



The Global Language of Business

Global summit on drug product labelling and packaging safety

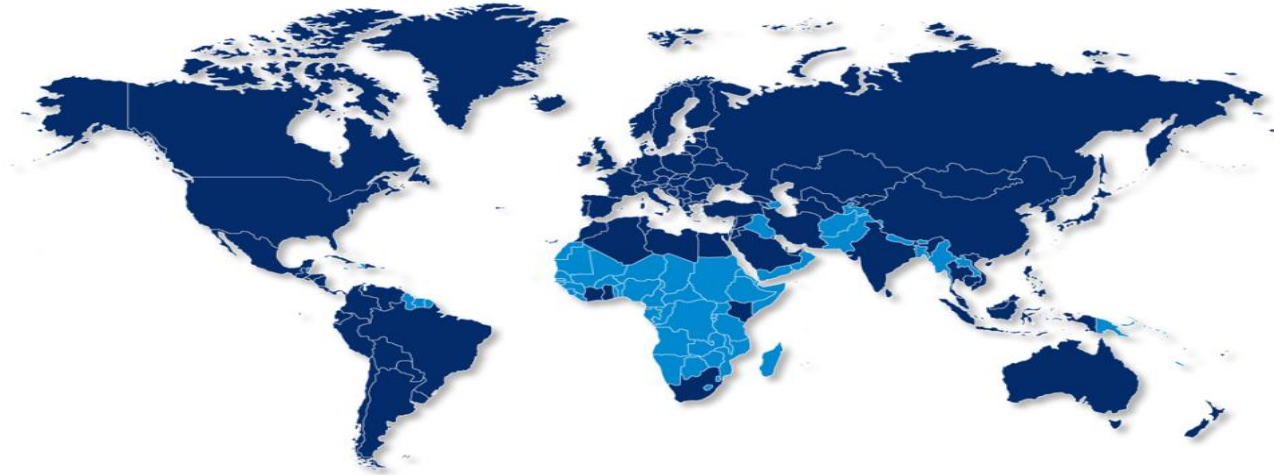
FDA/IMSN international regulator summit 19 – 20 June 2018

Géraldine Lissalde-Bonnet

Public Policy Director GS1 Healthcare, GS1 Global Office, Brussels



GS1 – a global non-for profit standard organisation



1 million

over 1 million
companies worldwide
use GS1 standards

**150
countries**

25 industries served
across 150 countries

6 billion

Barcodes scanned
more than 6 billion
times per day globally

112 MOs

112 Member
Organisations
around the world

GS1 Healthcare - an expanding, committed community of globally engaged stakeholders...much more locally



...and there are many more companies working with GS1 at a local level

Leading hospitals - implementing GS1



Getting it right ! “NEVER EVENTS”



Is the NHS safe?

- Of the top 20 risk factors for all deaths, adverse in-hospital healthcare events come eleventh – above alcohol, drugs, violence and road traffic accidents.
- In the NHS each year there are: 624 million prescriptions, 300 million GP visits, 13 million OPD visits, 5.3 million admissions, 2.9 million emergency ambulance calls, and an estimated 900,000 adverse events.
- Every week – two wrong site surgeries and two operations with kit wrongly left inside. NEVER EVENTS 2016/17= 400
- wrong site/retained foreign body/wrong implant = 79%; Medication error causing harm = 12%
- Adverse events (unintended injury caused by medical management rather than disease) lead to an additional three million NHS bed days. Costing at least £1 billion a year.



Imagine
a world where...

...the patient rights were reality,
all the time!



...dispensing and administration errors are a thing of the past



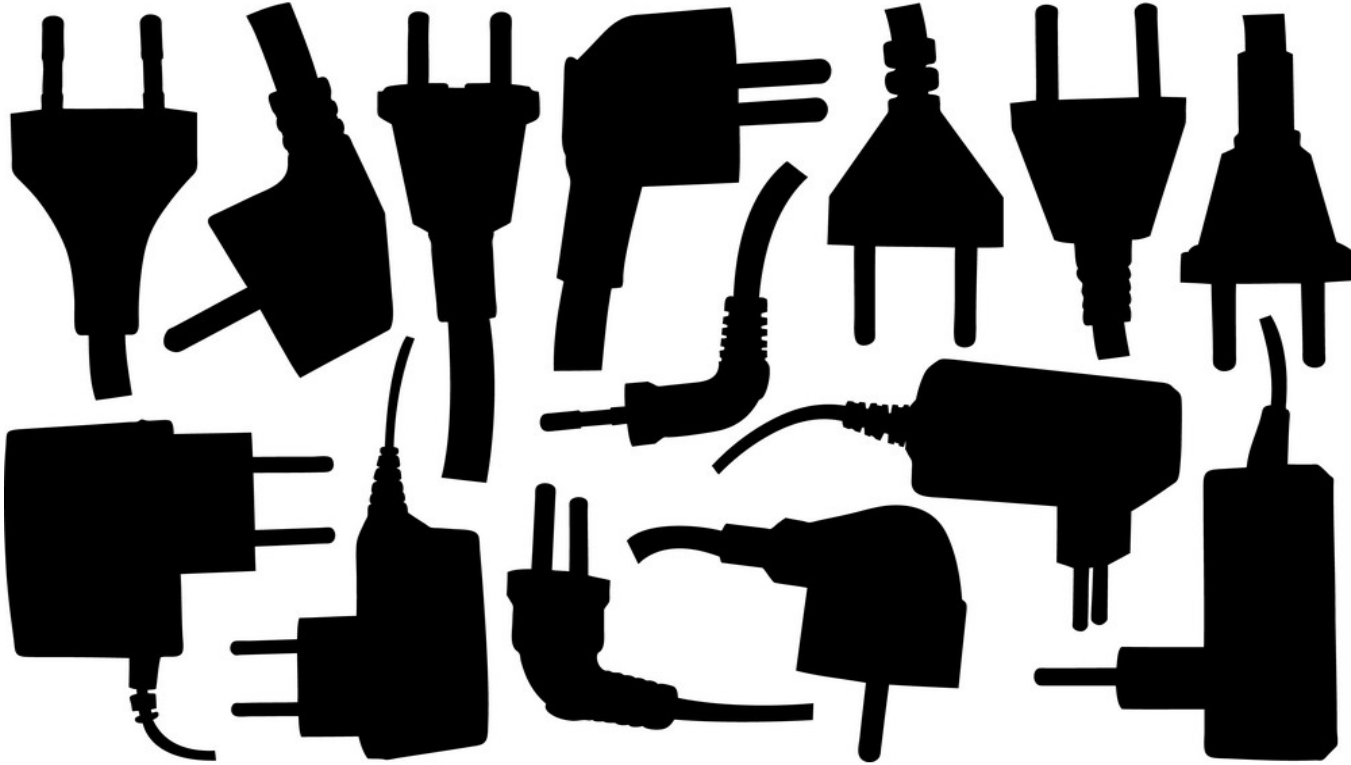
I still remember when dispensing errors due to typos, illegible handwriting or oversights was a risk we all had to live with.

It's good those days are over!

A future where¹:

- Computerised physician order entry (CPOE) has replaced hand-written prescriptions
- Barcode scanning procedures cut current potential adverse drug events by up to 75%
- There is a general >50% reduction of current medication errors saving lives, cost and time for better patient care

A need for global standards ...



- Inefficiencies
- Increased risk
- Lost opportunities
- Interoperability
- Costs
- Complexity

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"

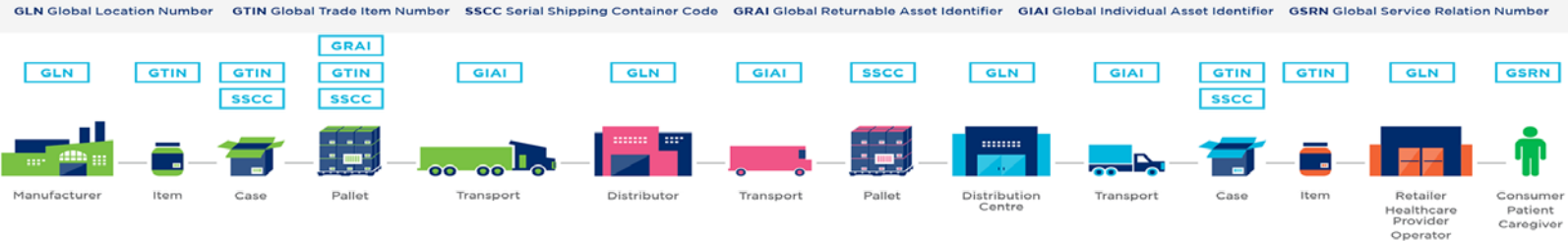
[We] "estimate that **healthcare cost could be reduced by \$40 billion-\$100 billion globally**" from the implementation of global standards

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

GS1: global system of standards to ensure visibility



Identify: GS1 Standards for Identification



Capture: GS1 Standards for Barcodes & EPC/RFID

GS1 Barcodes

EAN/UPC



GS1-128



ITF-14



GS1 DataBar



GS1 DataMatrix



GS1 QR Code



GS1 Composite Barcode



GS1 EPC/RFID

EPC HF Gen 2



EPC UHF Gen 2



Share: GS1 Standards for Data Exchange

Master Data Global Data Synchronisation Network (GDSN)

Transactional Data eCom (EDI)

Event Data EPC Information Services (EPCIS)

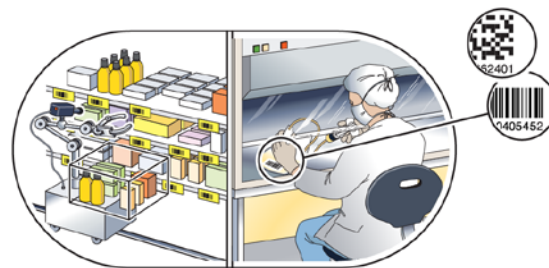




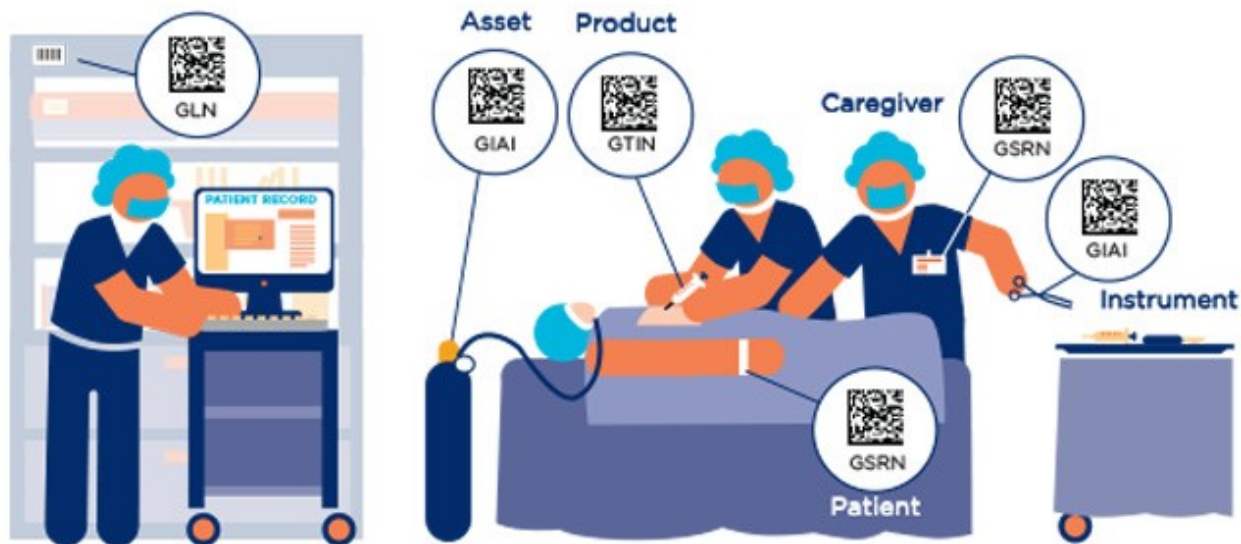
What can GS1 bring to hospitals and patients?



- Having complete and accurate information in the hospitals makes it possible to ensure the rights of the patients and improve the quality of care.
- Capturing this information automatically and accurately enables the hospitals to operate efficiently and cost-effectively.
- GS1 barcodes enable to improve the safety of patients by reducing errors associated with manual data entry.
- It also enable the healthcare supply chain actors to comply with regulatory requirements.



GS1 standards around patient treatment



GTIN – Global Trade Item Number

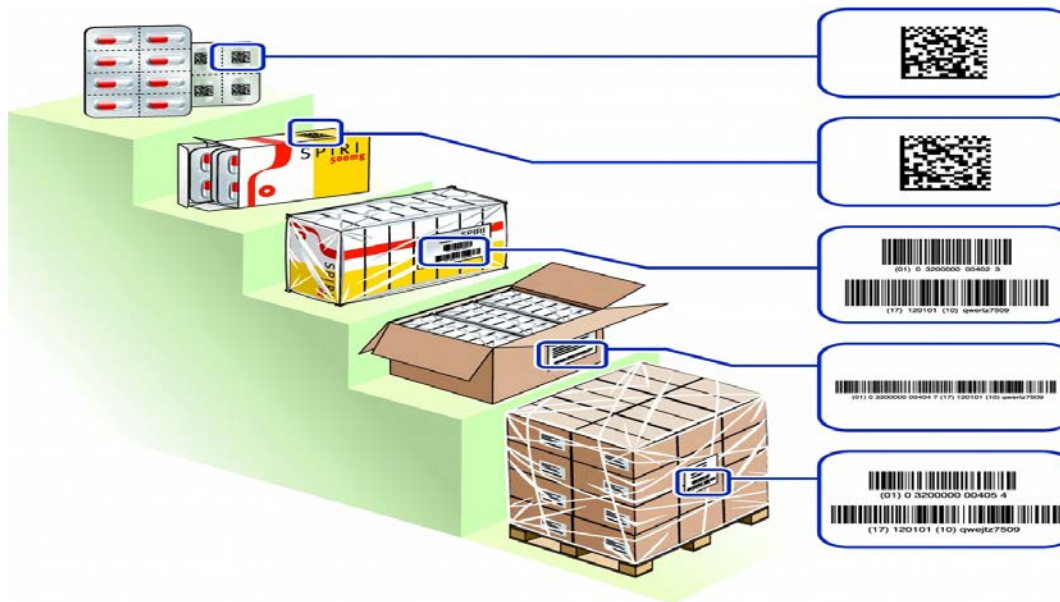


...used on **any item** upon which there is a **need to retrieve pre-defined information** and that may be **priced**, or **ordered**, or **invoiced** at any point in any supply chain.

The base for the unique identifier and implementation

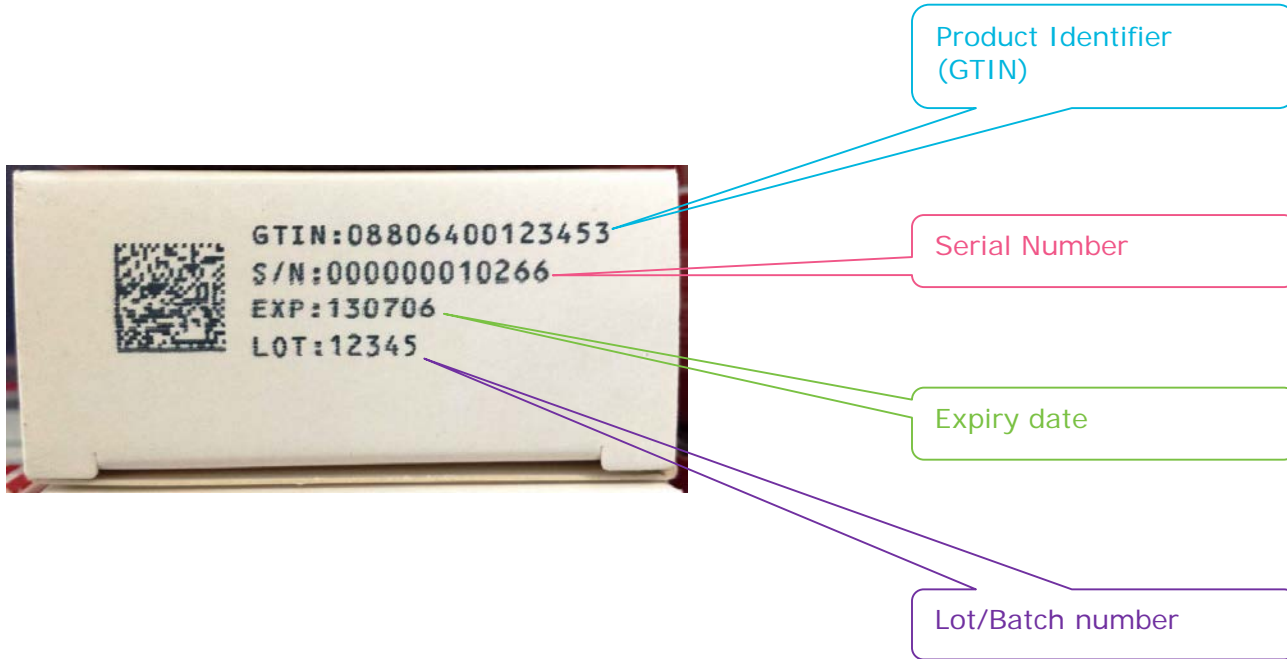
GTIN is an umbrella term for all GS1 “trade item” identification numbers. As noted a Global Trade Item Number may use the GTIN-8, GTIN-12, GTIN-13, or GTIN-14 numbering structure.

Different packaging levels require different GTIN's and potentially different data carriers



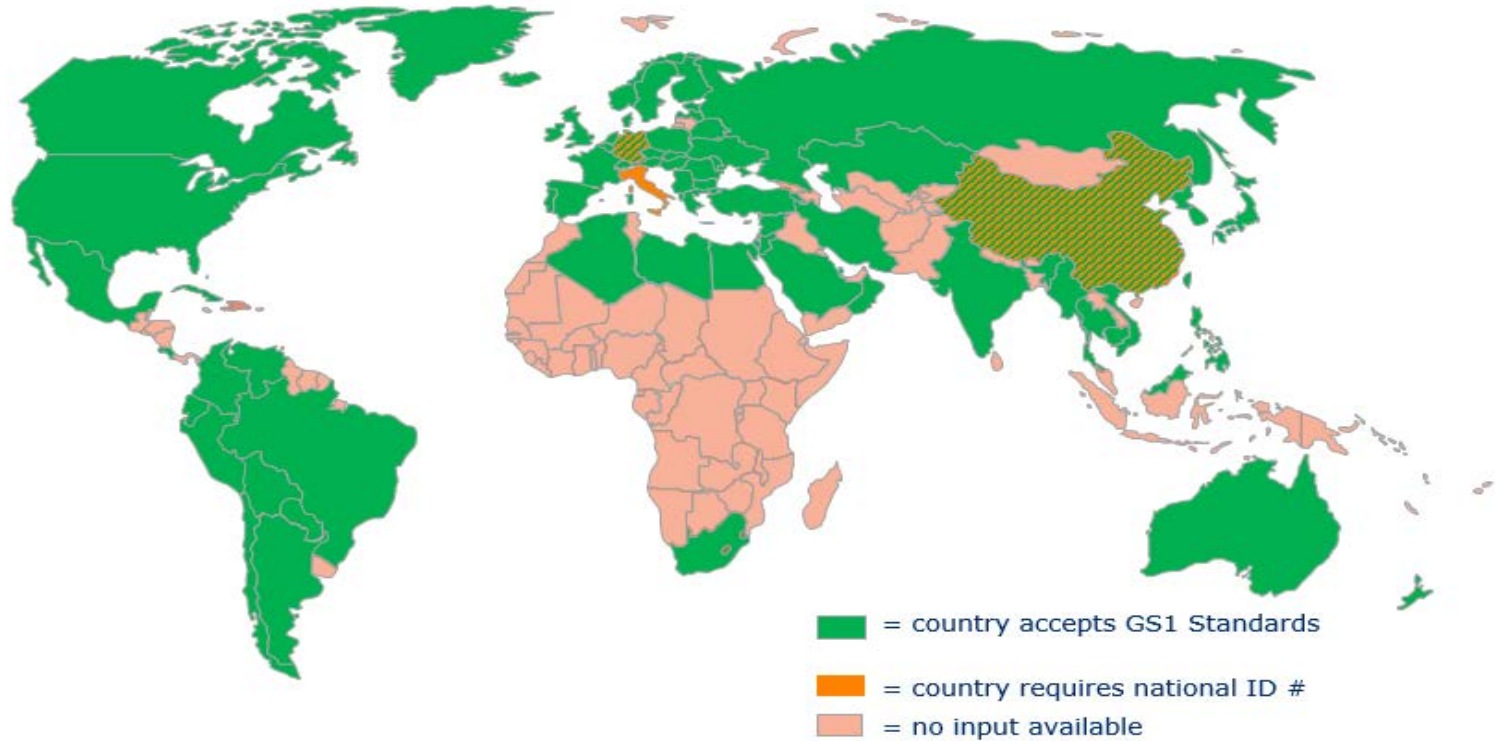
NOTE: Data carriers shown are for illustration purposes only!

Globally unique identification: 4 identification attributes in a GS1 DataMatrix





Identification of pharmaceuticals



Transforming Healthcare to improve patient safety and increase trust



Real-life examples



50.8%

reduction
potential
adverse drug
events

New England Journal of Medicine

Barcode scanning procedures cut current potential adverse drug events by 50.8%¹.

Use of barcodes on medicines to the single-unit level can help reduce medication error rates by 41.4%¹.

¹ E.G. Poon et al. "Effect of Bar-Code Technology on the Safety of Medication Administration," 362 (2010); 18

41.4%

reduction
in medication
error rates

74%

Reduced
medication
errors

Gelre Hospitals (The Netherlands)

Electronic prescription and barcode point-of-care system reduced medication errors by 74%

² GS1 Healthcare conference, 2010

Real-life examples



40%
reduction
in time

Hang Zhou Bin Jiang Hospital (China)¹

Implementation of a harmonised use of GS1 standards in all medicines and of an Automatic Identification and Data Capture barcode technology application. **Currently 60% of all medicines in the hospital are GS1 compliant.**

- **Accurate tracing of drugs from the warehouse to the point-of-dispense**
- **40% reduction in time spent by staff for verification, reception and storage of medicines**

¹ GS1 Reference Book 2015-2016

GS1 Standards help save 7% in medication purchasing and packaging in North York General, Canada (2006)



North York General Hospital - a 434-bed hospital in Toronto, Canada



Issue(s)

- Risk of medication errors at the point-of-care due to insufficient product identification
- Lack of unit-dose bar coding of medication

Solution

- Installation of an automated repackager and bar coding station
- Implementation of a point-of-care bar code verification system to ensure the five patient rights
- Implementation of GS1 Standards, incl, GTIN and GS1 BarCodes

Results

- Reduced medication errors at the point-of-care
Cost savings of 7-8% each year in terms of its medication purchasing and packaging activities
- Estimated cost to implement system in the hospital: €248k
 - Efficiently affixing bar codes to unit doses
 - Efficient bedside verification

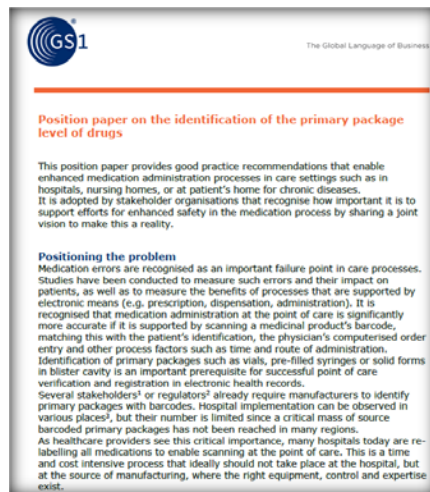


We have to
keep moving forward
to ensure GS1 standards
benefit all patients
worldwide

Identification on primary packaging level - enabling bedside scanning



GS1 position paper...



...on identification on primary packaging...



...in collaboration with:

Endorsed by:



Ultimately, it's all about...



PATIENT SAFETY!



Contact Details

Géraldine Lissalde-Bonnet
Public Policy Director
GS1 Global Office
E g.lissalde@gs1.org
W www.gs1.org/healthcare

Gregory Bylo
Vice President Healthcare
GS1 US
E gbylo@gs1us.org
W www.gs1us.org