trace, Authentication, UDI

= Visibility*

*Visibility = What, When, Where & Why
GS1 can help

Compliance

Prevent mislabelling

Traceability

Fight fraud

Recall readiness

Visibility

IDENTIFY
CAPTURE
SHARE
GS1 Standards

GS1 Standards are the global language of business

a language for identifying, capturing, and sharing information automatically and accurately, so that anyone who wants that information can understand it, no matter who or where they are.
GS1 Standards in Healthcare

Identify correctly, globally and consistently every time
GS1 Healthcare — a voluntary, global Healthcare User Group

To lead the healthcare sector to the successful development and implementation of global standards by bringing together experts in healthcare to enhance patient safety and supply chain efficiencies.
GS1 Healthcare User Group

Supply-side organisations engaging further
Leading healthcare organisations pave the way

Buyer/Provider-side organisations going global

France, Germany, Netherlands, Macedonia, Hong Kong, Switzerland, Austria, Saudi Arabia, Germany, USA, Austria, USA, Ireland, Netherlands, France, USA, USA
GS1 and Joint Initiative Council (JIC) in Healthcare

Joint Initiative Council

World Health Organization
World Customs Organization
International Society for Blood Transfusion
European Association of Hospital Pharmacists
European Association of Medical Device manufacturer
European Association of Pharmaceutical Manufacturer
Global GS1 Joins The Sustainability Consortium

Arizona, USA - August 23, 2013 – GS1, a neutral, not-for-profit, global organization that develops and maintains the most widely-used supply chain standards system in the world, has officially announced its’ membership with The Sustainability Consortium (TSC). Like TSC, GS1 is a member-based organization with 40 years of experience in over 110 countries driven by over a million user companies.

The GS1 system is an integrated system of global standards that provides for accurate identification and communication of information regarding products, assets, services and locations. It is the most implemented supply chain standards system in the world and is the foundation of a wide range of efficiency-building supply chain applications and solutions.
Good Distribution Practice for Pharmaceuticals supported by GS1 Standards

GDP Passport

- Quality
- Security
- Safety

IDENTIFY  CAPTURE  SHARE

Patient Safety, Traceability, Efficiency
The Future
Global automatic identification standards

GS1 Standards …
6 billion ‘beeps’ per day

Product identification in Healthcare should be as ubiquitous as it is in the retail and grocery industries
GS1 in Healthcare

Patient Safety

Healthcare Supply Chain Efficiency

- Automatic Data Capture: Barcodes, Data Matrix, RFID
- E-Commerce: EDI/XML Transactions
- Electronic Record Management: e-Records, e-Prescriptions
- Assets & Equipment Tracking
- Traceability: e-Pedigree, Recalls

Standardized Product Definition (GS1*)

Standardized Location Identification (GLN)

Standardized Product Identification (GTIN*)

Standardization → Interoperability
What's Next?

- **Read the documentation**
  - Falsified Medicines directive and
  - Medical Devices regulation
- **Familiarise** yourself with the Proposed solutions
- **Stay informed** by staying in touch with GS1 Ireland (Subscribe to Healthcare News)
- **Follow us** on LinkedIn and Twitter
- **Act Now** so you are ready for the 2017 Deadline!!

http://www.gs1ie.org/Healthcare/
http://www.gs1.org/healthcare/library

Global standards enable patient safety worldwide!
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