The Global Language of Business

By number - the global standards behind barcodes and serialization

GS1 - Safer, more efficient care starts with a simple scan

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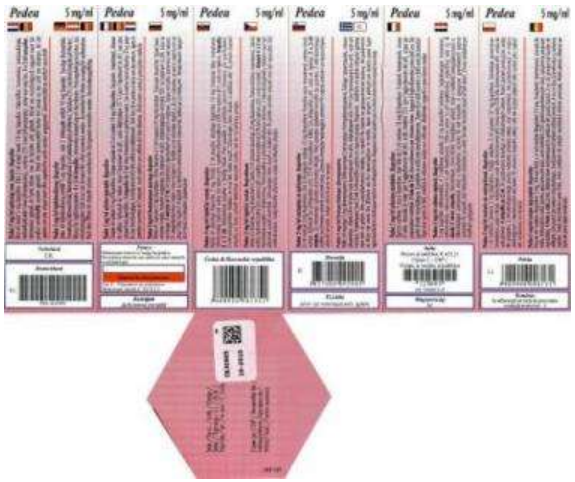
9 May 2019

Why do we need global standards?

Lack of standards in Healthcare is dangerous, ineffecient and creates additional costs!



- 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

GS1 – a global standards organisation

More than one million

over 1,5 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

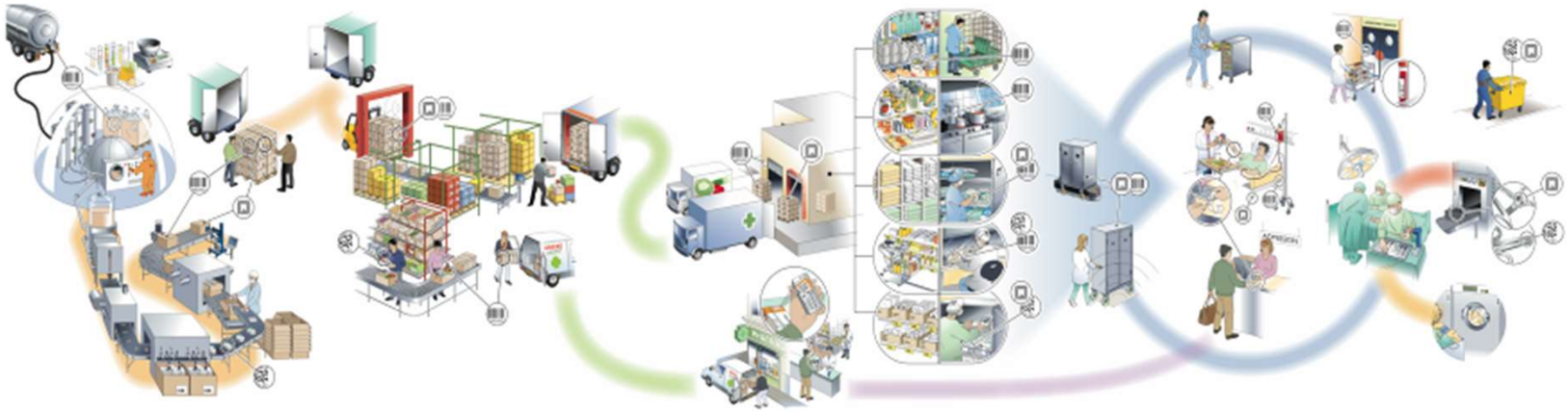
112 MOs

112 Member Organisations around the world

Poll: Are you using GS1 standards today?

- Yes
- We are planning to do so in the near future
- No

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**

patient safety

supply chain security & efficiency

traceability

product data

Working with global organisations…

International Organisation for Standardisation

European Committee for Standardization

Health Level 7 International

International Health Terminology SDO

Clinical Data Interchange Standards Consortium

Integrating the Healthcare Enterprise

Digital Imaging and Communications in Medicine

Personal Connected Health Alliance

Joint Initiative Council

World Health Organization

World Customs Organization

International Hospital Federation

International Council for Commonality in Blood Banking Automation

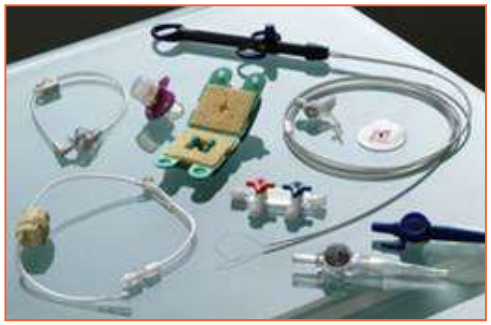
International Society for Quality in Healthcare

European Association of Hospital Pharmacists

European Federation of Pharmaceutical Industries and Associations

European Medical Devices Industry Association

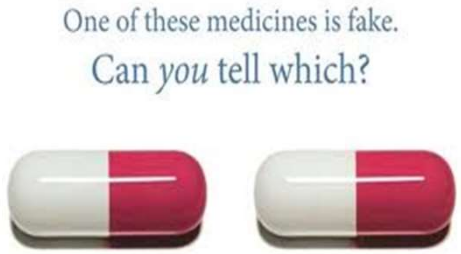
The healthcare supply chain needs global standards



- 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

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

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 !

GS1: global system of standards

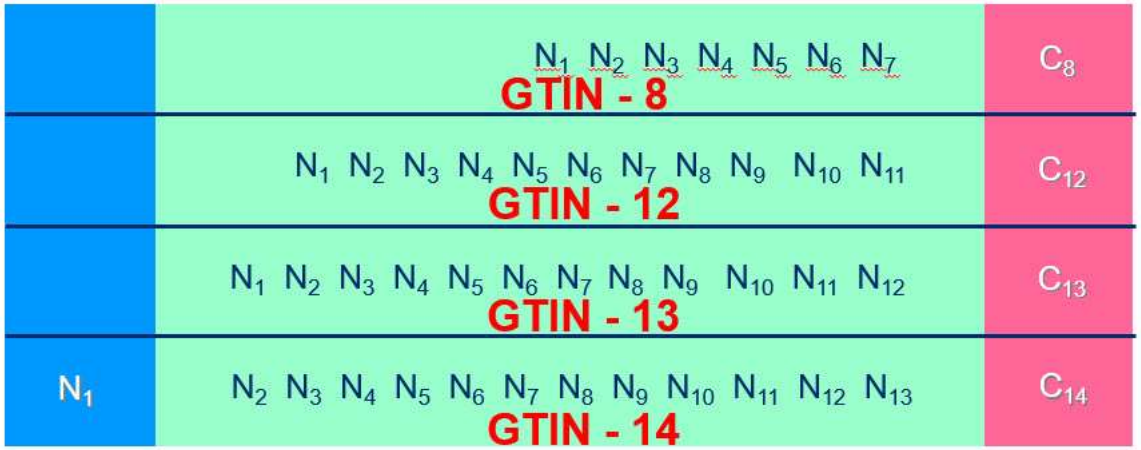
Traceability

GTIN – Global Trade Item Number…

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

The base for unique item identification... GTIN is an umbrella term for all GS1 "trade item" identification numbers. A Global Trade Item Number may use the GTIN-8, GTIN-12, GTIN-13, or GTIN-14 numbering structure.

GTIN Terminology & structure…



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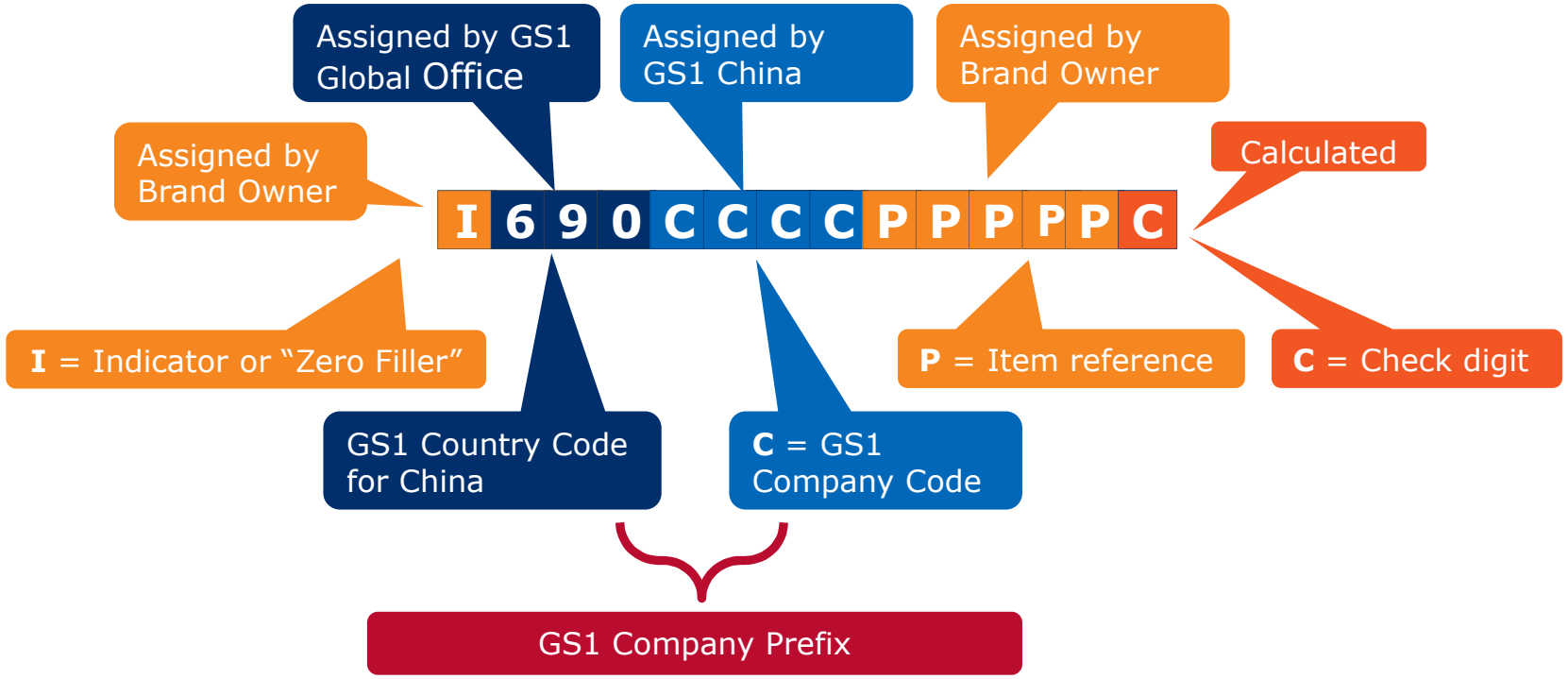
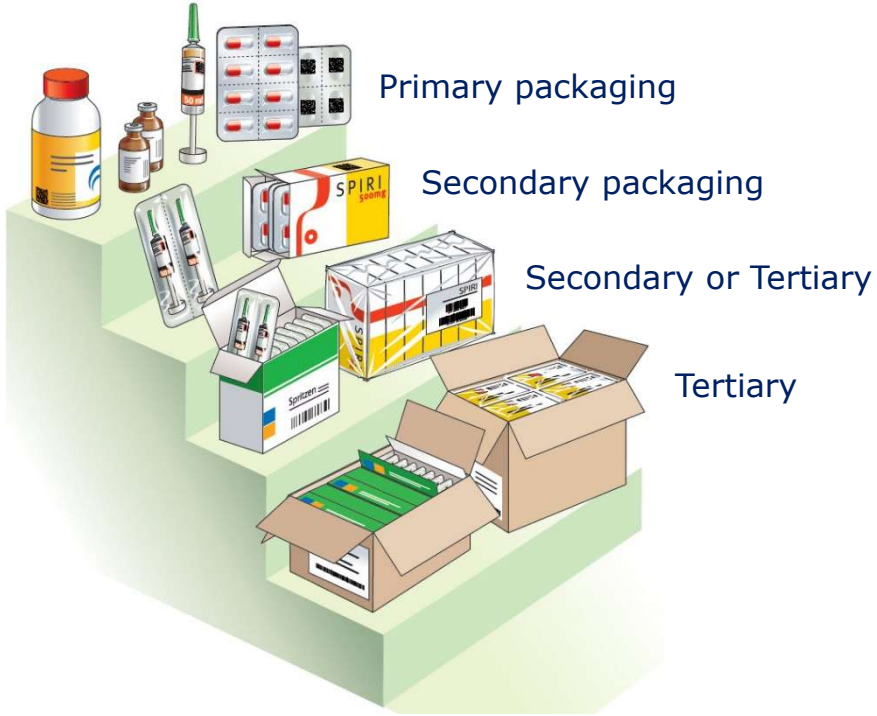
GTIN Terminology & structure…



Different pack levels… definitions…

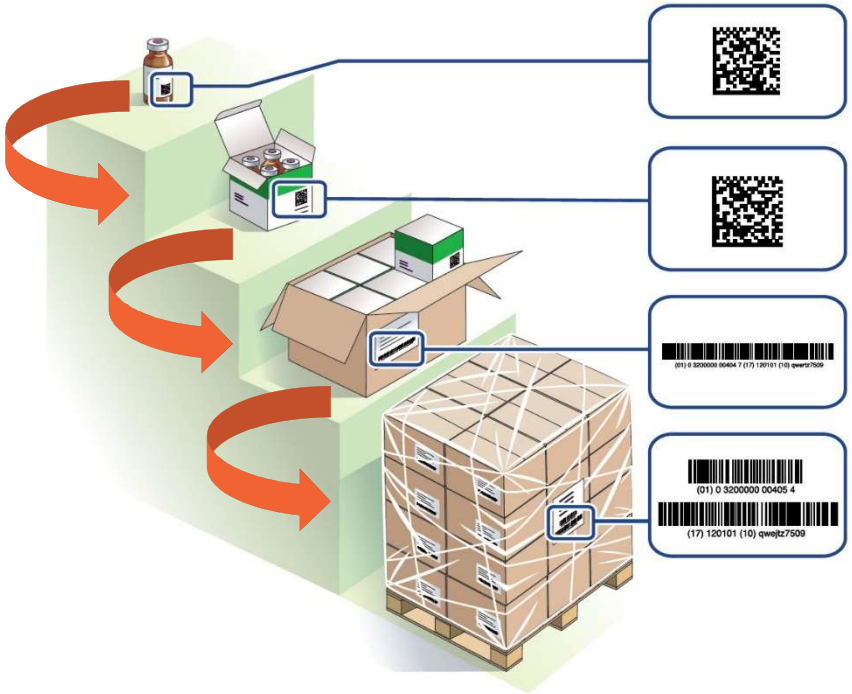


Healthcare primary packaging - The first level of packaging for the product marked with an AIDC data carrier either on the packaging or on a label affixed to the packaging. For non-sterile packaging, the first level of packaging can be the packaging in direct contact with the product. For sterile packaging, the first level of packaging can be any combination of the sterile packaging system, May consist of a single item or group of items for a single therapy such as a kit. For packaging configurations that include a retail consumer trade item, primary packaging is a packaging level below the retail consumer trade item.

Healthcare secondary packaging - A level of packaging marked with an AIDC carrier that may contain one or more primary packages or a group of primary packages containing a single item.

Notes:
[1] The above are GS1 General Specifications definitions.
[2] "Primary packaging" is usually also the "unit of use".
[3] As shown here "Tertiary" refers to **"Trade Items" only** and not "Logistic Units". (See the GS1 General Specifications for more detail.)

Ideally - ID and data carriers at all levels...



Primary Package

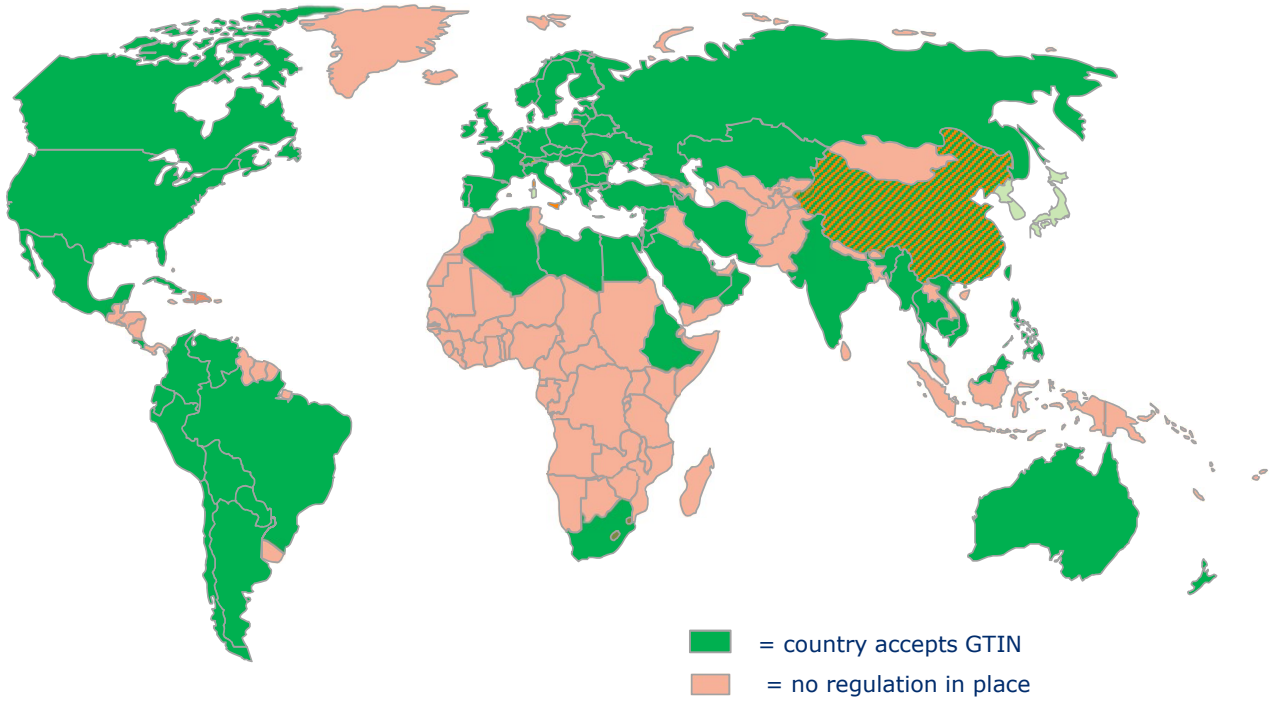
Secondary Package

Tertiary Package
(Case)

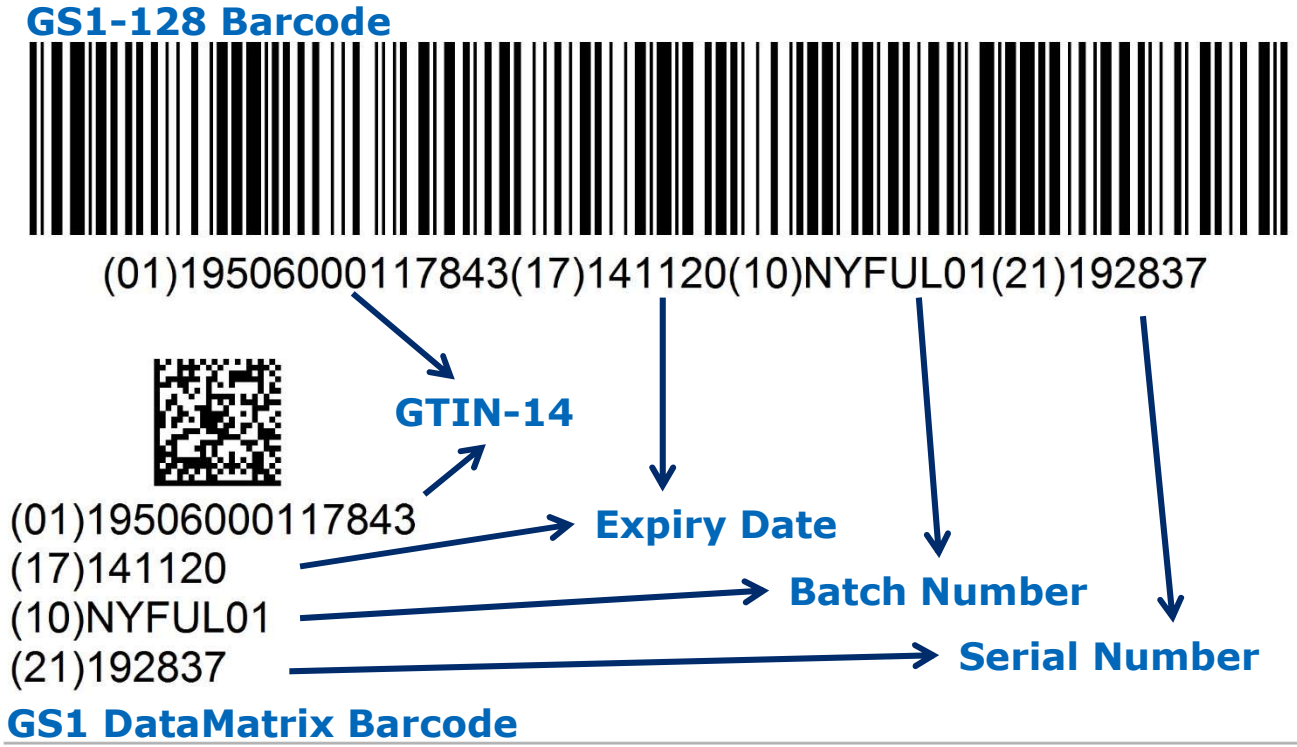
Tertiary Package
(Pallet as a Trade Item)

Note: Images shown are for illustration example only, refer to local regulations and/or the latest version of the GS1 General Specification for more detail.

Harmonisation around the identification of pharmaceuticals

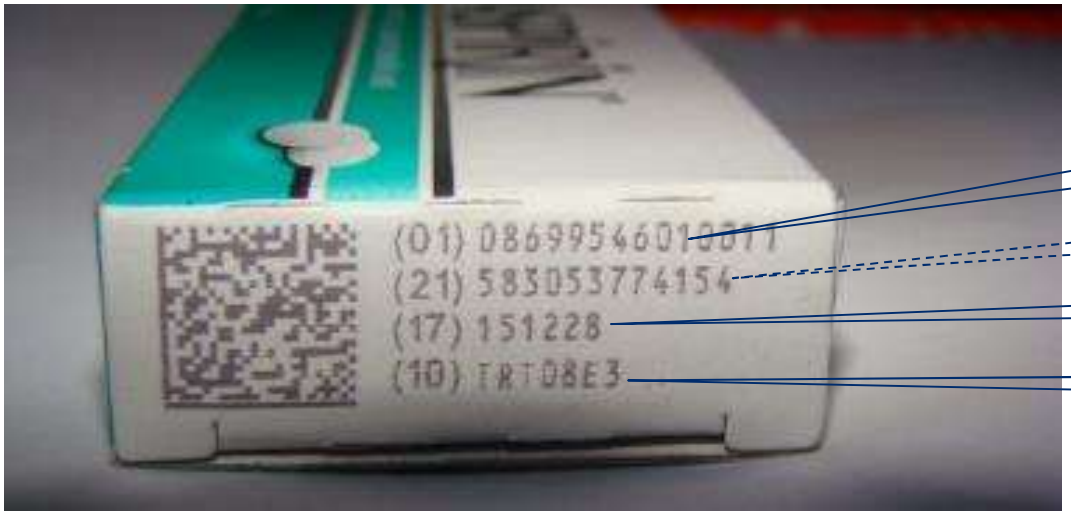


In Healthcare we need often more than the GTIN...



A GS1 Application Identifier (AI) is an element string that carriers dynamic or "production identification" data that... in conjunction with the GS1 "Key"... they provide more granular information about the items identified at the point of data acquisition (scanning).

The globally harmonised approach: a serialised secondary pack…



Assignment of GTIN, serial number, lot/batch number and expiry date is the responsibility of the manufacturer

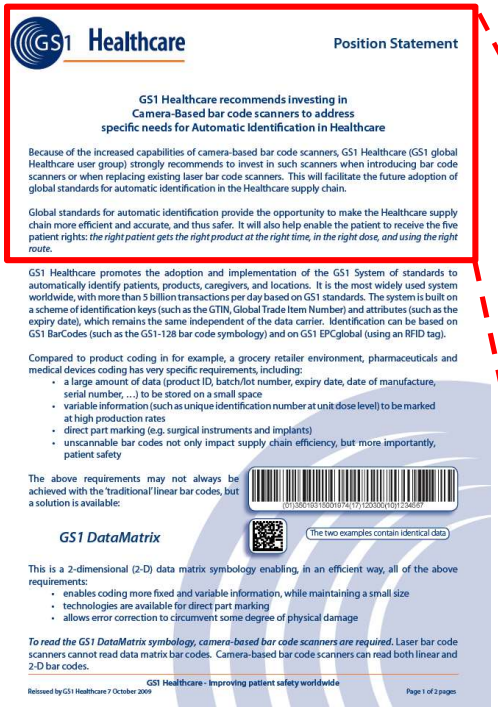
Why standardise on as few as possible...

- The barcode grows larger when too much information is included...
- With local variances costs increase beyond those already necessary for changing packaging lines...
- Increased complexity for manufacturers in managing “multi-market” or special packaging...
- When local rules are not aligned with rest of the world, it becomes an additional burden for any **exporting** and well as importing manufacturer...

Poll: Is your company already affected by serialisation/implementing it?

- Yes
- Just starting
- No

Position – 2D Imager/Camera scanners…



GS1 Healthcare — Position Statement

GS1 Healthcare recommends investing in Camera-Based bar code scanners to address specific needs for Automatic Identification in Healthcare

Because of the increased capabilities of camera-based bar code scanners, GS1 Healthcare (GS1 global Healthcare user group) strongly recommends to invest in such scanners when introducing bar code scanners or when replacing existing laser bar code scanners. This will facilitate the future adoption of global standards for automatic identification in the Healthcare supply chain.

Global standards for automatic identification provide the opportunity to make the Healthcare supply chain more efficient and accurate, and thus safer. It will also help enable the patient to receive the five patient rights: *the right patient gets the right product at the right time, in the right dose, and using the right route.*

GS1 Healthcare promotes the adoption and implementation of the GS1 System of standards to automatically identify patients, products, caregivers, and locations. It is the most widely used system worldwide, with more than 5 billion transactions per day based on GS1 standards. The system is built on a scheme of identification keys (such as the GTIN, Global Trade Item Number) and attributes (such as the expiry date), which remains the same independent of the data carrier. Identification can be based on GS1 BarCodes (such as the GS1-128 bar code symbology) and on GS1 EPCglobal (using an RFID tag).

Compared to product coding in for example, a grocery retailer environment, pharmaceuticals and medical devices coding has very specific requirements, including:

- a large amount of data (product ID, batch/lot number, expiry date, date of manufacture, serial number, …) to be stored on a small space
- variable information (such as unique identification number at unit dose level) to be marked at high production rates
- direct part marking (e.g. surgical instruments and implants)
- unscannable bar codes not only impact supply chain efficiency, but more importantly, patient safety

The above requirements may not always be achieved with the 'traditional' linear bar codes, but a solution is available:

The two examples contain identical data

GS1 DataMatrix

This is a 2-dimensional (2-D) data matrix symbology enabling, in an efficient way, all of the above requirements:

- enables coding more fixed and variable information, while maintaining a small size
- technologies are available for direct part marking
- allows error correction to circumvent some degree of physical damage

To read the GS1 DataMatrix symbology, camera-based bar code scanners are required. Laser bar code scanners cannot read data matrix bar codes. Camera-based bar code scanners can read both linear and 2-D bar codes.

GS1 Healthcare - Improving patient safety worldwide

Reissued by GS1 Healthcare 7 October 2009 — Page 1 of 2 pages

Preparing members, solutions providers and end users for the future…

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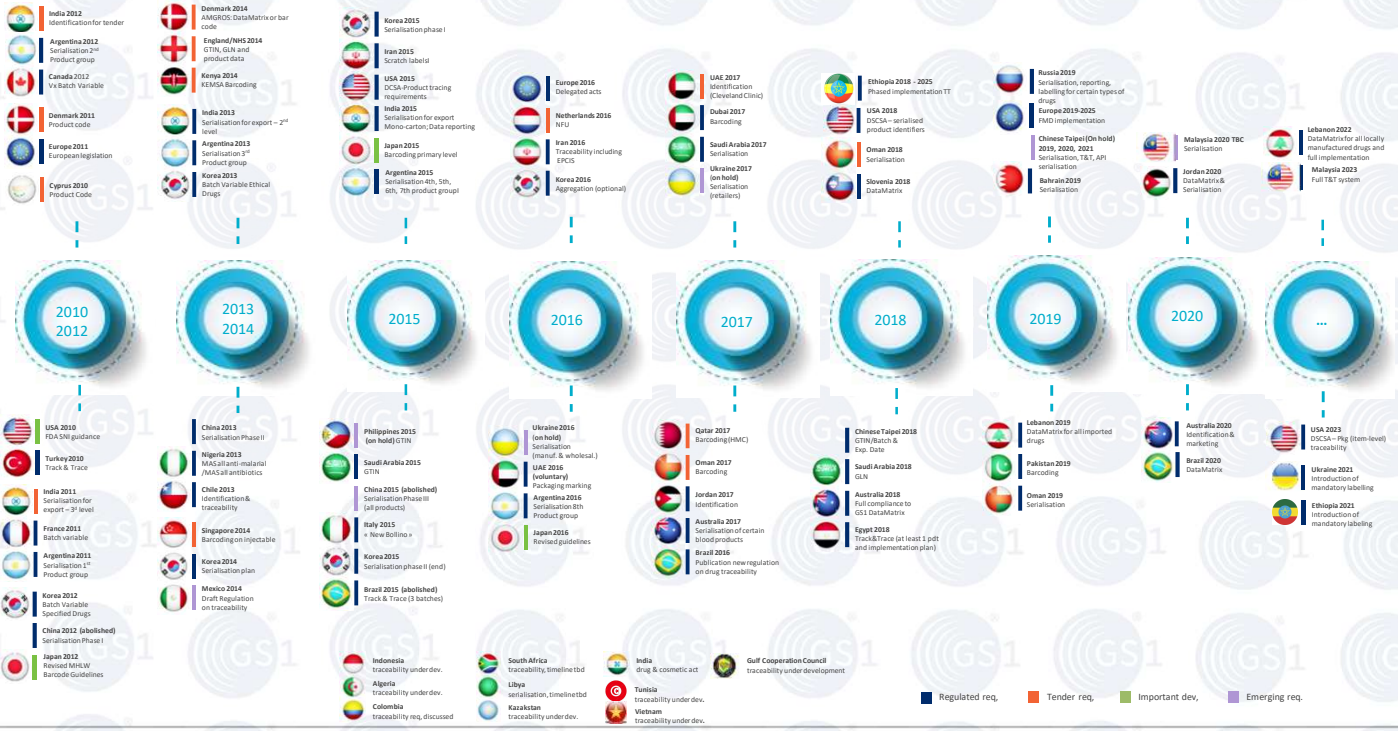
Get your copy at:

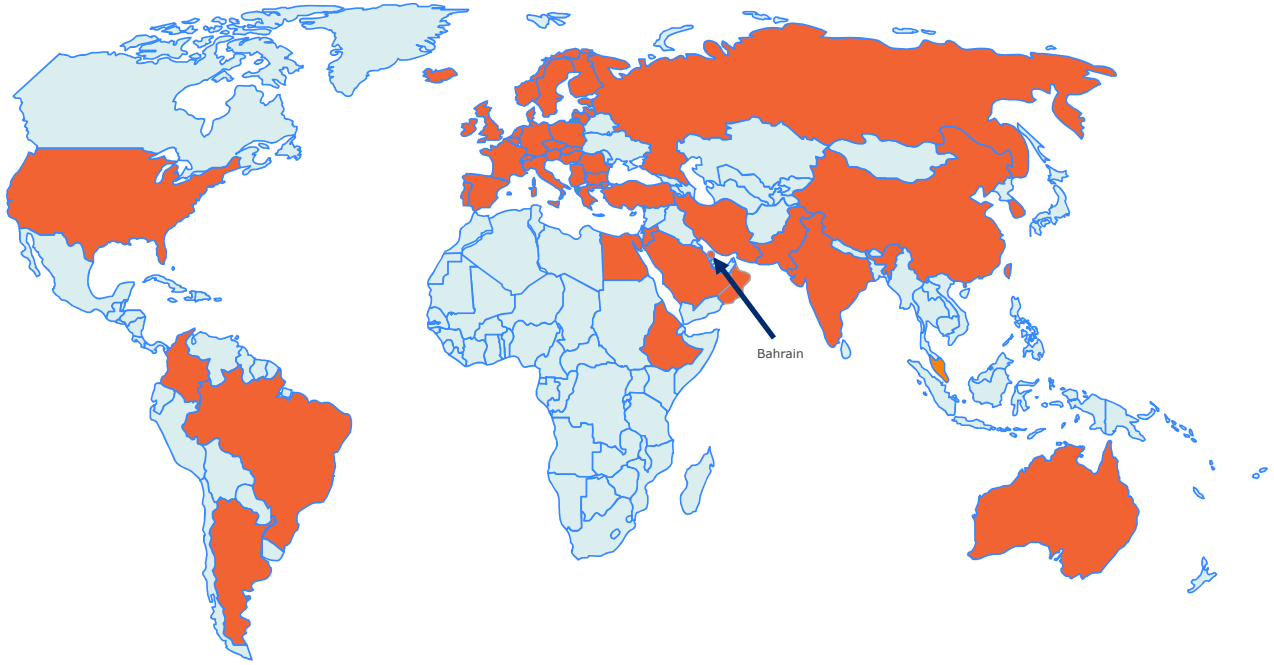
http://www.gs1.org/docs/healthcare/GS1_HUG_ps_Camera_Based_Scanners.pdf

Pharma – World* – an ever growing number of coding & serialisation requirements



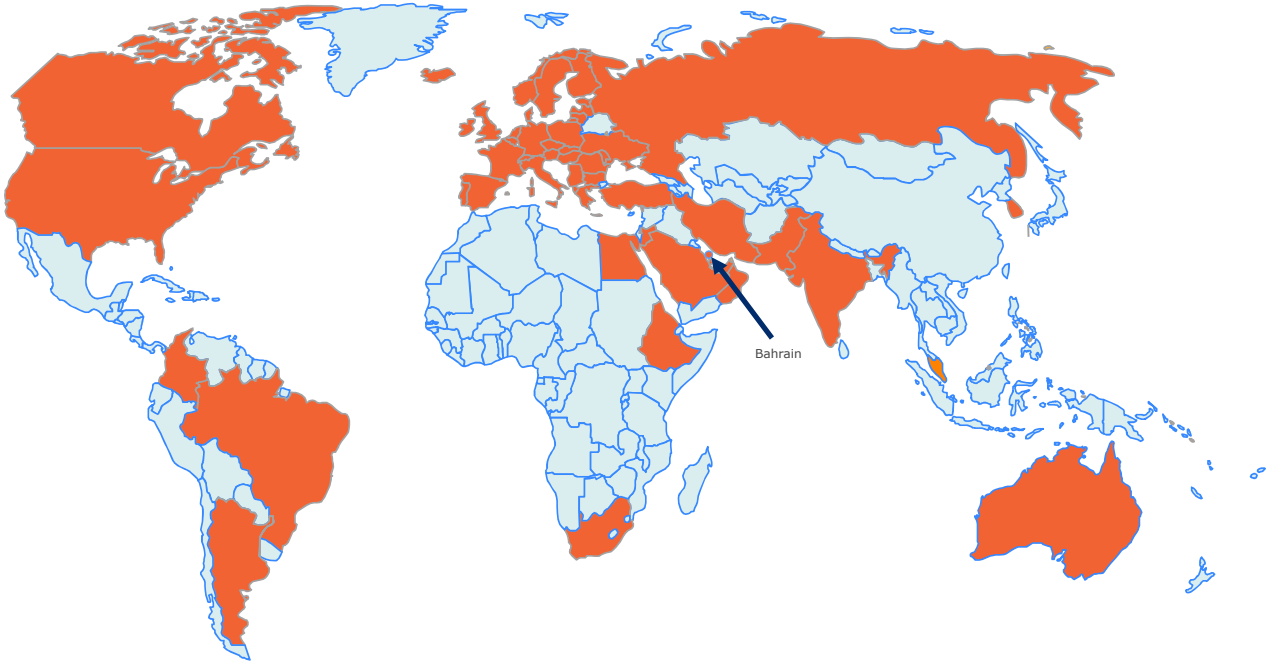
*Including Europe

Serialisation of pharmaceuticals



= country developing requirement or requiring serial number

GS1 DataMatrix on pharmaceuticals



country developing requirements or requiring DataMatrix and/or using DataMatrix in pilots

Healthcare

Turkish Pharmaceutical Track and Trace System (ITS)

ITS was the first successful application of a "Pharmaceutical Track and Trace System" in the world and is designed to track the location of every drug unit to ensure the reliable supply of drugs to patients.

Challenge

To ensure and guarantee the reliable supply of legitimate drugs to patients in Turkey. Like most countries, this supply was put at risk by illegal activities that could seriously impact public health and safety.

Approach

Turkey developed a Pharmaceutical Track and Trace System and built a centralised repository to monitor drug movement throughout the supply chain. With this central management system in place, the ITS can track and trace a drug from the point of manufacture to the point of dispense by leveraging GS1 identification keys, attributes and barcodes.

Results

Reliable and safe supply of drugs to patients

Enhanced ability to combat illicit drug sales, barcode scams and theft

More than
$1 billion
in annual savings

More than
45 million
daily transactions through ITS

Response time is 0.02 seconds per transaction

Sophisticated and efficient recall management

Many achievements and benefits

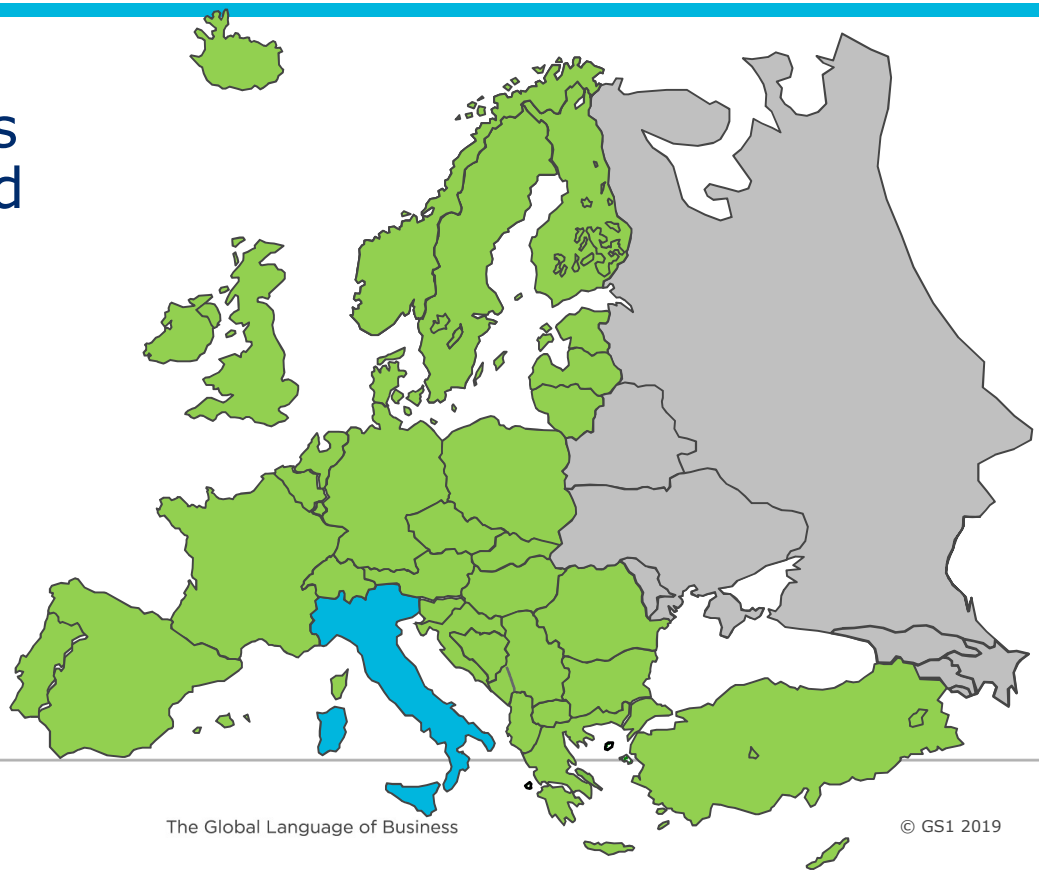
- Safe medicines, prevents counterfeiting
- Prevents resale of medicine
- Expedites recalling of medicine
- Prevents sale of expired medicine
- Preventing drug shortages
- Quality data for insurances
- Provides statistics to develop policies on Rational Medicine Use
- Enables pharmacovigilance and strategic planning

Source: Presentation of Turkish MoH

The Unique Identifier in the Delegated Regulation (EU) 2016/161 in force **NOW**

The move towards harmonisation and GS1 standards in Europe

Italy has until 2025 to comply



USA – 2015, 2017, 2023
Drug Supply Chain Security Act (DSCSA)

A full traceability system in 2023

- Identification on saleable units and homogeneous cases
- Data elements: NTIN, Expiry date, lot/batch number, serial number
- Data carrier: 2D DataMatrix
- **Serialisation (SNI) Nov. 2017** (will not be enforced for one year)

- The US FDA points to EPCIS as one of possible way for exchange of traceability data in their draft guidance, industry alignment
- GS1 US Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability (R1.2)
- New guideline for grandfathering published

Protect the product → **Protect the patient**

Latin America

Argentina

Secondary pack.: GTIN + Exp. date + Batch # + Serial #
GS1 128, GS1 DataMatrix, RFID
ANMAT Portal
Implementation since 2011

Brazil

Pilot finalized end of April 2019
Implementation starting in May 2020

Colombia

Draft on data standardization in 2018
National code for medicinal products (IUM) instead of GTIN

Chile, Mexico, Panama, Peru under discussion

MEMA – 1/2

Bahrain
Secondary pack.: GTIN+Exp.+Batch#+Serial#
GS1 DataMatrix
GCC attributes in BrandSync: end April 2018
Master data reporting: end July 2018
Serialisation: 31 Dec. 2019

Egypt
Secondary pack.: GTIN+Exp.+Batch#+Serial#
GS1 DataMatrix
Tertiary pack.: SSCC
GS1 128, GS1 DataMatrix
Serialisation: end of 2018
Reporting on MoH portal: June 2019
Possible use of EPCIS

Ethiopia
Roadmap towards TT in 9 years based on GS1
Currently Phase 1: "Strengthening environment"

Iran
Secondary pack.: GTIN+UID+Exp.+Batch#
GS1 DataMatrix
Deadline: 1 Jan. 2015
Use of EPCIS

Jordan
Secondary pack.: GTIN+Exp.+Batch#+Serial#
1D to 2D: end June 2018
Barcoding: end 2019
Serialisation:1 Jan. 2020

Lebanon
Secondary pack.: GTIN+Exp.+Batch#
GS1 DataMatrix
Barcoding - imported: end 2019
Barcoding – local: end 2022
Reporting to MoH: end 2022

MEMA – 2/2

Oman
Secondary pack.: GTIN+Exp.+Batch#+Serial#
GS1 DataMatrix
GCC attributes in BrandSync: 30 days before shipping
Serialisation: 1 March 2019
Also **tender requirements**

Qatar – TENDER (HMC)
Secondary pack.: GTIN+Exp.+Batch#
DataMatrix
Tertiary pack.: SSCC
GS1 128, GS1 DataMatrix
Deadline: 1 Jan. 2018

Saudi-Arabia
Secondary pack.: GTIN+Exp.+Batch#+Serial#
GS1 DataMatrix
Barcoding: March 2015
Serialisation: March 2017
Registration & reporting : 7 Jan. 2019
Aggregation: 1 Oct. 2019

South Africa
Secondary pack.: GTIN+Exp.+Batch#+Serial#
GS1 DataMatrix
Serialisation: June 2022 (tbc)
? Release final regulation

United Arab Emirates – Dubai HA
Secondary pack.: GTIN+Exp.+Batch#
GS1 DataMatrix
Master data: GTIN, DDC, DHA item ode, DHA item description
Deadline: 1 Jan. 2017
Also **tender requirements**

GCC
Secondary pack.: GTIN+Exp.+Batch#+Serial#
GS1 DataMatrix
Aggregation recommended
GCC attributes in BrandSync (17 M. – not for Saudi)

Asia Pacific - 1/2

Australia
Serialisation+DataMatrix on blood prdt.: 1 Jan. 2018
Medicines labelling: GTIN+DataMatrix: 1 Sept. 2020
TGA running public consultations

China
eCode on hold since Feb. 2016
Drug traceability system guide: 2018, distributed model
Implementation in 2022
Pilot with stakeholders
Vaccines: Pilot and first regulation expected soon

Chinese Taipei
Secondary pack.: GTIN+Exp.+Batch#+Serial#
GS1 DataMatrix
Identification: Jan. 2018
Serialisation: Jan. 2019
Registration for reporting: Jan. 2020
? Release final requirements

India
For export:
Serialisation since 2013
Reporting & Aggregation: 1 July 2019
? Primary pack as of 1 April 2020 with QR
For domestic market:
? timeframe
? SMS on primary pack

Indonesia
Secondary pack.: GTIN+Exp.+Batch#+Serial#
GS1 DataMatrix or QR code
Deadline: ID by 2023, authentication by 2023
Aggregation not mandatory

Japan
Secondary pack.: GTIN+Exp.+Batch#**or**Serial#
GS1 DataBar
Deadline: March 2021

Asia Pacific – 2/2

Kazakhstan
Pilot announced
2020/2012: voluntary labelling
2023/2024: mandatory labelling

Malaysia
In discussions on track & trace

Pakistan
Aligned with GS1 standards and 4 data elements

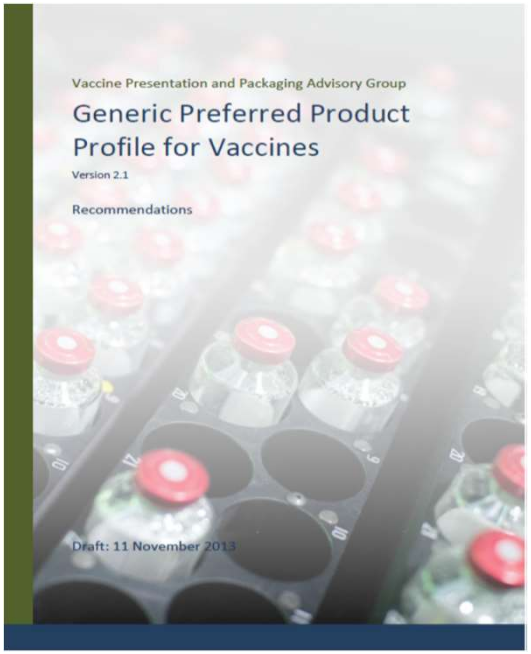
Also,
Ukraine, Kyrgyz Republic, Mongolia, Sri Lanka, Vietnam

Russia
Secondary:DataMatrix,GTIN+Serial#+Exp.+Lot#
+crypto (AI(91) AI(92))
Tertiary: GS1 128, SSCC or sGTIN
Aggregation required
Reporting: Labelling Information System (LIS)
? 1 Oct 2019: 12 Nosologies
? 1 Jan 2020: Full track and trace

South Korea
Secondary:GTIN+Serial#+Exp.+Lot#
DataMatrix (for narcotics: RFID)
All products serialised by end 2015
Aggregation voluntary by 2016
Reporting by 1 July 2016

WHO VPPAG recommendations

- 2019 Generic Preferred Product Profile for Vaccines (PSPQ2) recommends barcodes on all packaging levels used by manufacturers, with the exception of primary packaging
- GS1 standards and associated specifications are being used to encode the Global Trade Item Number (GTIN), lot number, and expiry date
- http://www.who.int/iris/bitstream/10665/148168/1/WHO_IVB_14.10_eng.pdf



The vaccines supply chain

Often the supply chain is broken

- Vaccines are expired or not stored correctly
- Vaccines are not available when needed
- Inventory management is not optimal
- Traceability is not achievable
- Responsibility towards donors not fulfilled

Supporting documents

- VPPAG Bar Code Implementation Technical Guideline
- Barcode implementation considerations document
- Pilots, experiences, learnings

Several pilots have been going on

- Tanzania
- Gambia
- Nicaragua
- Pakistan

All with very good results!

Interagency Supply Chain Group (ISG) Adoption of global GS1 standards

The ISG: **Bill and Melinda Gates Foundation, DFID, Global Affairs Canada, the Global Drug Facility, KfW, the Global Fund, Gavi, NORAD, UNDP, UNFPA, UNICEF, USAID, World Bank, WFP and WHO** published a position paper in August 2017 on the **adoption of GS1 standards** committing to the process of transitioning to include established, global data standards as part of their procurement requirements and support country uptake of these standards.

From the Interagency Supply Chain Group:

Visibility for Health Systems: Adoption of Global Data Standards (GS1)

About the ISG

The broad purpose of the Interagency Supply Chain Group (ISG) is to share information and seek greater alignment across supply-chain investments to bring more impact to individual agency supply chain strategies. The group promotes coordination both globally across programs, and locally through national leadership with the overall aim of improving the efficiency and effectiveness of in-country supply chains. The ISG is an informal partnership of 15 major actors involved in providing supply chain support to countries: Bill and Melinda Gates Foundation, DFID, Global Affairs Canada, the Global Drug Facility, KfW, the Global Fund, Gavi, NORAD, UNDP, UNFPA, UNICEF, USAID, World Bank, WFP and WHO.

Boxes of medical supplies are sorted before being distributed among the mobile health brigades at the Chicuadacuala District hospital in Maputo, Mozambique, in July 2016. ©UNICEF/Rich.

Background

Medicines supply chain execution and responsiveness require synchronization of supply and demand, as well as the orchestration of three flows of commerce, that are the movement of goods, information and funds, across an increasing number of logistics and trading partners, spanning a wide (if not global geographic) region. Whilst the implementation of traceability systems has been identified by National Regulatory Authorities as a useful and efficient tool to combat falsification and illicit distribution of medical products, only some countries have issued progressive traceability regulation. Many have not, and are still assessing various implementation mechanisms, alternatives or otherwise have not approached this topic at all*. The international community has recognized the need to support countries in determining what these best approaches are. Since 2014, the international development community has promoted the use of global data standards (GS1) to provide a wider and harmonized framework for supply chain visibility, strengthening anti-counterfeiting measures and sharing of data between parties. The Interagency Supply Chain Group recognizes the value for advocating for both effective and sustainable solutions to enable traceability and safe passage of medicines through national supply chains and have committed to strengthening this response accordingly.

Current activities of the ISG

- Strengthen global and country advocacy for the adoption of GS1 standards and traceability systems with countries, in collaboration with other relevant stakeholders.
- Accelerate the understanding and adoption of an open and global supply chain standard, globally, through technical support, education, and collaboration with manufacturers.
- Collaborate to improve donor procurement guidelines, including the requirement for the use of GS1 standards for identification and barcoding on the different packaging levels, and coordinate with manufacturers on an implementation timeline.
- Develop a roadmap & timeline for the adoption of GS1 standards in labelling all health commodities and products.
- Provide technical assistance to several countries in defining parameters necessary to implement National Traceability Systems. These include development and finance implementation plans for barcoding of health commodities for member states. e.g. support to the Government of Ethiopia to implement a nation-wide adoption of barcoding technology.

* Fourth meeting of the member state mechanism on substandard/spurious/falsely-labelled falsified/counterfeit medical products, 13 November 2015, provisional agenda item 4C. Existing technologies and 'track and trace' models in use and to be developed by member states. Draft document submitted by Argentina.

Alignment on global standards

Published end of March - new guideline for global health commodities, requesting all components of the GS1 system:
Identify, Capture and **Share**
https://www.ghsupplychain.org/global-standards-technical-implementation-guideline-global-health-commodities-v21

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

Source:
http://www.mckinsey.com

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

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)

SOURCE: McKinsey report, "Strength in unity: The promise of global standards in healthcare", October 2012

36th GS1 Healthcare Conference

New Delhi, India • 5-7 November 2019

- Traceability, unique medical device identification (UDI) and global regulatory developments
- Implementation success stories from manufacturers, wholesalers and hospitals – experiences and benefits
- How to improve patient safety and quality of care
- Hospital implementation awards
- And much more…

Contact Details

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