Supply Chain Traceability

GS1 Healthcare and standards – more important than ever

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NEVER...

...has a GLOBAL, secure and efficient supply chain been more important than today!
In these difficult times we learned that...

We are ALL dependent on an efficient supply chain across countries and continents.

We need to be able to interact clearly and unambiguously with each other – using a global language.

We need to make sure that the resources and supplies needed are effectively made available to support our health systems in the best possible way.

We need to prevent substandard and falsified products entering our supply chains and markets, putting patients and caregivers at risk.

GLOBAL STANDARDS ARE NEEDED
stand·ard  [stan-derd]
noun
1. something considered by [...] general consent as a basis of comparison; an approved model.

www.dictionary.com
GS1 is a **neutral not-for-profit organisation** driven by its users, that facilitates collaboration amongst trading partners, to create more **efficient, safer and sustainable** supply chains through **global standards**.
GS1 – a global standards organisation

- 2 million companies worldwide use GS1 standards
- 150 countries served
- 6 billion barcodes scanned more than 6 billion times per day globally
- 114 Member Organisations around the world
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.
**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**.
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.

Our vision:

- **Patient Safety**
- **supply chain security & efficiency**
- **traceability**
- **product data**
GS1 is a Standards Development Organisation working with others

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<td>European Committee for Standardization</td>
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**Joint Initiative Council**

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<td>European Association of Medical device and diagnostics industry</td>
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User-driven: 
GS1 Healthcare Leadership Team 2019/2020

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- Feargal Mc Groarty, St. James’s Hospital
- Mark Hoyle, Teleflex

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“EFPIA, IFPMA and PhRMA support the use of harmonized and internationally recognized standards for the identification of products.”

“EFPIA, IFPMA and PhRMA believe that serialization initiatives should conform to the internationally recognized standards, for example a GS1 2D barcode. Using GS1 standards allows manufacturers to deploy a single set of standards across their operations and with supply chain partners, to identify and serialize products.”
The healthcare supply chain needs global standards – why?

• A well functioning supply chain is important – manual interventions in the healthcare supply chain decrease its efficiency and accuracy
• Counterfeiting is an increasing global threat
• Traceability from manufacturer to patient is needed!
• Medication errors result in additional treatments, disabilities and even loss of life
• Product recalls can be difficult to manage, in particular for healthcare providers
• We need to have reliable data – DATA will be the gold of the future!
The Healthcare Supply Chain – very complex
Traceability in Healthcare

A key driver in the Healthcare sector for

- Patient Safety
- Preventing counterfeiting
- Enabling correct patient records
- Enabling effective product recalls
- Traceability down to the patient
- Enabling regulatory compliance
- Enhancing business processes (e.g. inventory management, optimized supply chain efficiency, eProcurement)
Traceability/Visibility

• Where is the product now?
• Where has it been? Who owned it?
• When has it been shipped/delivered/received?
Ensuring the ‘5 Patient Rights’

The *right* patient

The *right* product

Today more important than ever – we need to have the *right* material for patient and staff when needed!

The *right* route

The *right* dose

The *right* time
We are at risk...

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
COVID-19 and criminals

• During the COVID-19 crisis we have seen more substandard and counterfeits than before!
• Many organisations are looking into the global challenge of movement of illicit medicines and medical supplies across borders.
• OECD, WHO, regulatory bodies like EU Commission, Interpol and many others try to ensure that only safe and reliable products reach the patients and caregivers.
• Profit is made by counterfeiters from face masks, gloves, hand sanitizers to over the counter medicines like paracetamol and specialized drugs like antibiotics and painkillers during this pandemic!
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
- Regulation for traceability
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!**
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 NOW
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
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)

Recognising the possibility to improve the supply chain with global standards:

**WHO**’s 2015 Generic Preferred Product Profile for Vaccines (PSPQ2) recommends barcodes with GS1 standards (Global Trade Item Number - GTIN, lot number and expiry date) on all packaging levels with the exception of primary packaging and logistic level.

UNICEF and GAVI announcement

• After WHO recommendation for GS1 standards since 2015 now announcement of UNICEF and GAVI that they will require GS1 standards for secondary packaging level

• https://www.unicef.org/supply/index_103734.html

• Starting 1st October 2019, for vaccine tenders backed by Gavi financing issued by UNICEF, it will be a requirement to have GS1 barcoding on the secondary packaging by latest 31 December 2021.
All patients must have access to safe vaccines

• Session at **World Economic Forum in Davos 2020**:  
  “The Role of Open Collaboration in the Fight Against Disease Outbreaks”  
• **Everybody must work together to ensure a safe, secure and efficient supply chain**

With Kathy Wengel, Executive Vice President, Chief Global Supply Chain Officer, J&J  
Seth Berkeley, CEO GAVI and Greg Reh, Deloitte
The Healthcare supply chain is global

After the COVID-19 pandemic healthcare stakeholders will concentrate on optimizing processes for a better and safer future

Manufacturers who want to export into the world will need to implement GLOBAL standards

Let’s work together to improve patient safety – with a simple scan!
Developments across the world

➢ Regulatory bodies need to address Public Health and ensure that all patients can be treated

➢ We are moving into a more digital world

➢ Hospitals and global organisations look for improvement in inventory management, patient care and cost reduction

This is a global development...

Be prepared, informed, ready for it! Regulatory requirements and your customers will request it from you!
Pharma – World* – an ever growing number of coding & serialisation requirements

*Including Europe

© GS1 2019
My very personal reasons to care about patient safety...

...and the highest quality of care.

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Thank you!

Safer, more efficient care starts with a simple scan!
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