Introduction to GS1 and GS1 Healthcare

Safer, more efficient care starts with a simple scan

Ulrike Kreysa, Senior Vice-President Healthcare, GS1 Global Office, Brussels/Belgium
21st January 2019
My background

- Studied pharmacy
- Worked 9 years in public pharmacies
- Worked 11 years in large university hospital
- Worked 3 years at data exchange provider
- Since 14 years at GS1
- Responsible globally for healthcare
standard  [stan-derd]
noun
1. something considered by [...] general consent as a basis of comparison; an approved model.

www.dictionary.com
WHY?
Lack of standards in daily life is inefficient and annoying...
..in Healthcare it is dangerous and inefficient!

- Multiple bar codes on one package – which one to scan?
- Different types of bar codes – inconsistency; incompatibility
- No bar code – need to bar code; re-package; re-label
The Need for Global standards in Healthcare

Diverging country requirements
Manufacturing headache

“CUSTOMIZED ACTIONS MEAN COSTS!!
Harmonisation of regulatory requirements and data standards will enable efficiency of a global product offering – otherwise complexity and cost will continue to raise”

Senior Executive, MD company
GS1 – a global standards organisation

- over 1 million companies worldwide use GS1 standards
- 25 industries served across 150 countries
- Barcodes scanned more than 6 billion times per day globally
- 112 Member Organisations around the world
GS1 is both global and local

**GS1 Global Office**
Identification, creation, development and maintenance of standards and our foundational architecture, coordination with other international bodies, development of training programmes...

**GS1 Member Organisations**
Local offices in 112 countries around the globe. Implementation of standards, local regulatory adjustments, community management and relationship management with local governments and regulatory agencies...
Dear NGO Representative,

I am pleased to inform you that the Economic and Social Council (ECOSOC) at its Substantive Session of July 2011 adopted the recommendation of the Committee on Non-Governmental Organizations (NGOs) to grant Special consultative status to your organization “GS1”. On behalf of all staff of the Non-Governmental Organizations Branch, please accept our heartfelt congratulations.
Voluntary, Global Healthcare User Group

GS1 Healthcare is a neutral and open community bringing together all related healthcare stakeholders to lead the successful development and implementation of global GS1 standards enhancing patient safety, operation and supply chain efficiencies.
Our vision

GS1 Healthcare envisions a future in which the healthcare sector achieves harmonised implementation of global standards in business and clinical processes enabling interoperability, optimal quality and efficiency of healthcare delivery to benefit patients.
GS1 Healthcare: an expanding, committed community of globally engaged stakeholders...

...and there are many more companies working with GS1 at a local level
Leading hospitals implement GS1
Working with global organisations...
User-driven:
GS1 Healthcare LT 2018/2019

**Tri-Chairs:**
- Scott Mooney, McKesson
- Feargal Mc Groarty, St. James’s Hospital
- Mark Hoyle, Teleflex

**LT Members:**
- Charity Hovey, 3M
- Cyndi Poetker, Abbott
- Jeff Denton, Amerisourcebergen
- Volker Zeinar, B. Braun
- Stefan Artlich, Bayer
- Dennis Black, BD
- Patrick Main, Cook Medical
- Kevin Downs, University Hospitals of Derby and Burton NHS Foundation Trust
- Mike Meakin, DHL
- Sébastien Langlois-Berthelot, F. Hoffmann-La Roche
- Karen Conway, GHX
- Grant Courtney, GSK
- Jean-Michel Descoutures, IHF
- Gerry Collins, Johnson & Johnson
- Jackie Elkin, Medtronic
- Pascal Aulagnet, Pfizer
- Grant Hodgkins, Smith & Nephew
- Dr. Hajo Reissmann, University Medical Center Schleswig-Holstein
- Catherine Koetz, GS1 Australia
- Marcelo Oliviera, GS1 Brazil
- Arthur Smith, GS1 Canada
- Valérie Marchand, GS1 France
- Hans Lunenborg, GS1 Netherlands
- Rami Habbal, GS1 UAE
- Glen Hodgson, GS1 UK
- Siobhan O’Bara, GS1 US
One of these medicines is fake.

Can you tell which?
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
The Healthcare Supply Chain

- Manufacturer
- Distributors/Wholesalers
- Counterfieter
- Transporter providers
- Internet
- Consumer
- Retail
- Healthcare provider
- Patient

The Global Language of Business

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Medication Errors – happening today

**US**
- 44,000-98,000 die in the US alone as the result of medication errors (IoM, 2006)
- More than Motor vehicle accidents (43,458), breast cancer (42,297) or AIDS (16,516)
- Estimates of cost for US figures- $17-$29 Billion annually $2,000- $5,000 per event (HDMA, 2004)

**UK**
- Approximately 10% of inpatient episodes result in a medication error (DH 2007)
- Of the 8 million hospital admissions in England, about 850,000 result in a patient safety incident, Costing the National Health Service £2 billion

**New Zealand**
- In hospital adverse events (50% of these are preventable) 5,000 patients experience an error - 150 die, 400 are permanently disabled

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

**East Africa**
- “Medical error is expensive for life” (In2EastAfrica, January 22, 2012)

Globally this is the equivalent of a Jumbo Jet falling out of the sky every day with 100% fatalities
Ensuring the ‘5 Patient Rights’

The right patient

The right dose

The right route

The right time

The right product
Benefits for Patient Safety

- Improved recall procedure and adverse event reporting
- Documentation of product/patient relationship – in electronic health records (EHR) and registries
- Visibility of inventory – availability of devices
- Reduction of medical errors
- Supply chain security/anti-counterfeiting
Why regulation? A main driver - counterfeiting

According to Interpol more than one million people die each year from counterfeit drugs!

An estimated 1 in 10 medical products in low- and middle-income countries is substandard or falsified. They affect every region of the world.

WHO Fact Sheet on Substandard and Falsified Medical products, 31 January 2018
The Need for Global Standards in Healthcare

Lack of transparency in the Healthcare supply chain, making it **vulnerable to infiltration** by counterfeiters.

Which is counterfeit?
Healthcare Scenario – Pharmaceutical Counterfeits

Could you tell the difference?

• One of these tablets is counterfeit and the other one is genuine
• Counterfeit tablets may have:
  • no active pharmaceutical ingredient (API) or
  • a dangerous coating, e.g. lead-containing paint or floor wax
  • OR worse...

The Global Language of Business
Healthcare Scenario – Crisis and Impact: counterfeit cancer treatment in the legitimate US distribution
Is Europe safe?

In 2018: Parallel import companies have discovered four falsified batches of cancer medication, Velcade, in the Dutch and Danish supply chain.
Healthcare Scenario – Pharmaceutical Counterfeits

A counterfeit medicines “factory”

- The Pharmaceutical industry deals with the most frequently counterfeited products worldwide.
- This is a manufacturing process: the tableting machine and drying process belong to a criminal gang of counterfeiters.
- Where’s the traceability, GMP*, safety, lot management?

* Good manufacturing practices
But also substandard drugs are a danger for patient safety

Tuberculosis

- 8 million people get sick every year, in 2011 1.4 million died from it
- Recently research team collected samples of two commonly used medicines, isoniazid and rifampicin, from neighborhood pharmacies and markets in 17 countries where tuberculosis is pervasive
- Nearly **one of every 10 pills** failed to meet basic quality standards. In African countries, **one in six pills** was substandard.
- Consequences: People die - resistance is developing, which could be a global threat

Another example of substandard medicines

- Substandard diphtheria, pertussis, and tetanus (DPT) vaccines in China caused major concern in the public in 2018
- Requests for a better controlled system
- Draft regulation for traceability
- Recently expired vaccines were used
The economic impact

European study on the economic impact of counterfeit medicines in the European Union marketplace and its wider costs to industry, government and society shows.

- **Main findings:**
  - 4.4% of sales lost annually by the sector due to counterfeiting
  - EUR 10.2 billion of revenue lost annually by the sector
  - Additional EUR 7.1 billion of revenue lost annually in related sectors
  - 37,700 direct jobs lost annually
  - 90,900 direct and indirect jobs lost annually
  - EUR 1.7 billion of government revenue lost annually (taxes and social contributions).

Source: EU IPO (Intellectual Property Office), September 2016
Combating counterfeiting

The introduction of a unique identification for drugs or medical devices, where appropriate, will enable authentication and traceability systems.

This will make it much more difficult for counterfeiters to intrude into the Healthcare supply chain.

GS1 standards play a major role!
Multiple standards put benefits at risk

- Higher costs
- Higher risks
- Slower adoption
The need for global standards

**Healthcare is local**
- Healthcare providers are local
- Regulations are local

**Healthcare is global**
- Healthcare supply chains often cross borders

*Country-by-country solutions are not sufficient nor effective*
*A global harmonised approach and implementation is needed*
New McKinsey & Company report quantifies supply chain issues in Healthcare

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.gs1.org/healthcare/mckinsey

Source:
http://www.mckinsey.com
McKinsey did extensive research to quantify the business case for global standards and to define a roadmap for adoption.

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<th>Objective</th>
<th>Description of our research</th>
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<td>• Step change for global standards awareness amongst key healthcare</td>
<td>• Reviewed existing case studies and relevant literature</td>
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<td>stakeholders in all the countries by publishing a research report</td>
<td>• Interviewed ~80 top healthcare executives along the value</td>
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<td>explaining and quantifying the benefits of global standards and services</td>
<td>chain in 15 countries</td>
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<td>for the healthcare industry</td>
<td>• Used McKinsey proprietary databases and benchmarks, and</td>
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<td>various experts</td>
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<td>• Developed business cases including cost and benefit of global</td>
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<td>standards</td>
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<td>• Defined a high-level industry adoption roadmap</td>
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Huge cost savings and patient safety benefits when adopting a single global standard in healthcare

“Implementing **global standards** across the entire healthcare supply chain could save **22,000-43,000 lives** and avert 0.7 million to 1.4 million patient disabilities”

“Rolling out such standards-based systems globally could **prevent tens of millions of dollars’ worth of counterfeit drugs** from entering the legitimate supply chain”

[We] “estimate that **healthcare cost could be reduced by $40 billion-$100 billion globally**” from the implementation of global standards

“Adopting **a single set of global standards** will cost significantly less than two” (between 10-25% less cost to stakeholders)

Developments across the world

Regulatory bodies need to address Public Health

Hospitals and global organisations look for improvement in patient care and cost reduction

This is a global development...

Be prepared, informed, ready for regulatory requirements and your customers
My very personal reasons to care about patient safety...

...and the highest quality of care.