GS1 Australia

The Global Language of Business

Track & Trace – Securing Drug Supply

A review & discussion of some current trends & regulations related to medicinal products globally & in Australia

Catherine Koetz, Industry Manager - Healthcare, GS1 Australia

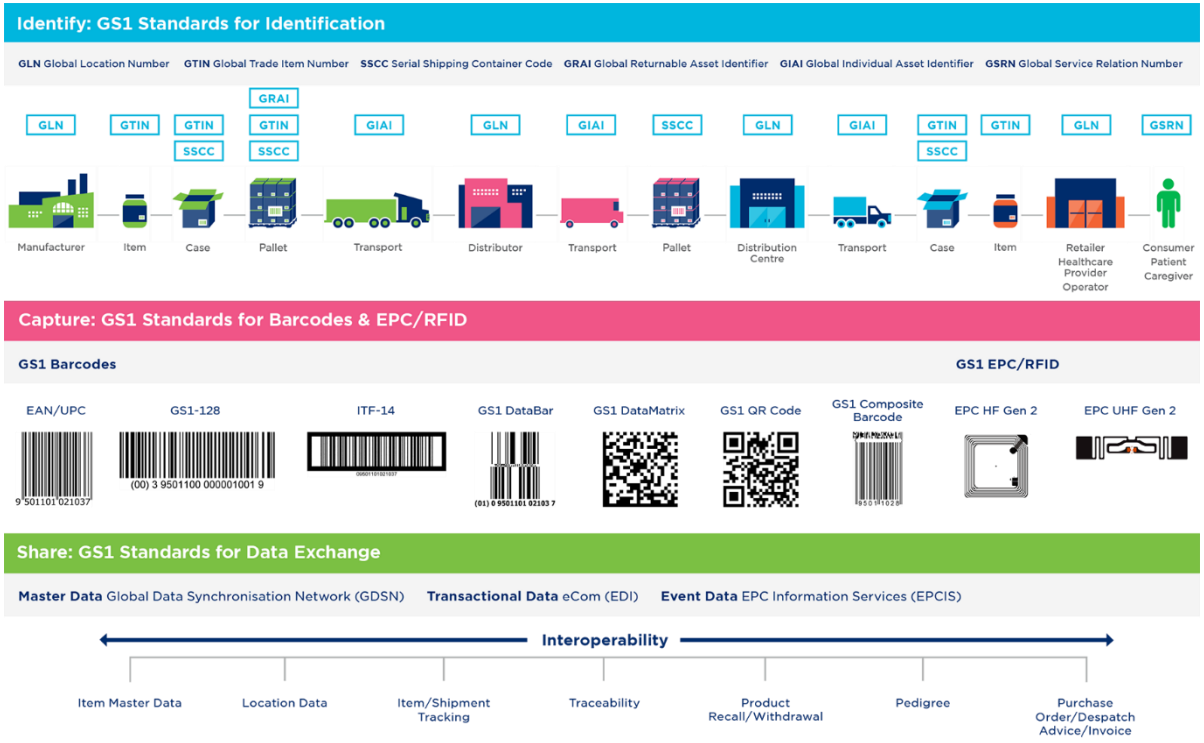
November 2018

GS1 Standards - the global language of business

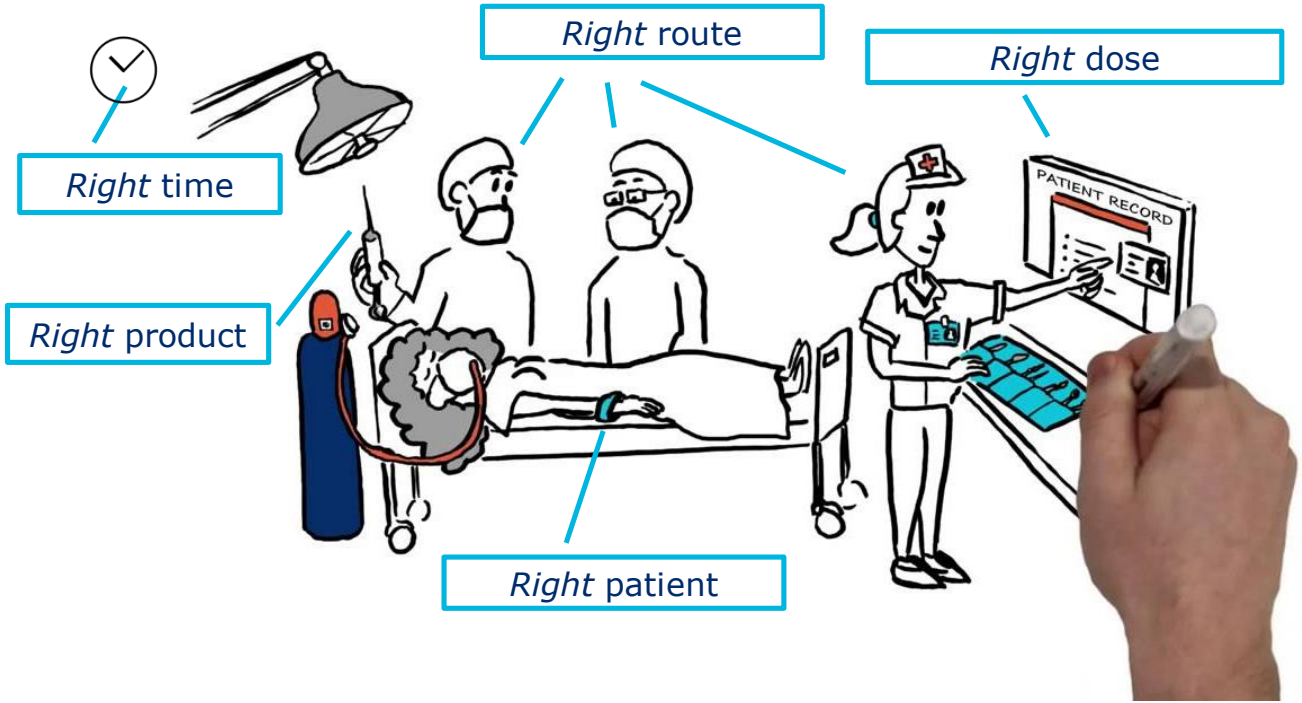
a language for **identifying**, **capturing**, and **sharing** information automatically and accurately, so that anyone who wants that information can understand it, no matter who or where they are.

1 million	150 countries	6 billion	112 MOs
over 1 million companies worldwide use GS1 standards	25 industries served across 150 countries	GS1 enabled transactions per day globally	GS1 Member Organisations around the world

GS1: global system of standards



GS1: system of standards to ensure visibility



GS1 is a Standards Development Organisation working with others

GS1 Healthcare: an expanding, committed community of globally engaged stakeholders…

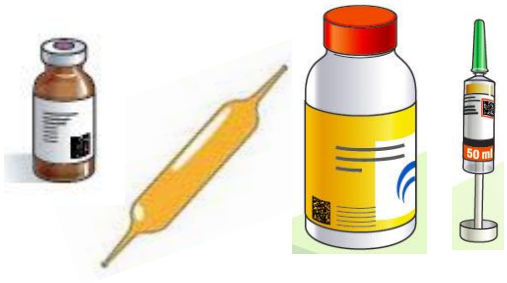
…and there are many more companies working with GS1 at a local level

…as well as with leading hospitals and government agencies to implement GS1

Traceability v Track & Trace v …

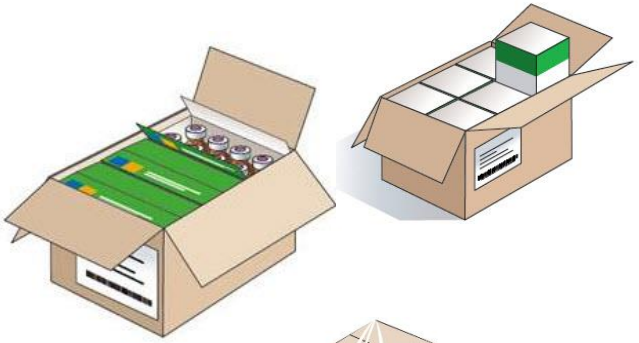
Where do we start?

Packaging level…



Primary

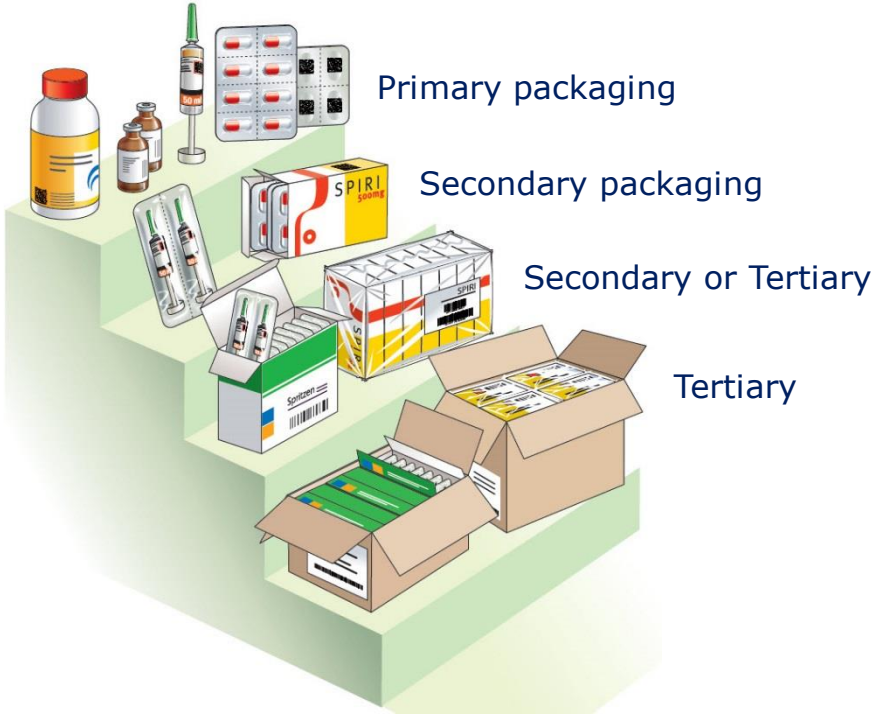
Tertiary
Case / Shipper



Secondary

Tertiary
Pallet

Packaging levels… definitions & roles…

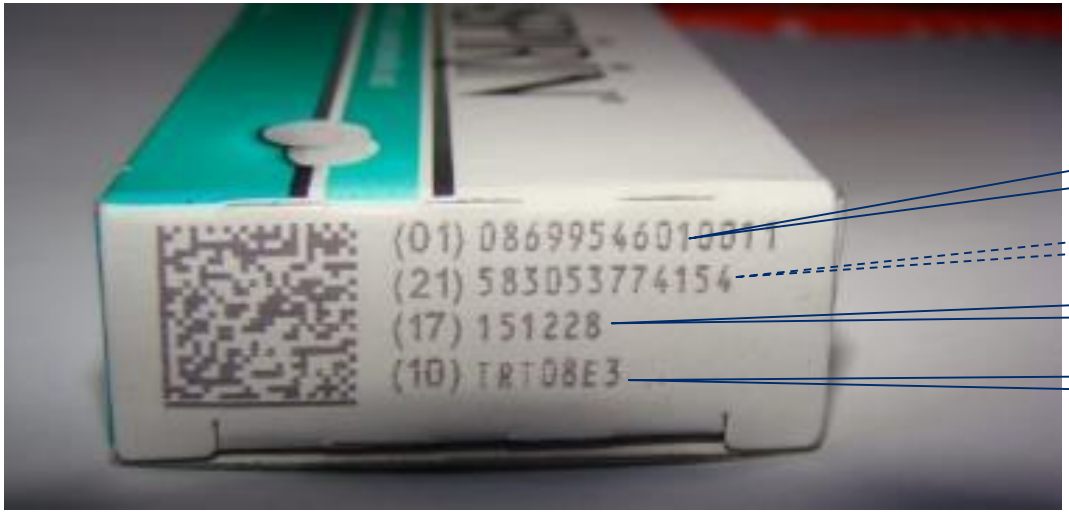


Healthcare primary packaging - The first level of packaging for the product marked with an AIDC data carrier either on the packaging or on a label affixed to the packaging. For non-sterile packaging, the first level of packaging can be the packaging in direct contact with the product. For sterile packaging, 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.

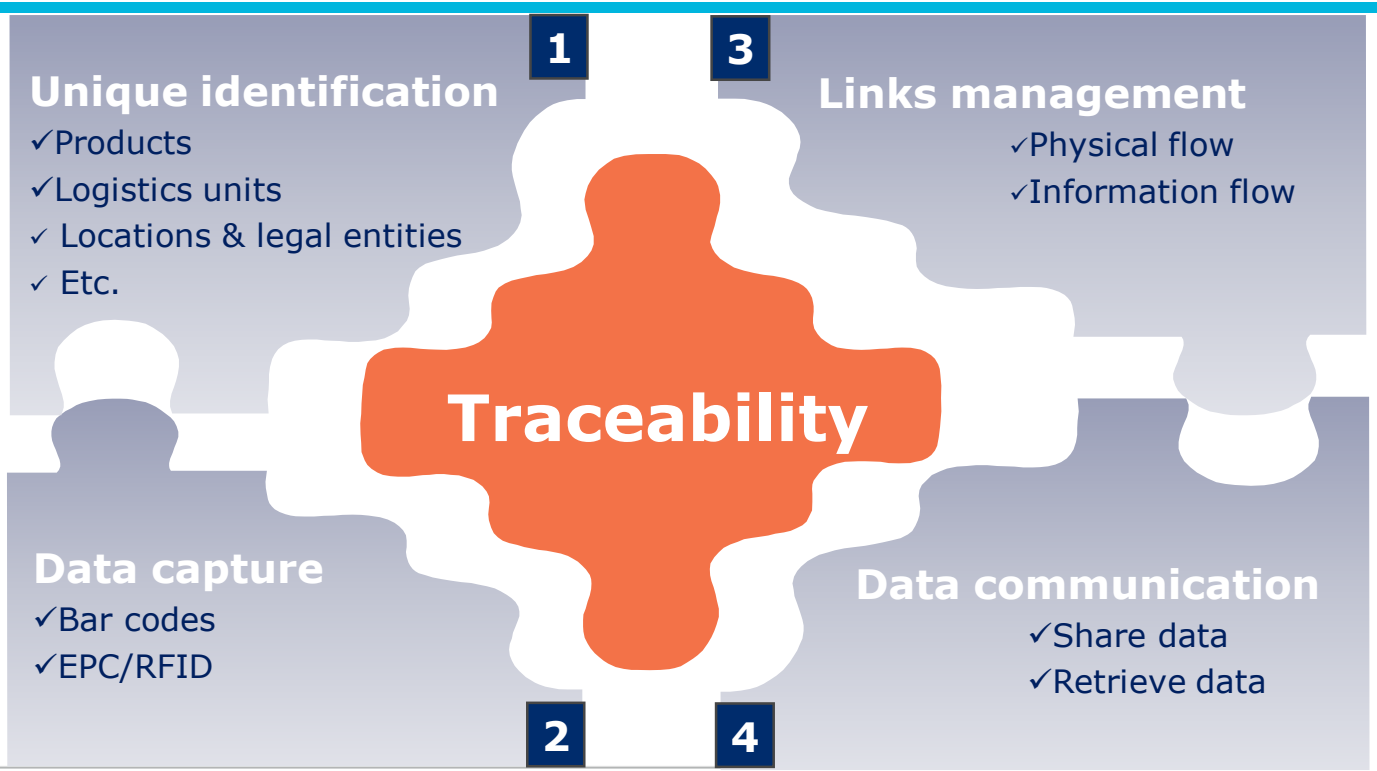
Healthcare secondary packaging - A level of packaging marked with an AIDC carrier that may contain one or more primary packages or a group of primary packages containing a single item.

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.)

A serialised secondary pack…

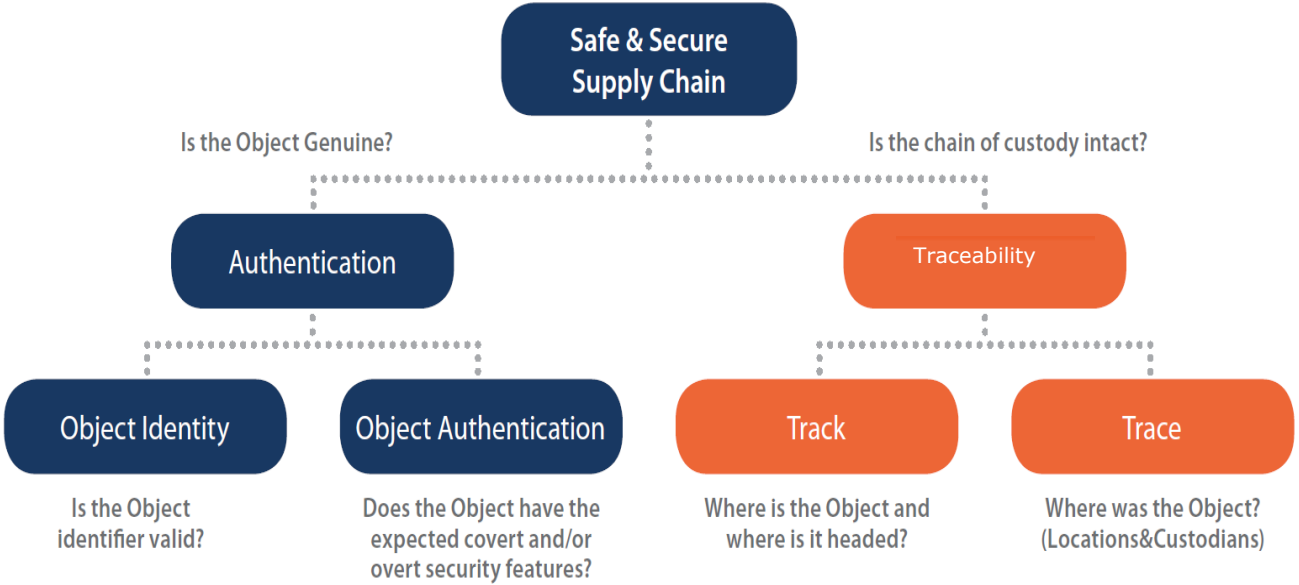


Building blocks for traceability

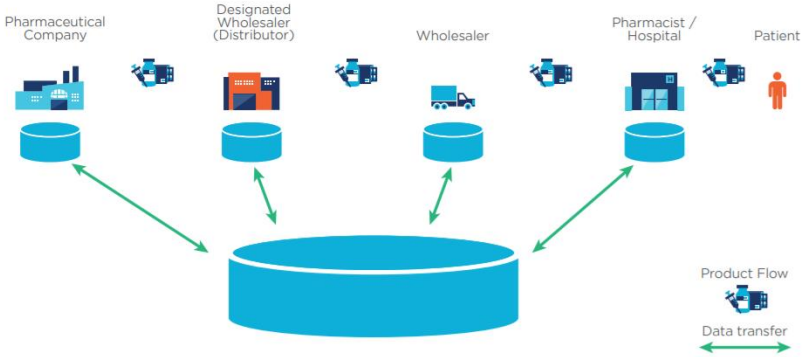


Two different main approaches

- Can the product identification features be verified?
- Can the product be tracked to where it is – or traced from where it has been?

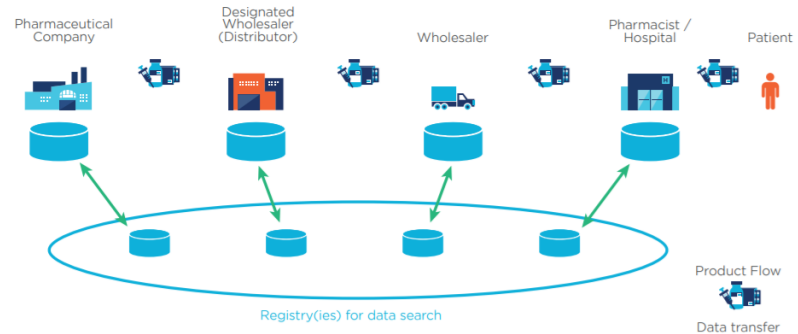


Centralised Track & Trace model



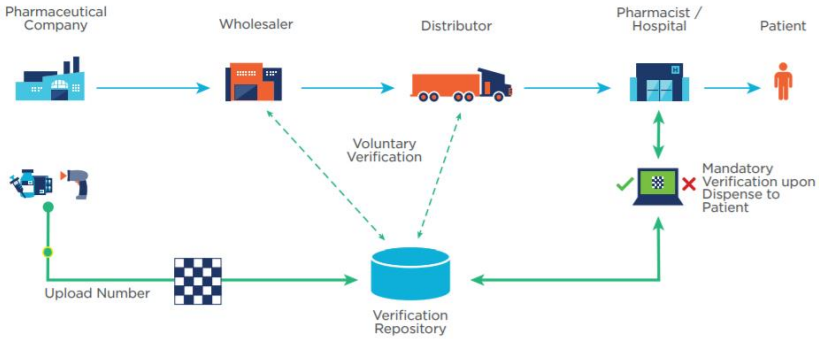
Benefits	Limitations
• Can be implemented in a phased approach • Governance usually managed by a single organisation such as the Ministry of Health • Data and system security is handled by a single organisation • GS1 identification standards are key • Provides high level of visibility across the supply chain	• Limited selection of solution providers • Often includes proprietary interfaces • Complex security

Distributed Track & Trace model



Benefits	Limitations
• Supports collaboration • Cleary defined data ownership and data exchange standards • GS1 Identification standards are key	• Complex governance model • Complex security • Takes coordination and a longer timeframe to implement and make changes to the system • Limited visibility throughout the entire supply chain • All systems must coordinate downtime to ensure real-time response

Point of dispense verification model



Benefits	Limitations
• Supports collaboration • Cleary defined data ownership and data exchange standards • GS1 Identification standards are key • Data owner drives solution decision • Visbility for products registered in the system	• Complex security, governance and funding model • Limited visibility throughout the entire supply chain • Takes coordination and longer timeframe to make changes to system

Simple comparison of traceability systems

Objectives*	Anticipated Benefits	Centralised system	Distributed system	Point of Dispense Verification system
Improve patient safety	Minimises counterfeits or stolen products in the legitimate supply chain	✓	✓	✓
	Minimises counterfeits or stolen products dispensed and consumed by patients	✓	✓	✓
	Provides visibility of product status (e.g., expired, recalled)	✓	✓	✓
Improve payment monitoring	Enables efficient payment and payment monitoring processes	✓		✓
	Minimises reimbursement fraud	✓		✓
Improve supply chain efficiency	Provides visibility of where the product is throughout the supply chain	✓	✓	
	Enables efficient reverse logistics processes for returns and recalls	✓	✓	
	Enables efficient inventory management at the central level	✓		
	Enables efficient reverse logistics processes for returns and recalls	✓	✓	✓

The drivers…

- Regulation
- Government requests
- Hospitals / hospital groups
- Humanitarian organisations

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

Examples of some of the requirements, regulations and other developments

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 Chicuecuecue 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[1]. 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.

[1] 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.

USAID requiring GS1 standards

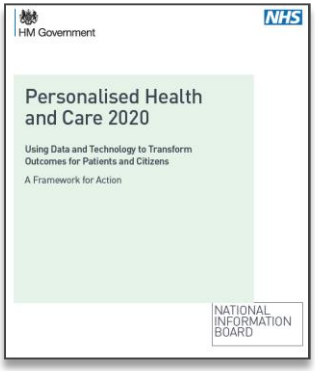
- After publication of guidelines for Reproductive Health Products USAID is now starting to implement GS1 standards.

- Letter sent to 700 suppliers sharing **USAID requirements for product identification, labeling, and data exchange following GS1 standards**, with a phased implementation from 2018 – 2022.

- Supporting material such as technical implementation guides, FAQ's etc. have been published – details can be found at http://www.ghsupplychain.org/globalstandards

USAID
FROM THE AMERICAN PEOPLE

England – NHS



Objectives:

- Deliver efficiency and productivity gains
- Improve data, information and transparency
- Re-think clinical engagement in procurement
- Improve trust capabilities in procurement

Actions:

- **Mandate through contracts GS1 standards GTIN, GLN and GDSN**
- **Create a single NHS GS1 data pool**
- Define standards for eProcurement
- Establish standards for datasets/classification
- Put implementation support in place

Protecting patients - the EU Falsified Medicine Directive

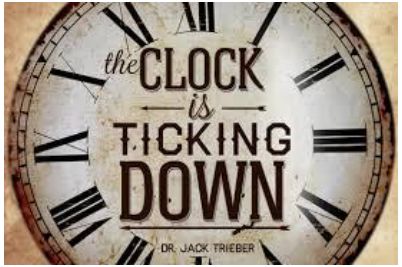
EU Falsified Medicine Directive 2011/62/EU (FMD)

http://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2011_62/dir_2011_62_en.pdf

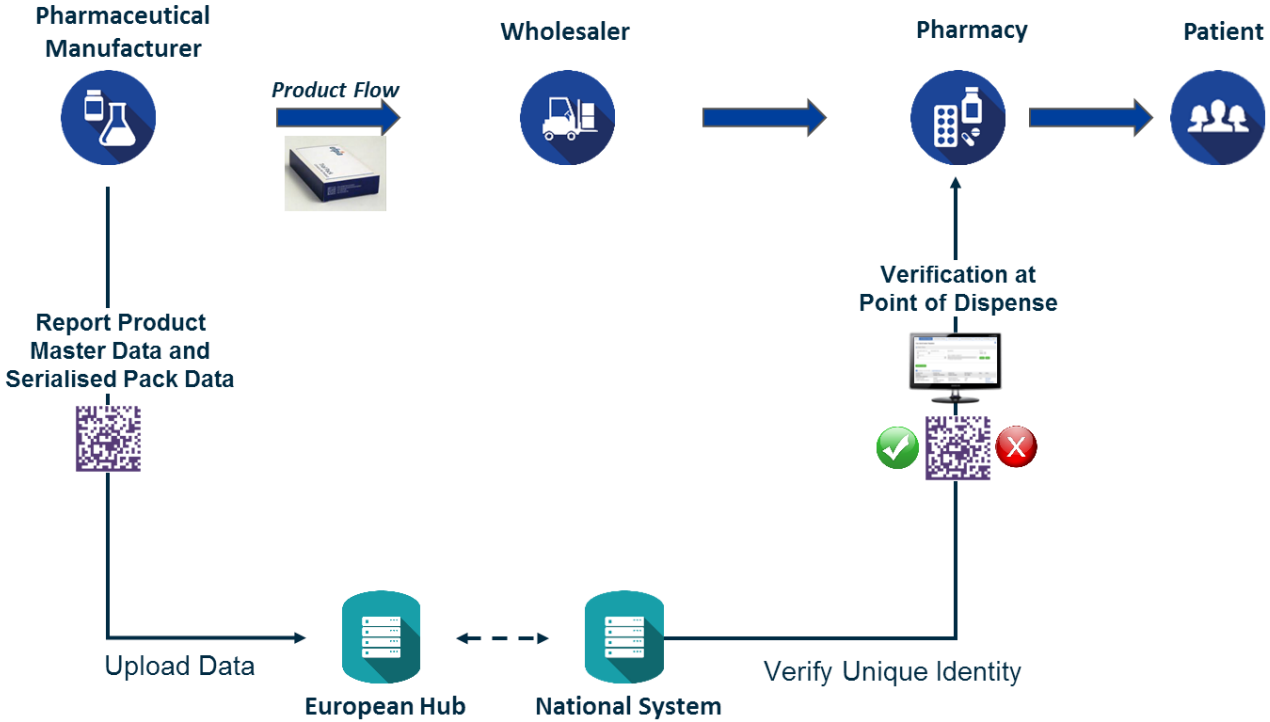
EU Commission Delegated Regulation 2016/161

https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2016_161/reg_2016_161_en.pdf

Prevent the entry into the legal supply of falsified medicinal products by requiring the placing of safety features consisting of a **unique identifier and an anti-tampering device** on the packaging of certain medicinal products for human use for the purposes of allowing their **identification and authentication**.



EU FMD representation - Authentication



EU pharmaceutical labelling requirements

Falsified Medicines Directive (FMD) 2011/62/EU outlines Unique Identifier (UI) required across medicinal products

– UI defined as alphanumerical code enabling the identification and authentication of individual packs

- Required by 9th Feb 2019

The UI will contain:

Product code: ISO 15459 compliant, <50 characters; globally unique (**GTIN** in GS1 terms)

Batch number

Expiry date

Serial number (≤20 characters; randomised)

A national reimbursement or ID #, optional **NTIN**)

Data Carrier

The UI is carried by a 2D barcode (Data Matrix ECC200, e.g. **GS1 DataMatrix**), the only 2D barcode allowed for authentication and identification of medicinal products

Resource

Falsified Medicines Directive (FMD) 2011/62/EU - **LINK**

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

Scope: Pharmaceuticals (prescription drugs)

Purpose: Traceability, combat counterfeit

Requirements :

- Packaging level: saleable units and homogeneous cases
- Data elements: NTIN, Expiry date, lot/batch number, serial number
- Data carrier: 2D DataMatrix
- Deadlines - Full track & trace after 10 years (2023)
- First phase lot based (2015) – delayed to 1 March 2016 for dispensers
- 2017: Serialisation by manufacturers & repackagers (SNI)
- 2018: Verification of saleable returns
- 2023: Provision of transaction info back to manufacturer

Traceability Model:
First lot based traceability, full track & trace in 10 years

US FDA draft guidance (Nov 2014) names **EPCIS** as a means of interoperable exchanging of pharmaceutical traceability data

India pharmaceutical labelling requirements

Directorate General of Foreign Trade's (DGFT)
Authentication, Track and Trace Requirements specify the following use of GS1 standards for coding and marking products at various packaging levels:

- Effective already

Product identifier consists of:

GTIN (GTIN-14)

Expiry date

Batch number

Serial number

Refer to 'BARCODING REQUIREMENT' in DAVA guide for specifics re: packaging level and type

Data Carrier

GS1 DataMatrix

GS1-128

Refer to 'PACKAGING LEVEL' and 'PACKAGING TYPE' of DAVA guide

Note: **EAN-13** with **GTIN-13** encoded as additional barcode ok on pack if required for other markets/POS - GTIN to be same across all barcodes applied to a pack

Resource

Drugs Authentication and Verification Application (DAVA) guideline – **LINK**

Australia – 2017, 2018
Serialisation of certain blood products

Status: Barcode specifications for blood and blood products funded under the National Blood Arrangements of Jan. 2015

Scope: Blood products – GS1 related requirements for all plasma, recombinant and diagnostic products

Requirements as applicable:

- 1 February 2015 – suppliers can commence the introduction of transition labelling
- 1 January 2016 – suppliers must implement transition labelling for all impacted products
- 1 January 2017 – suppliers must include the serial number data element for all impacted products
- 1 January 2018 – suppliers can cease the transition labels. All impacted products supplied must fully comply with the GS1 DataMatrix elements identified in the Barcode specifications for blood and blood products funded under the National Blood Arrangements.

Australia – 2020
Medicines labelling

Status: TGA requirements for medicines labelling – TGO91 & TGO92
Scope: all medicines

Requirements as applicable:

- All medicines must be compliant by 1 September 2020. There is a transition period from TGO69 to comply with all elements of the new acts
- In particular, on the use of GS1 standards for Prescription Medicines (detailed scope attached) the following has been included to TGO91:

  "machine readable code means a code that:

  (a) encodes the Global Trade Item Number (GTIN) for the medicine as allocated under the GS1 System; and

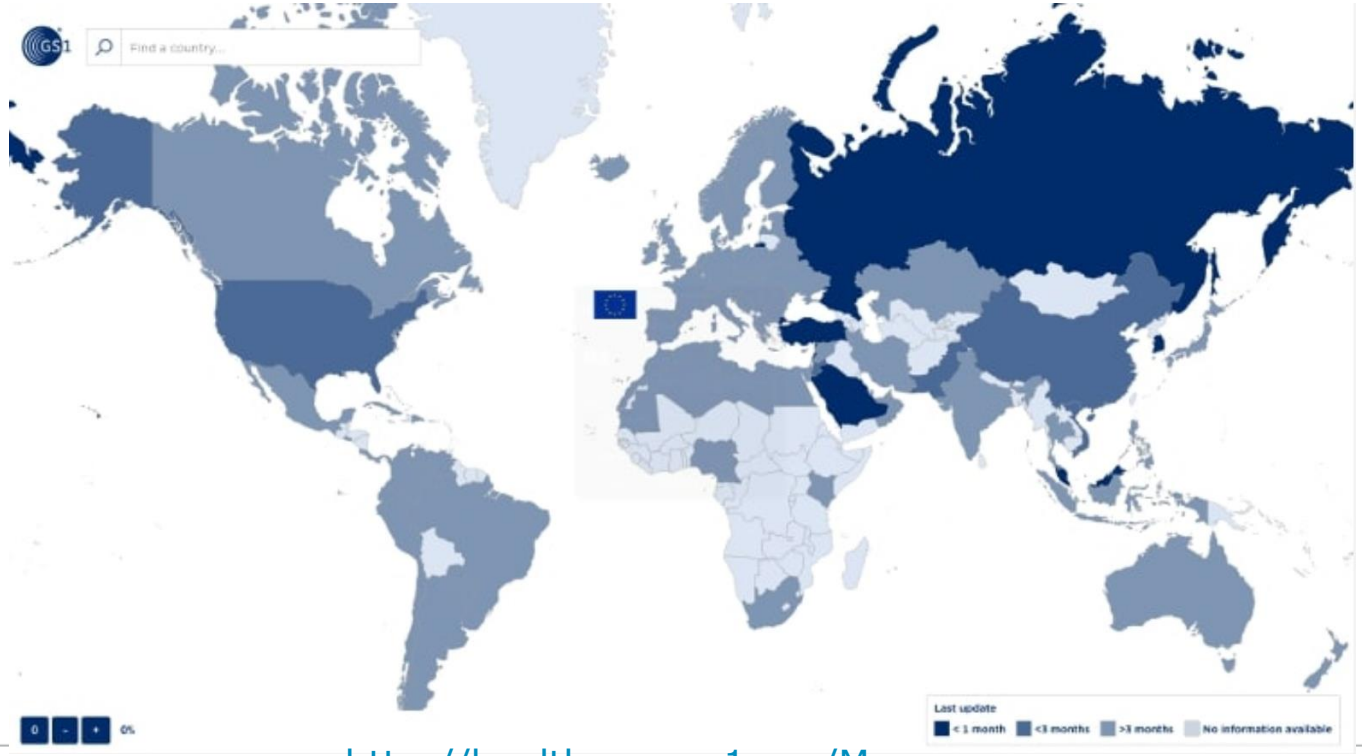
  (b) identifies different product variants and differentiates between different strengths, pack sizes and dose forms;

  (c) is formatted as one of the GS1 Bar Codes specified within the GS1 General Specification, which includes 2D / Matrix bar codes such as GS1 DataMatrix;
- Note: The machine readable code may also include additional information such as batch number and expiry date details."

  - Section 8 Information to be included on the label , subsection (n) states

  "a machine readable code, except where the medicine is a starter pack;"
- Important to note that TGO92 - which covers all products not covered by TGO91 (including non prescription, homoeopathic etc) - does not contain a machine readable definition nor requirement.

Interactive Map – Medtech/Pharma regulation



http://healthcare.gs1.org/Map.aspx

Primary Packaging identification…

For further information

Catherine Koetz
Industry Manager – Healthcare, GS1 Australia
Catherine.koetz@gs1au.org
+61 3 9550 3403

Useful links

- Interactive Map http://healthcare.gs1.org/Map.aspx#
- Medicinal Product Regulatory Roadmap https://www.gs1.org/docs/healthcare/Public-Policy/GS1_Healthcare-ROAD-MAP_FINAL.pdf
- GS1 standards within US FDA DSCSA
  https://www.gs1us.org/industries/healthcare/standards-in-use/dscsa
- Subscribe to Industry news

https://www.gs1au.org/for-your-industry/healthcare/subscribe-for-healthcare-industry-newsletters/

- Healthcare website https://www.gs1au.org/for-your-industry/healthcare/
- Primary Packaging paper https://www.gs1.org/sites/default/files/docs/healthcare/position-papers/single_unit_position_paper_final300617.pdf
- Position/Discussion Papers developed by GS1 Public Policy
  https://www.gs1.org/healthcare/position-papers