

The Global Language of Business

By number - the global standards behind barcodes and serialization

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

November 2019

Why do we need global standards?









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



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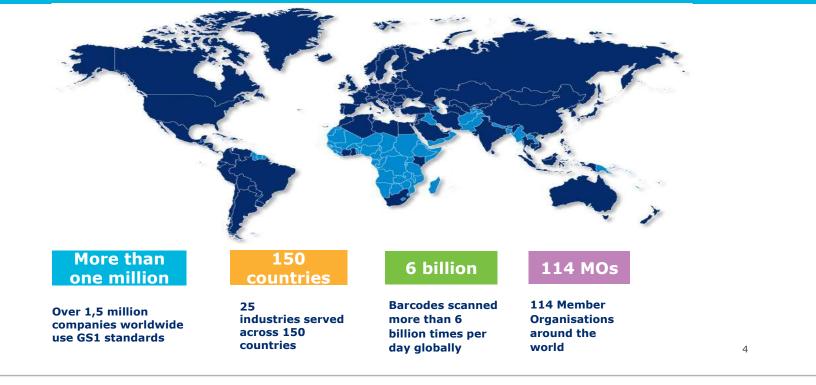
- Multiple bar codes on one package – which one to scan?
- Different types of bar codes – inconsistency; incompatibility
- No bar code need to bar code; re-package; re-label



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GS1 – a global standards organisation







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Are you using GS1 standards today?



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



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GS1 Vietnam Main Services

Barcodes

GS1 VIETNAM IS THE ONLY OFFICIAL AUTHORITY IN VIETNAM PROVIDING AND MANAGING PRODUCT BARCODES FOR MORE THAN 40,000 ENTERPRISES WITH OVER 1,000,000 PRODUCTS

Traceability

FROM19/01/2019,PRIMEMINISTERAPPROVETHEDECISION100CALLED"APPROVALOFTHEDEPLOYMENT,THEAPPLICATIONANDMANAGEMENTOFTRACEABILITY SYSTEM"

LEI

THE LEI IS A REFERENCE DATA TOOL TO STANDARDIZE HOW A COUNTERPARTY IS IDENTIFIED ON FINANCIAL TRANSACTIONS.



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About Healthcare Product Regulations In Vietnam



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Regarding the Circular 32 issued by Ministry of Healthy, at article 23 (14), all the barcode, QR code and DataMatrix is acceptable.

All three types of barcodes are accepted for medical devices in Vietnam, but **GS1 only recommends to use DataMatrix to be accepted globally.**





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Voluntary, Global Healthcare User Group





GS1 Healthcare <u>is a neutral and open community</u> bringing together <u>all related healthcare stakeholders</u> to lead the successful <u>development and implementation of global GS1 standards</u> enhancing **patient safety, operational** and **supply chain efficiencies**.



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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**





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Working with global organisations...









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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



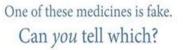
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Why regulation? A main driver - counterfeiting



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



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Combating counterfeiting

The introduction of a unique identification for drugs, 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 !

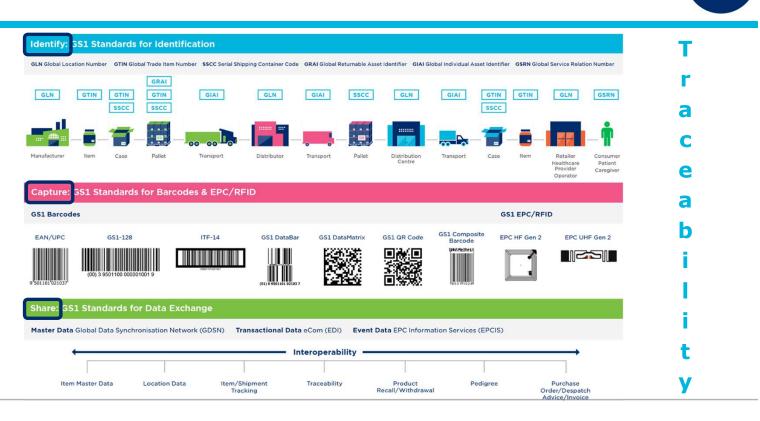


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GS1: global system of standards





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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 <u>umbrella term</u> 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.



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GTIN Terminology & structure...



	N ₁ N ₂ N ₃ N ₄ N ₅ N ₆ N ₇ GTIN - 8	C ₈
	$N_1 N_2 N_3 N_4 N_5 N_6 N_7 N_8 N_9 N_{10} N_{11}$ GTIN - 12	C ₁₂
	$N_1 N_2 N_3 N_4 N_5 N_6 N_7 N_8 N_9 N_{10} N_{11} N_{12}$ GTIN - 13	C ₁₃
N ₁	$N_2 N_3 N_4 N_5 N_6 N_7 N_8 N_9 N_{10} N_{11} N_{12} N_{13}$ GTIN - 14	C ₁₄

- GTIN is an umbrella term for all GS1 "trade item" identification numbers.
- A GTIN may use the GTIN-8, GTIN-12, GTIN-13, or GTIN-14 numbering structure.

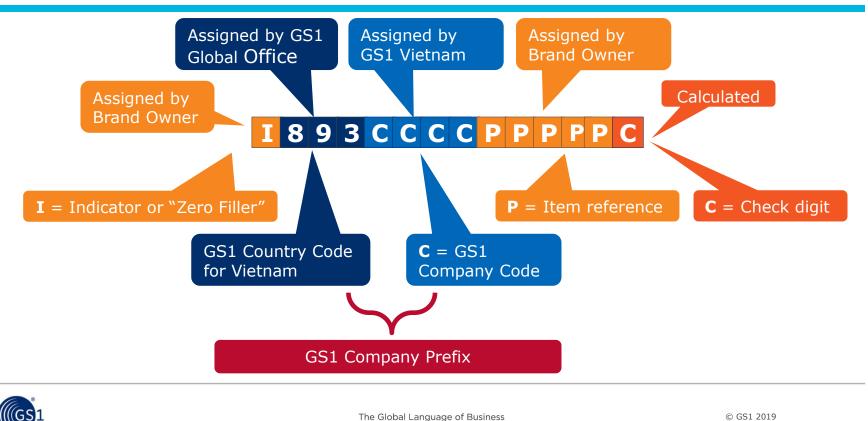


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GTIN Terminology & structure...



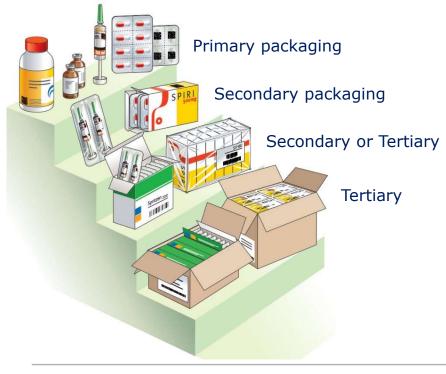
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Different pack levels... definitions...





<u>Healthcare primary packaging</u> - 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.

<u>Healthcare secondary packaging</u> - 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:

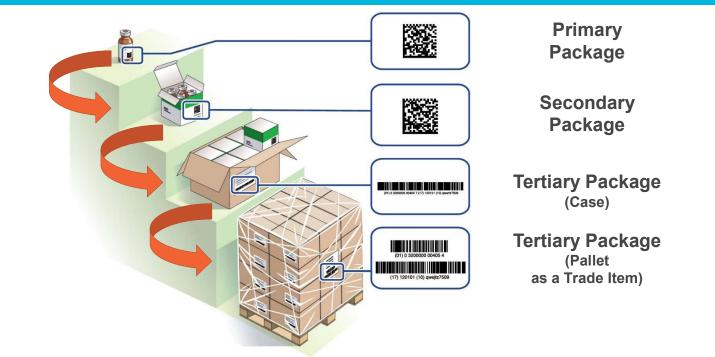
The above are GS1 General Specifications definitions.
 "Primary packaging" is usually also the "unit of use".
 As shown here "Tertiary" refers to "Trade Items" only and not "Logistic Units". (See the GS1 General Specifications for more detail.)



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

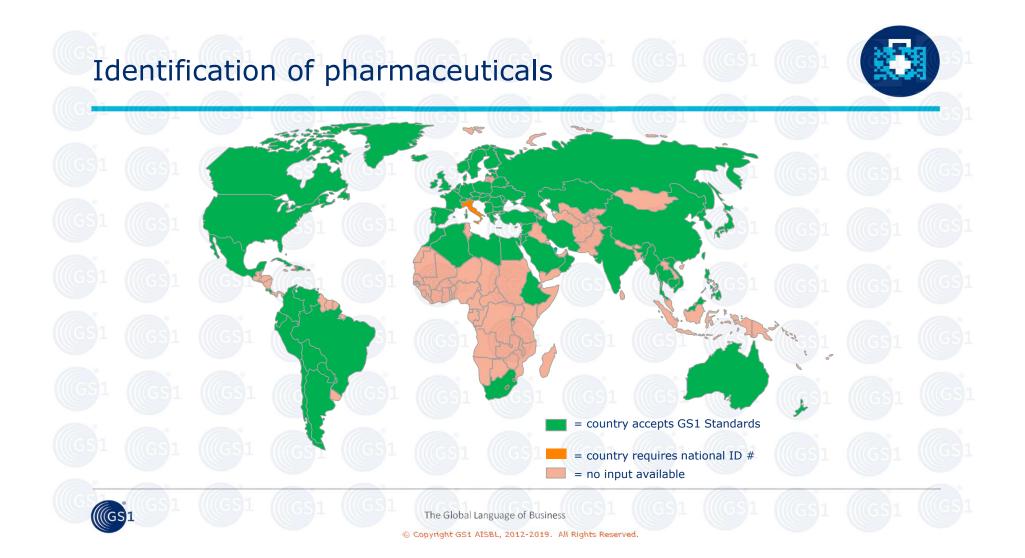




Note: Images shown are for illustration example only, refer to local regulations and/or the latest version of the GS1 General Specification for more detail.

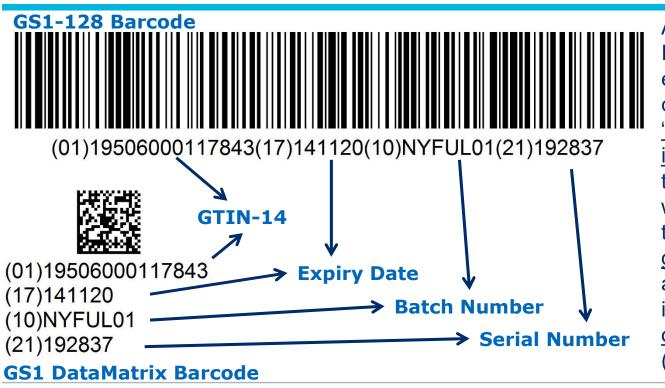


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In Healthcare we need often more than the GTIN...





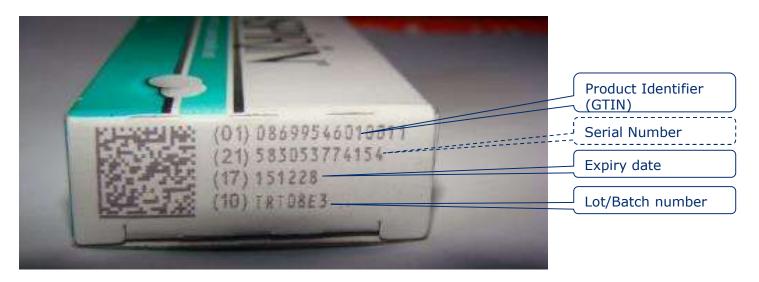
A GS1 Application Identifier (AI) is an element string that carriers <u>dynamic or</u> "production identification" data that... in conjunction with the GS1 "Key"... they provide <u>more</u> granular information about the items identified <u>at the point</u> of data acquisition (scanning).



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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



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Position – 2D Imager/Camera scanners...







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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...



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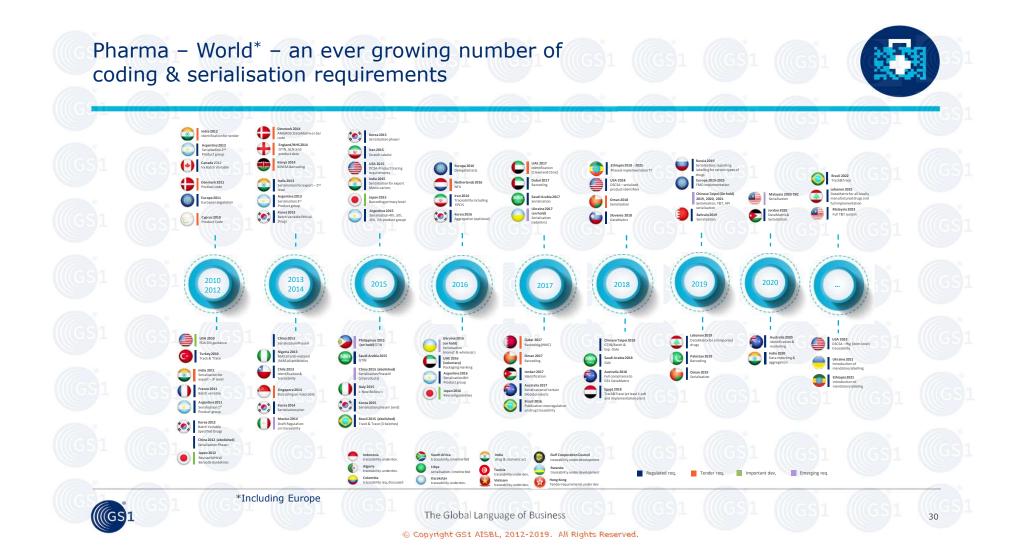
Poll: Is your company already affected by serialisation/implementing it?

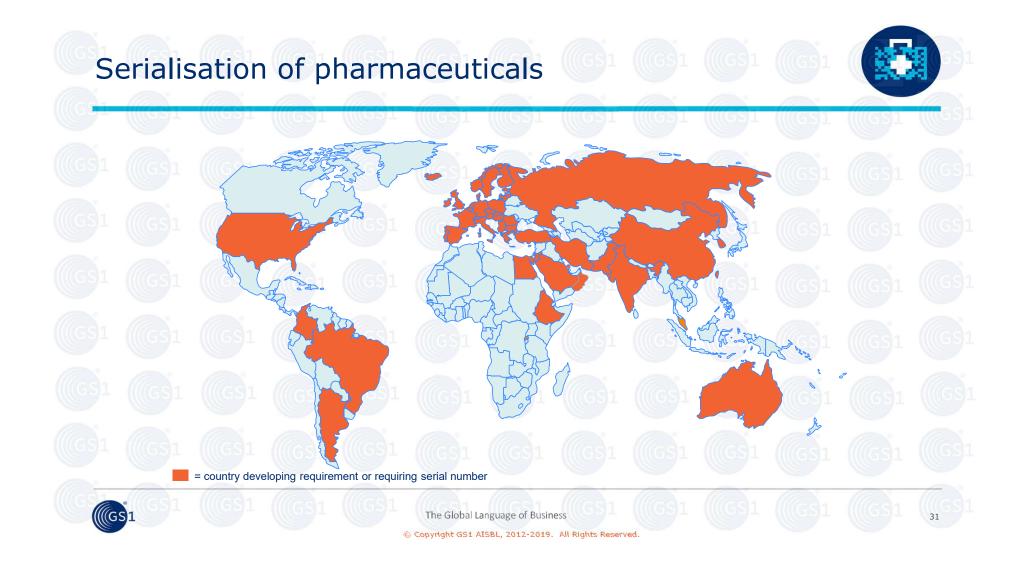


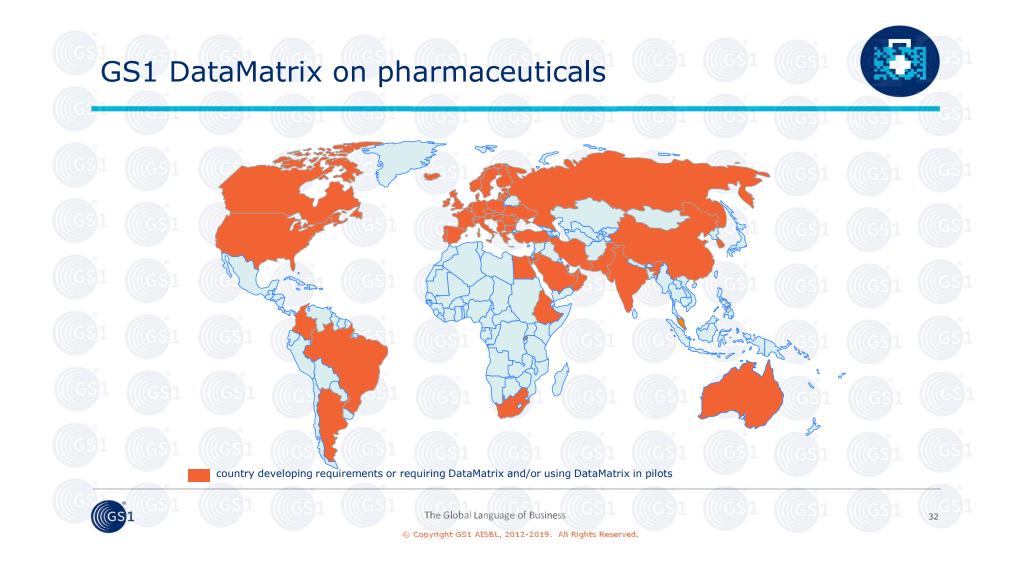
- Yes
- Just starting
- No



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Healthcare

Turkish Pharmaceutical Track and Trace System (ITS)

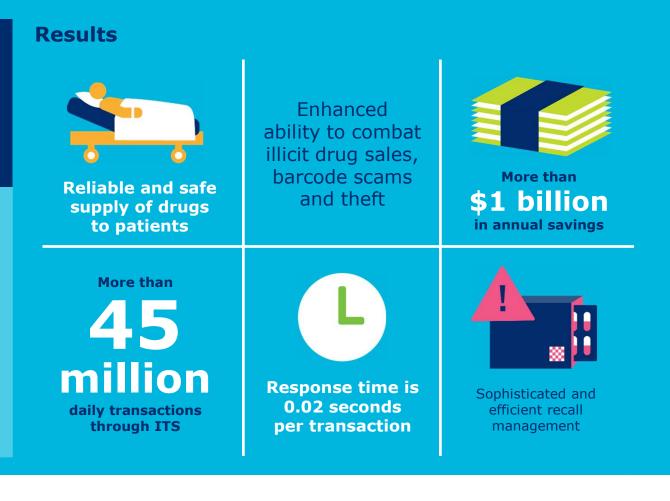
ITS was the first successful application of a "Pharmaceutical Track and Trace System" in the world and is designed to track the location of every drug unit to ensure the reliable supply of drugs to patients.

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.





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Many achievements and benefits

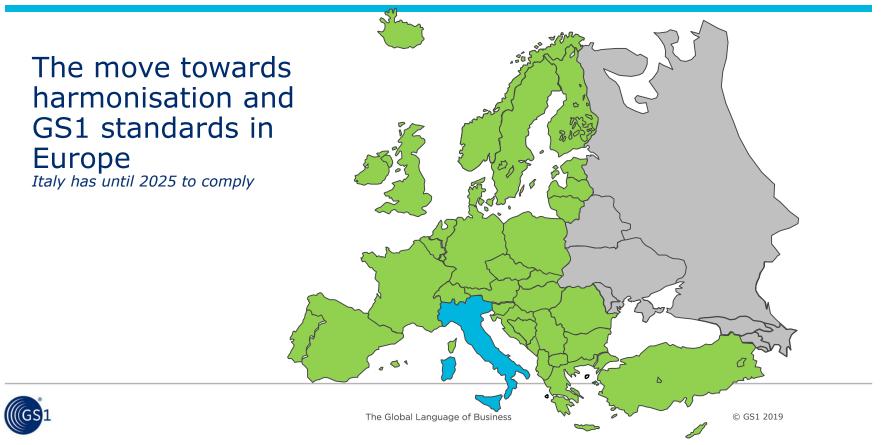
- Safe medicines, prevents counterfeiting
- Prevents resale of medicine
- Expedites recalling of medicine
- Prevents sale of expired medicine
- Preventing drug shortages
- Quality data for insurances
- > Provides statistics to develop policies on Rational Medicine Use
- > Enables pharmacovigilance and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





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





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)





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Some other countries implementing GS1 standards for pharma traceability

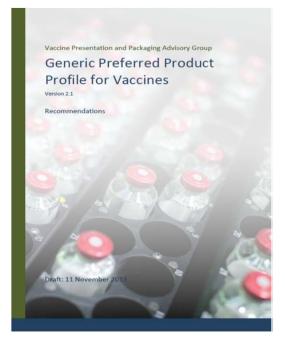


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WHO VPPAG recommendations



- 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
- <u>http://www.who.int/iris/bitstream/10665/14</u> 8168/1/WHO_IVB_14.10_eng.pdf





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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



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Supporting documents



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





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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: bility for Health Systems: Ad ion of Global Data Standards (GS1)

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 strate s. The group promotes across programs, and locally through national ship with the overall aim of improving the effici fectiveness of in-country supply chains. The ISG is n informal partnership of 15 major actors involved in roviding supply chain support to countries: Bill and Velinda Gates Foundation, DFID, Global Attains Cana da, the Global Drug Facility, KW, the Global Fund, Ga vi, NDRAD, UNDP, UNFPA, UNICEF, USAID, World Bank, WFP and WHO.



Background

Medicines supply chain execution and responsiveness require synchro ng a wide (if not global geographic) region. Whilst the rentation of traceability systems has been identified framework for supply chain visibility, st lonal Regulatory Authorities as a useful and effimbat faisification and illicit distribution of tucts, only some countries have issued prooutation. Many have not, and are

natives or otherwise have not approached this topic sing number of logistics and trading partners, span- ment community has promoted the use of global data standards (GS1) to provide a wider and he rfeiling measures and sharing of data be ties. The Interagency Supply Chain Group recognizes the ability and safe passage of me ines through national supply chains and have committee gthening this response accordingly

urrent activities of the ISG

- gthen global and country advocacy for the adoption of GS1 s in collaboration with other relevant stakeholders.
- ate the understanding and adoption of an open and global supply chain standard, glo pport, education, and collaboration with manufacturers.
- rement guidelines, including the requirement for the use of GS1 s mue donor proc
- dop a roadmap & timeline for the adoption of GS1 standards in labeling all health co Provide technical assistance to several countries in defining parameters necessary to implement National ability Systems. These include development and finance implementation plans for barcoding of health com al Tran
- les for member states. e.g. support to the Government of Ethiopia to implement a nation-wide adoption of bar-



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Alignment on global standards







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Call to Action for the "Africa Strategy for Pharmaceutical Traceability"

Signed by...

- 25 African regulatory authorities
- 6 health financing and donor organisations

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Follo



SAID







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GAVI announcement: vaccine manufacturer GS1 compliance



 Starting 1st October 2019, for vaccine tenders backed by Gavi financing and issued by UNICEF, GS1 barcoding on the secondary packaging will be a requirement by latest 31st December 2021.

unicef 🕲		Q	
for every child	WHO WE ARE WHAT WE DO 🗸 WHERE WE WORK 🗸 PRESS CENTRE	STATISTICS BLOGS	
We're building a new As we swap out old for new,	w UNICEF.org. pages will be in transition. Thanks for your patience – please keep coming back to see the improvements.		
Supplies and L	ogistics		https://www.unicef.org/s pply/index 103734.html
Supply home	GAVI announcement: vaccine manufacturer GS1	ShareThis	pply/index 105754.html
About Supply	compliance	RSS feed	
For suppliers and service providers		Printer friendly	
Procurement Services	Starting 1st October 2019, for vaccine tenders backed by Gavi financing and issued by UNICEF, GS1 barcoding on the secondary packaging will be a	Email this article	
	requirement by latest 31st December 2021.		
Strengthening supply chains	Gavi, the Vaccine Alliance is supporting countries to improve vaccine visibility and traceability from manufacturer to	Children need your help	
Immunization	beneficiary, contributing to our efforts to secure quality assured vaccines delivered to the right place, in the right quantities, at the right time to all children and adolescents.		
Health emergency supplies	as the right time to an emotion and accessence.		
HIV	international identification and serialization standards on vaccines to improve visibility and traceability. Since 2015, UNICEF has recommended the use of GS1 standards on the secondary package of vaccines. Gavi, the Vaccine Alliance is planning		
Malaria	to require GS1 data and barcode standards on the secondary package to improve product identification, labeling, and data	Children worldwide need your help right now. Please donate	
Medical devices	exchange within the immunization supply chain. 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	what you can today.	
Supplies for children	2021. An implementation roadmap will be developed in consultation with partners in the coming months.	DONATE NOW	



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The need for global standards





Healthcare is **local** Healthcare providers are local Regulations are local Healthcare is **global** Healthcare supply chains often cross borders

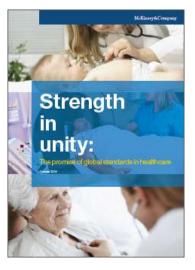
Country-by-country solutions are not sufficient nor effective <u>A global harmonised approach and implementation is needed</u>



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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



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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)

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



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It is important to remember that...



Safer, more efficient care starts with a simple scan





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