GS1 South Africa

consumer goods council of south africa

GS1 Standards are Vital for Pharma Serialisation

Michele Francis Padayachee

23 November 2018

GS1 South Africa

Antitrust Caution

Participants on GS1 committees, task forces, work groups, task groups, or other similar bodies, must always remember the purpose of the committee, task force, or work group is to enhance the ability of all industry members to compete more efficiently and effectively to provide better value to the consumer or end user. Because GS1 activity almost always involves the cooperation of competitors, great care must be taken to assure compliance with anti-trust laws. This means:

- Participation must be voluntary, and failure to participate shall not be used to penalize any company.
- **There shall be no discussion of prices, allocation of customers or products, boycotts, refusals to deal, or market share.**
- **If any participant believes the group is drifting toward impermissible discussion, the topic shall be tabled until the opinion of counsel can be obtained.**
- Meetings shall be governed by an agenda prepared in advance, and recorded by minutes prepared promptly after the meeting. Agendas, where appropriate, and minutes are to be reviewed by counsel before they are circulated.
- Tests or data collection shall be governed by protocols developed in consultation with and monitored by counsel.
- The recommendations coming out of a GS1 committee, task force, work group or task group are just that. Individual companies remain free to make independent, competitive decisions.
- Any standards developed must be voluntary standards.

GS1 – the global language of business

1 million

Developing standards for over 1 million companies worldwide

150 countries

25 industries served across 150 countries

5 billion

Barcodes scanned more than 5 billion times per day globally

112 MOs

112 Member Organisations around the world

GS1 Purpose

- **GS1 believes in the power of standards to transform the way we work and live.**

  - **We create** a common foundation for business by uniquely identifying, accurately capturing and automatically sharing vital information about products, locations and assets
  - **We enable** visibility through the exchange of authentic data
  - **We empower** business to grow and to improve efficiency, safety, security and sustainability

We are:

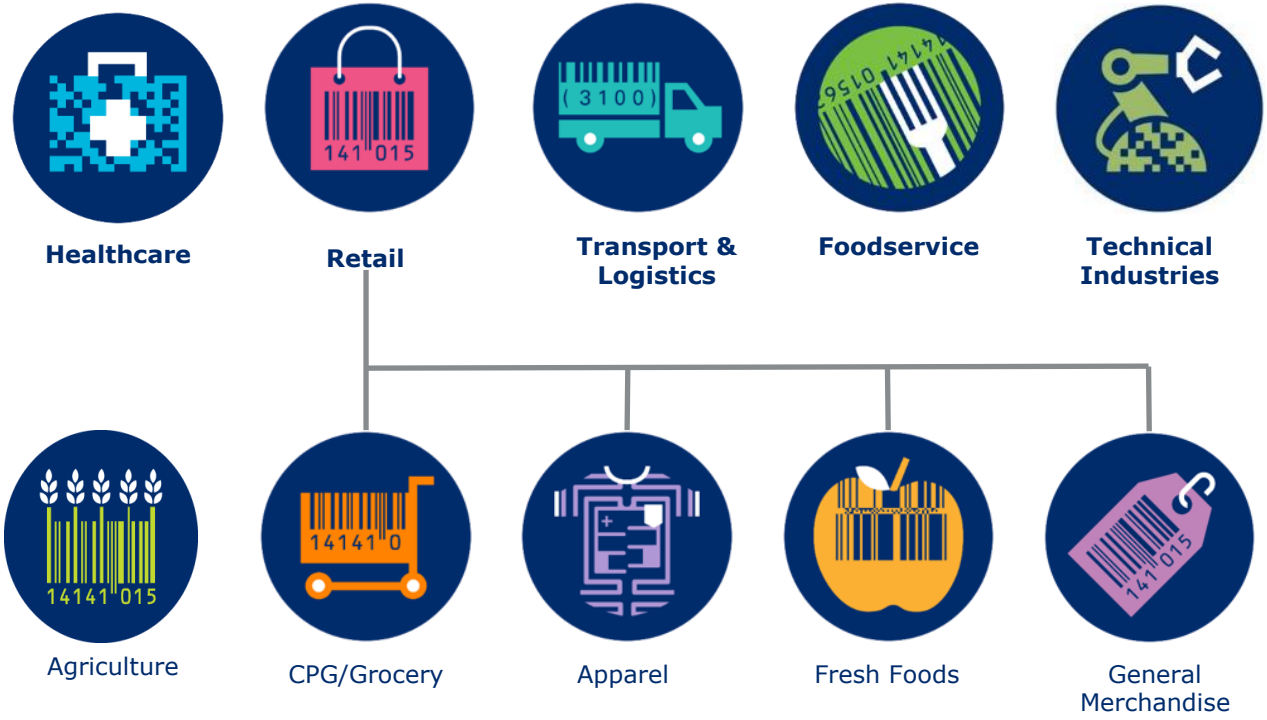
Neutral and not-for-profit

User-driven and governed

Local and Global

Inclusive and collaborative

Key industries served



GS1 Vision for healthcare

GS1 vision in healthcare is to be the ***recognised***, ***open*** and ***neutral*** source for regulatory agencies, trade organisations and other similar stakeholders seeking ***Input*** and ***direction*** for global standards in healthcare for:

Patient Safety

Supply chain security & efficiency

Efficient Traceability

Product Data

Healthcare sector in South Africa

- ***Future Health index*** ranked South Africa last, among ***19 emerging nations*** that measured ***healthcare system*** set for the future. Study included France, US, China, Brazil, Argentina. ***(commissioned by Phillips 2017)***

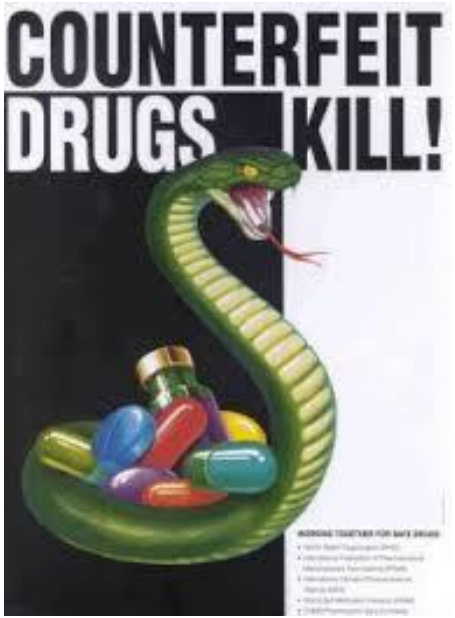
Public Sector	Private Sector
8.8 % of National Gross Domestic Product, 4 Trillion rands annually	
4.1 % of GDP	**4.4% of GDP**
Services 80% of Population	**Services 20% of Population**
48% of healthcare spending	**50% of healthcare spending**
2% spent by Non – Governmental organisations	
3 Private hospital groups, Netcare, Life Healthcare and Mediclininc South Africa	

Between the lines NHS Video

Counterfeiting medicine

Definition WHO

- A counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and/or source.
- Counterfeiting can apply to both branded and generic products and counterfeit products may include products
  - with the correct ingredients or with the wrong ingredients
  - without active ingredients
  - with insufficient active ingredients or
  - with fake packaging.



SFFC = Spurious, Falsely labelled, Falsified, Counterfeit

The Impact

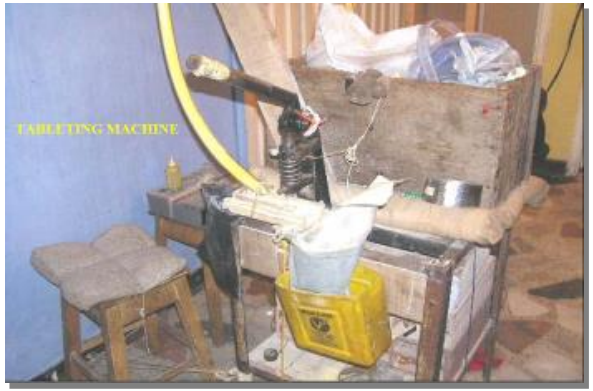
According to Interpol more than **one million people** die each year from counterfeit drugs!

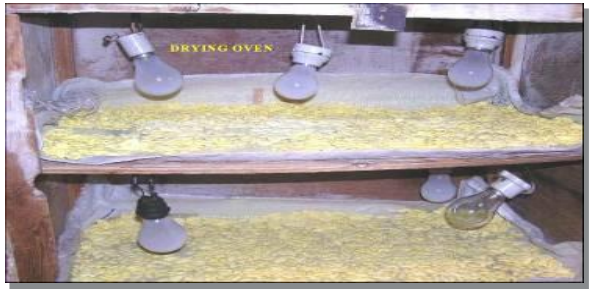
In some areas of Asia, Africa and Latin America counterfeit medical goods can form up to 30% of the market

The “favourites”

- Antibiotics
- HIV/AIDS
- Cancer medication
- Antidepressants
- Drugs to treat erectile dysfunction
- Weight-loss supplements
- Anti-Malaria medication
- Anti-Allergica
- …and more!

GMP ???



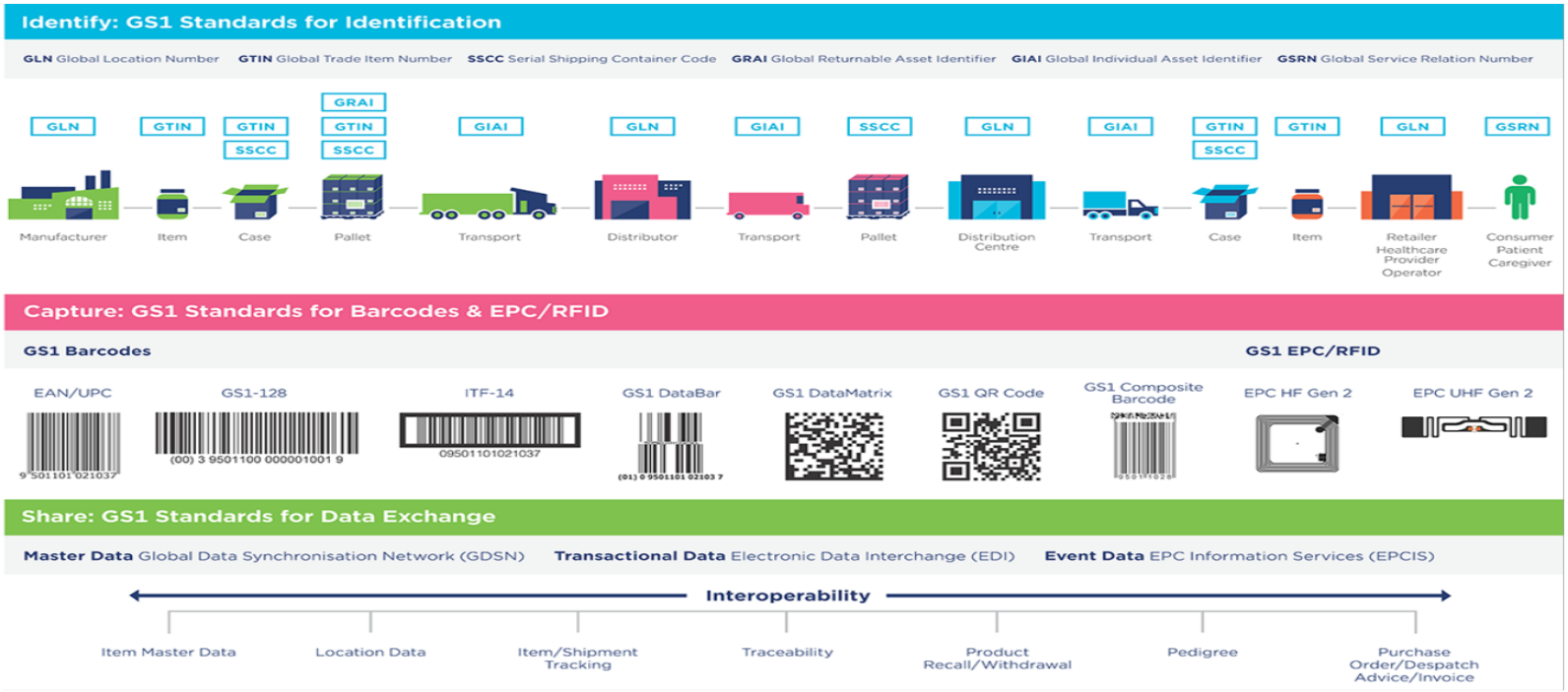


A counterfeit medicines « factory »

- The Pharmaceutical industry deals with the most frequently counterfeited products worldwide.
- This is a manufacturing process: the tableting machine and drying process belong to a criminal gang of **counterfeiters.**
- Where's the traceability, GMP*, safety, lot management?

** Good manufacturing practices*

Healthcare global system of standards



Many activities are going on…

...to prevent counterfeits reaching the patients and to secure the supply chain

in international cooperation with regulatory bodies like
US FDA, EU Commission and many other organisations

Actions

…are comprised of

- Creating awareness
- Securing the supply chain
- Building networks – single point of contacts
- Increasing penalties
- Serialization and Data Sharing.
- The intent of the Drug Supply Chain Safety Act (DSCSA) is ensure that every pharmaceutical item dispensed to a patient has a known path that is traceable through the supply chain.
- Deploying the system to enable this level of traceability is easier discussed then done.

For a secure supply chain

Supply Chain Dialog


Manufacturers


Logistic Providers


Customs


Distributors


Pharmacy/ Hospital /Clinic Dispensers


Regulators

Traceability Functions


Identify

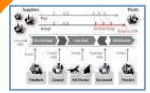

Verify


Track

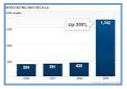

Trace

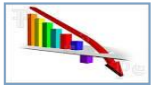

Report

Drivers


Supply Chain Visibility

Product Protection

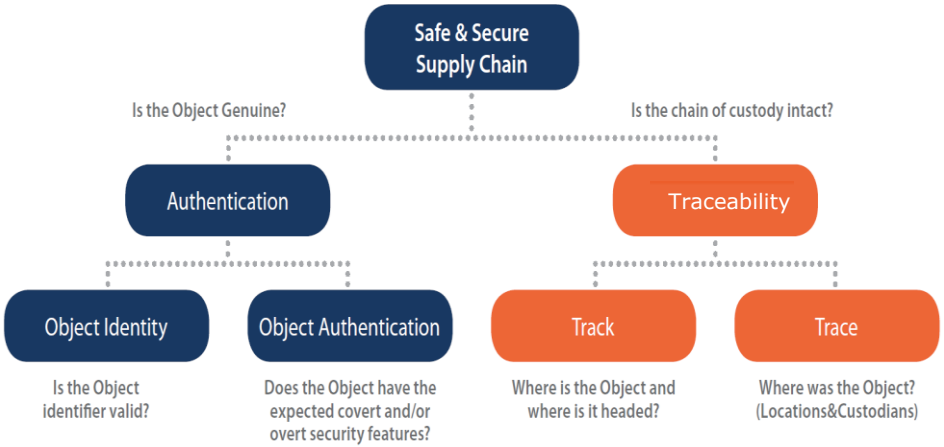

Recall Improvement


Returns, Shipment accuracy and efficiency


Reimbursement

Different approaches

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



Traceability across borders

Regulatory bodies need to address Public Health issues – one important being counterfeiting of drugs

Ensuring supply chain security and visibility can help to address this - deviations from a global harmonised approach make implementation much more costly and complex than with global data standards

WCO and GS1 cooperation

- GS1 has a long-time working relationship with the WCO since both organisations are committed to enabling a secure, efficient global supply chain

- In 2007, a MoU between GS1 and WCO was signed in recognition of the wide range of business interest shared by our organisations.

2005

Unique Consignment Reference (UCR)

2005/06

SSCC as UCR Pilot Project

2007

Memorandum of Understanding (MoU)

2006/09

EPCglobal pilot initiatives

2010

Global Shipment Identification Number (GSIN)

TODAY

Cooperation Agreement on Anti-counterfeiting

The challenges in healthcare industry

Master Data

- **No standard format for Product identification**
- **Medication procurement errors**
- Poor e-business communications
- Unable to authenticate Brand Owner
- Possible use of fake/ counterfeit products
- **Manual Processes throughout the supply chain**

Logistics

- Poor capacity planning
- **High volumes of returns**
- Picking errors
- **Incorrect product deliveries**
- Costs of excess weights at weighbridges
- Unable to track drug recalls.

Internal Process

- Lack of product visibility
- **No supply chain traceability critical for their patients**
- Poor inventory management
- Administrative errors
- Poor expiry date product management
- Reduction of credit notes due to expired product returns
- **Not able to link medical products to the patients in theatre.**

NDOH and GS1 Standards Update

Ephodia Nyathi from the DOH currently finalizing the Gazette Drafted in September 2018

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

- *Challengers with a follow up meeting with SAHPRA.*
- *With the proposed implementation dates looming, the matter is now being escalated to higher structures within SAHPRA.*

CAPTURE

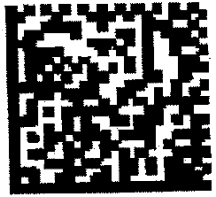
GTIN:	(01) 07046261398572
Batch:	(10) TEST5632
Expiry:	(17) 130331
S/N:	(21) 19067811811

f) Expiry date.

4. Proposed new requirements and timelines

This requirement would mean that the current scenario of an EAN-13 (European Article Number) barcode which identifies the package at an item level will be replaced with a GTIN-14 (Global Trade Item Number) barcode as a means of identification. The GTIN-14 barcode will include batch/lot and expiry data, and eventually a unique serial number.

EAN-13 Barcode

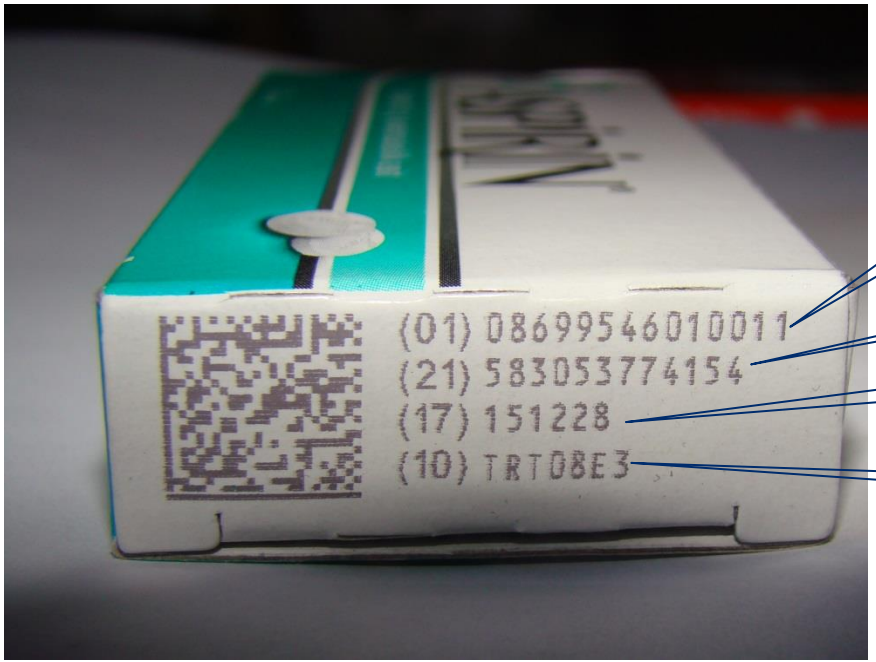


(01) 07046261398572
(10) TEST5632
(17) 130331
(21) 19067811811

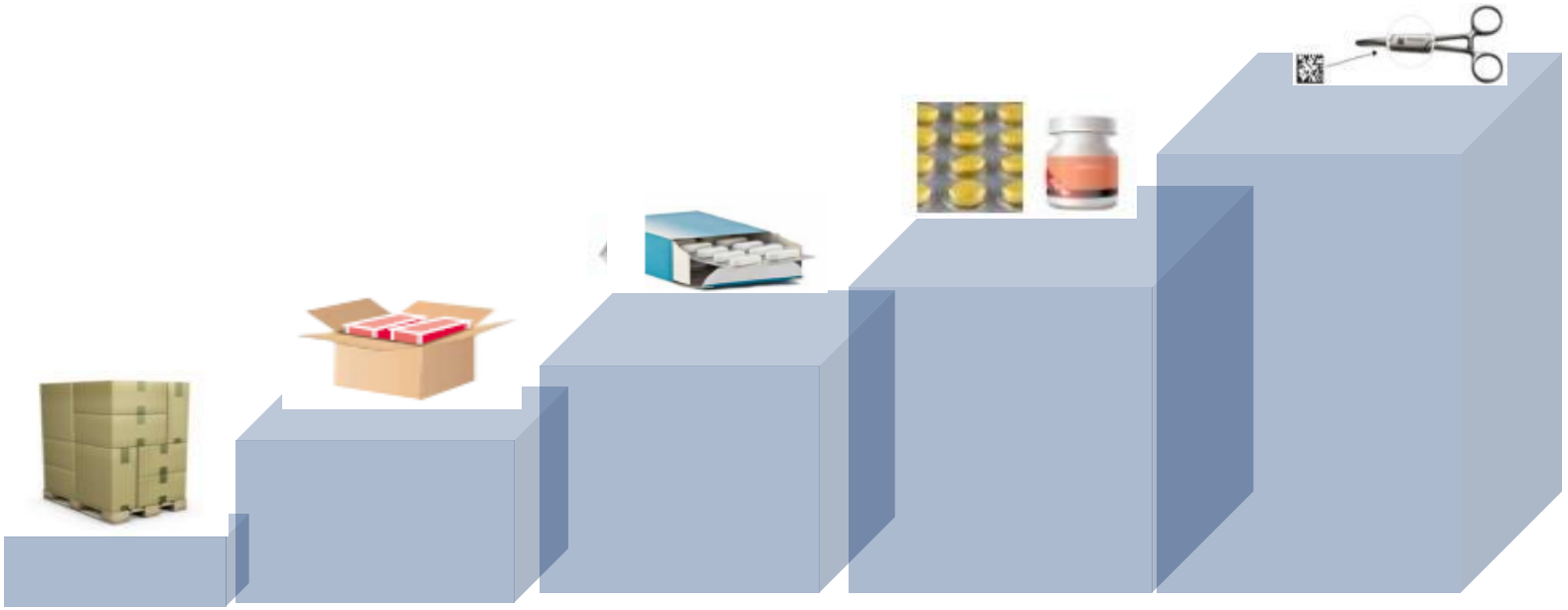
GTIN-14 Datamatrix Barcode

It is envisioned that the implementation of the GTIN-14 Barcode structure will be phased in according to international suggested best practice implementation timeframes as follows:

GS1 Datamatrix



Packaging hierachy in healthcare



Data requirements in healthcare

	Healthcare Product	GS1 Identification Key	Additional data	Encoded information and GS1 data carrier
Primary packaging (one pill in the blister cell)		GTIN "1"	Lot ABC Expiry date 31-Dec-2010	(01)07665431234566(17)101231(10)ABC Suggested GS1 Data Carriers: GS1 **DataMatrix,** or (01)07665431234566 Suggested GS1 Data Carriers: GS1 DataMatrix
Secondary packaging** (two blisters in one box)		GTIN "2"	Lot ABC Expiry date 31-Dec-2010	(01) 07665433456781(17)101231(10) ABC Suggested GS1 Data Carriers:GS1 **DataMatrix** and **EAN/UPC

Data requirements in healthcare

	Healthcare Product	GS1 Identification Key	Additional data	Encoded information and GS1 data carrier
Multi-pack (7 boxes) This is only an example of another packaging level		GTIN "3"	Lot ABC Expiry date 31-Dec-2010	(01)07665431234887(17)101231(10)ABC or (01)17665431234563(17)101231(10)ABC Suggested GS1 Data Carriers: **GS1-128**; GS1 DataMatrix
Case (8 multi-packs)		GTIN "4"	Lot ABC Expiry date 31-Dec-2010	(01)07665431234573(17)101231(10)ABC or (01)27665431234560(17)101231(10)ABC Suggested GS1 Data Carriers:**GS1-128**, GS1 DataMatrix

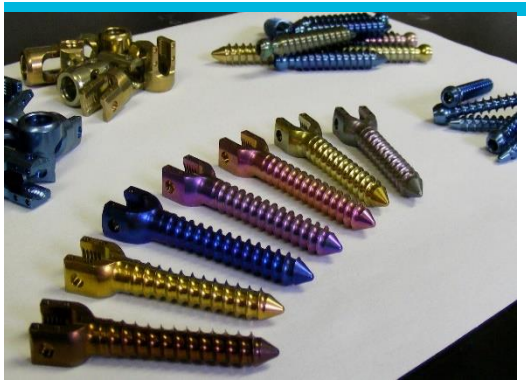
Timelines

Requirement	AIDC	December 2018	June 2020	June 2022
Primary Packaging	• GS1 Linear Barcodes. • GS1 128 • GS1 Datamatrix	(01) GTIN	• (01) GTIN • (10) Batch/lot number • (17) Expiration Date	• (21) Serial Number
Secondary Packaging, Trade item or Case	• GS1 Datamatrix • GS1 128- Linear • ITF 14	• (01) GTIN • (10) Batch/lot number • (17) Expiration Date (if available)	• (01) GTIN • (10) Batch/lot number • (17) Expiration Date	• (21) Serial Number
Tertiary Packaging, Logistics Item(Pallet)	• GS1 Datamatrix • GS1 128- Linear	• (01) GTIN • (10) Batch/lot number • (17) Expiration Date • (if available)		• (21) Serial Number

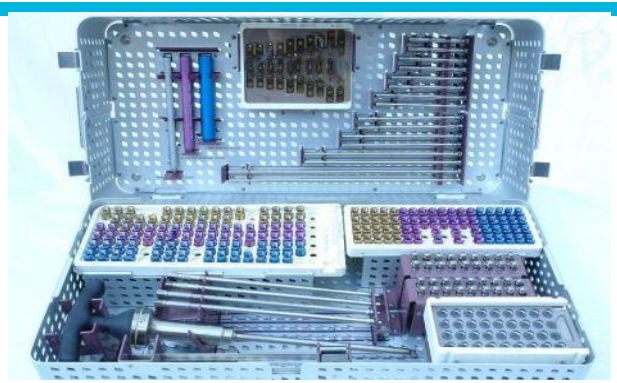
Netcare GS1 Standards Project

- Initiated in 2016
- Motivated by the National Health Service implementation of GS1 Standards
- Netcare Unitas and Waterfall identified as pilots
- Two part compliance:
  - Products to have GS1 data Carriers
  - Load Master data attributes on Global Data Synchronisation Network (GDSN)
  - Publish product information to Netcare electronically.

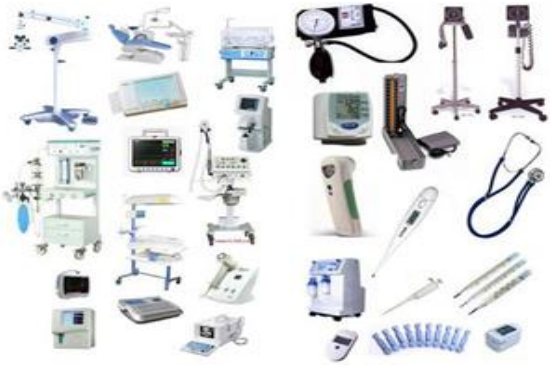
Global Healthcare items



Surgical Implants



Loan Sets



Medical Devices

Pharmaceutical products

Medical Kit

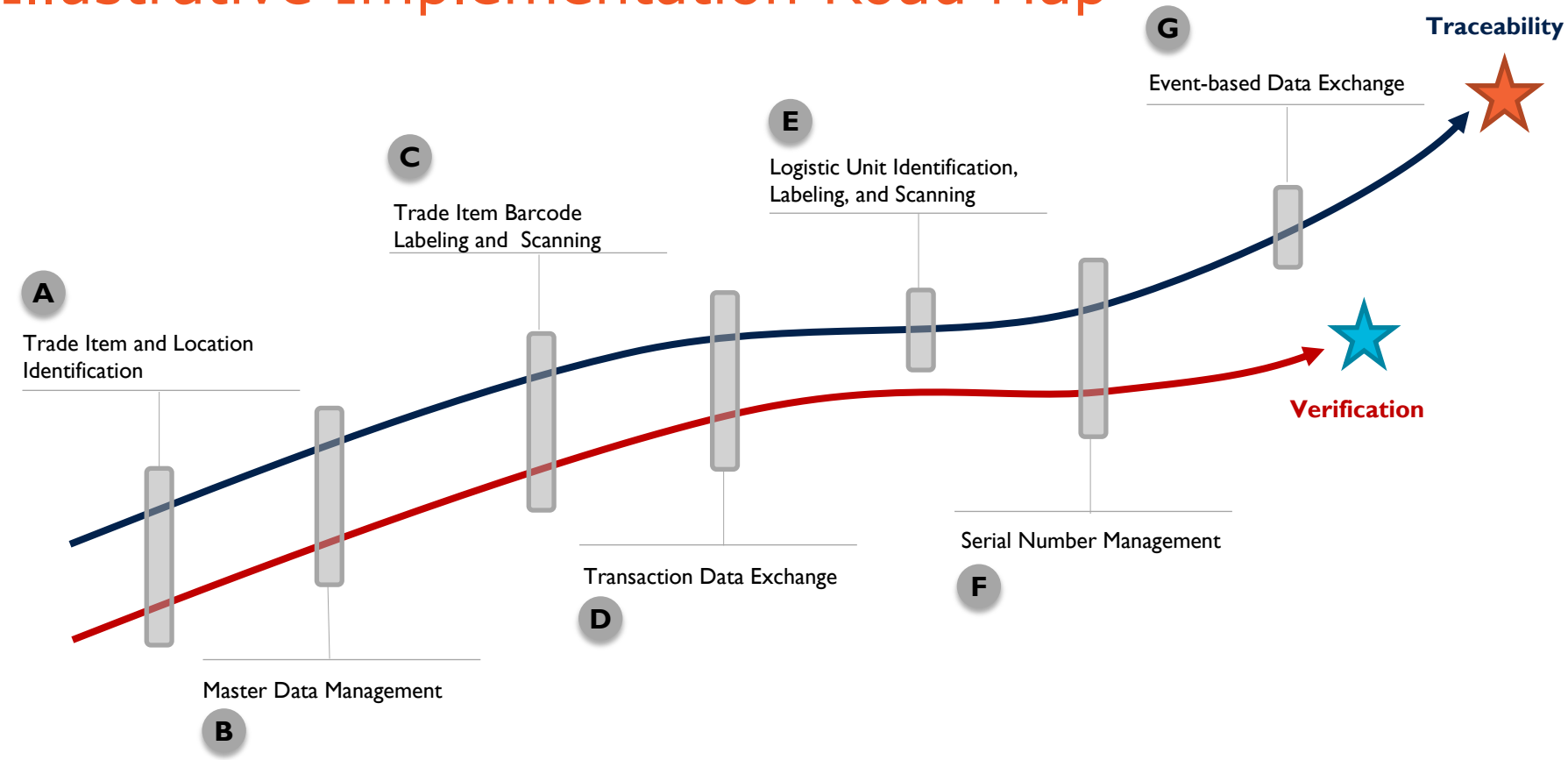
Directly on item identification

- ***Direct part marking***, is done by dot peening on items, such as medical instruments, medical devices *(FDA UDI using GS1 System to comply)* and surgical implants
- ***Laser or chemically*** etched parts with low contrast or light marked elements on a dark background (e.g. medical instruments, surgical implants)

GS1 Symbology in Healthcare

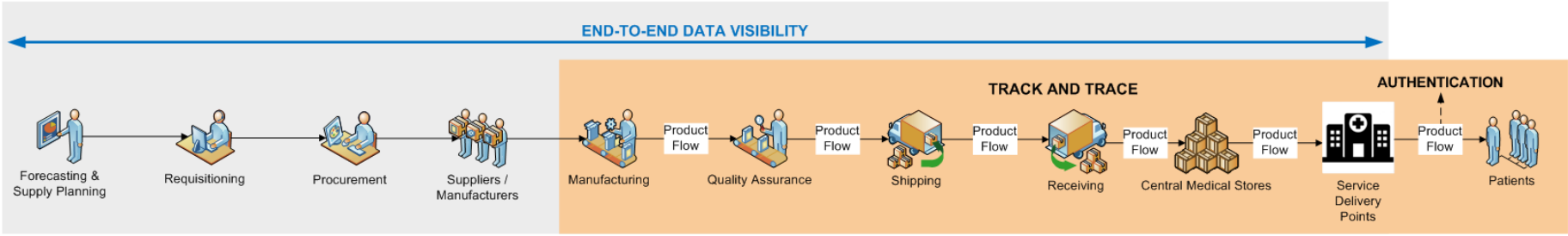
- GS1 128

Illustrative Implementation Road Map



For more detail on the capabilities required at each Road Marker, please see Appendix B.

Traceability **vs.** End-To-End Data Visibility



	End-to-End Data Visibility	Traceability
Objective	• Visibility of data from planning till delivery of products/commodities ✓ to enhance decision making • Monitor execution ✓ to guide every task and manage supply chain exceptions	• Tracking movement of products across supply chain ✓ to improve supply chain efficiency. • Tracing where products came from and where they went to ✓ to facilitate product recalls & patient safety • Verification of products ✓ to remove counterfeit & improve patient safety
Scope	• Strategic, Tactical & Operational • Processes & data related to supply chain planning, order management as well as physical product movements	• Operational/Transactional • Processes & data related to physical product movements
Level of Detail	• Data aggregated at product level	• Data at Trade item level, batch level & serial number level
Benefits	• Manage supply chain exceptions such as delays, stock outs & demand fluctuations • Facilitate better decision making around supply planning • Better coordination across supply chain enabling efficient allocation of resources	• Ability to locate products accurately through different stages of supply chain • Improved Patient safety • Elimination of counterfeit products • Ability to recall products effectively

So to make it easier…

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…there is help

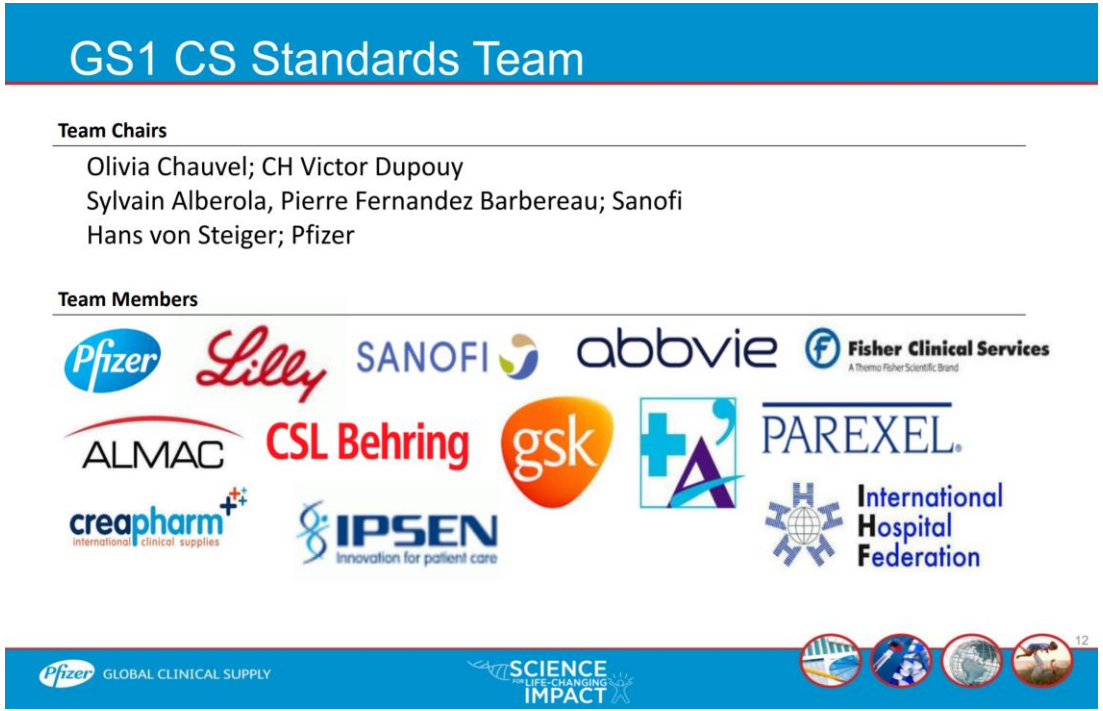
Bar Code Print Quality Verifiers are available for testing 2D Matrix symbols like GS1 DataMatrix

Check out the AIM Buyer's Guide for a listing of most manufacturers

GS1 clinical trial processes work group

- Commenced April 2018, meeting weekly
- By early next year, will develop **a guideline that details how GS1 standards can apply in pharma clinical trial processes**
- Run via teleconference
- Collecting business requirements to inform standards application

The work group…



Lots of progress made, and lots that we need to consider!

- Identification of levels of packaging
- Blinded / non-blinded trials
- Protocol / trial identification
- Packaging space
- Ancillary and auxiliary products
- Many other things to consider… Would love your feedback!

The goal is to have the guideline ratified and released by Feb 2019

Working in collaboration

Explore and develop opportunities to work together
to address the challenges facing the development of global therapies and health-related research endeavours

Bridging Blockchains

Interoperability is essential to the future of data sharing

Bridging Blockchains

Interoperability is essential to the future of data sharing

- Improving the flow of products and enabling more sustainable and transparent supply chains are critical goals for many organisations today. Increasingly, these organisations are evaluating blockchain technology due to its potential to transform business processes and deliver new capabilities for data sharing, visibility and trust.
- Blockchain technology gained initial popularity as an enabler of Bitcoin and cryptocurrency exchange. GS1 is bringing industry together to evaluate distributed ledger technologies through the lens of enabling enterprise business processes, removing friction and reducing costs.

Call To Action

Industry has recognised GS1's proven standards for identification and event-data sharing as best practice to support information-related business processes. A number of solution providers and ecosystems are already using GS1 standards in their enterprise blockchain implementations across a number of sectors and around the world.

As the number of blockchain ecosystems increase and begin to tackle enterprise business challenges, the need for interoperability rules and discovery of data between ecosystems is growing. Additionally, a need for governance around ecosystem interoperability is becoming increasingly important for industry.

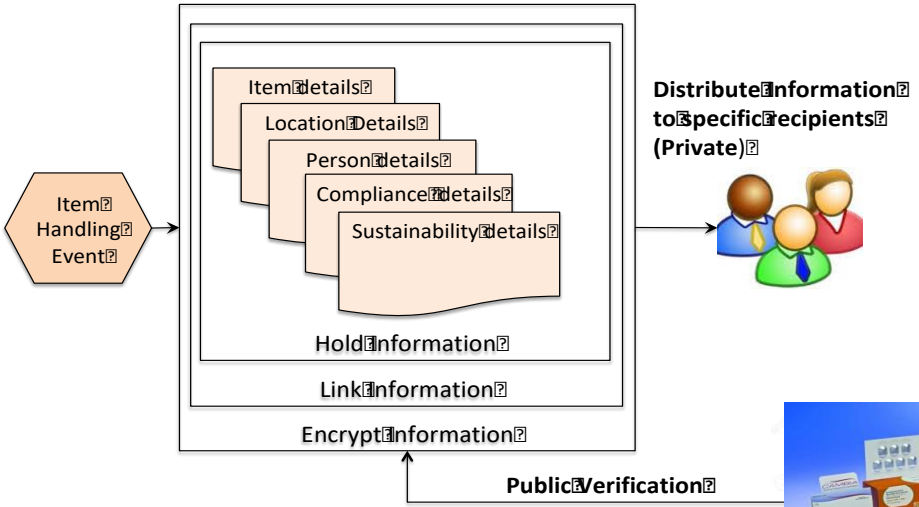
GS1 has been a place for collaboration for 45 years and is ready to facilitate conversations about interoperability and to provide a place where collaboration can happen globally. Solution providers, industry leaders and consortium operators are invited to come together to start the conversation.

GS1 will soon be forming a discussion group to outline and formulate necessary industry requirements for interoperability. We hope that you'll join us to solve these next challenges together.

Interested in participating or learning more?
Contact blockchain@gs1.org

"Aligning to GS1 standards for item identification and transactional data sharing is at the center of Wegmans' strategy to prepare ourselves for the promise of blockchain by ensuring those data fundamentals are in place all along the supply chain. In addition, we encourage active participation in developing guidelines for governance and interoperability across the various blockchain platforms that are emerging."

Promising new technologies: Distributed Ledger Technologies (e.g. Blockchain)

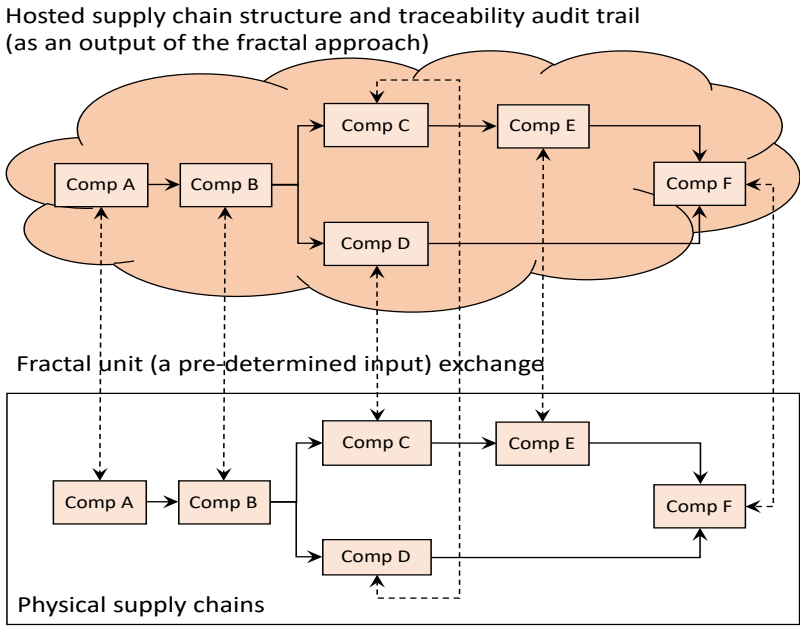


Promising new technologies: Fractal Traceability

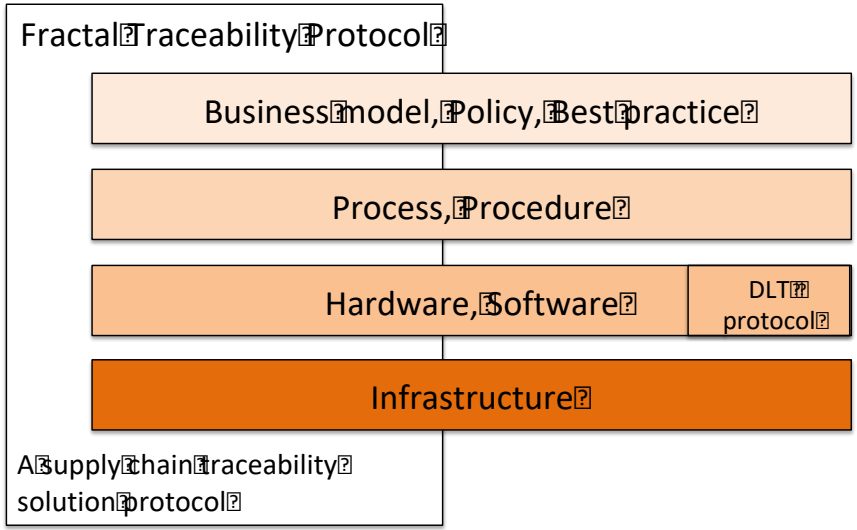
1. A way:
- to re-construct within-organisation traceability and between-organisation traceability, and
- to map out the supply chain as companies trade, and
- to create and maintain a traceability audit trail per item per organisation per supply chain in a value chain

2. Based on the use of a predetermined fractal unit as defined in fractal theory

3. Embedded as an artificial intelligence algorithm in a system



Promising new technologies: Co-existence of fractal traceability and DLT's



Promising new technologies: Value Chain Architecture

Value Chain Management Approach		Enterprise Management Approach
Value Chain level, i.e. Virtually Integrated Value Chain Programmes	**Business Model**	Enterprise level, i.e. Low Cost Leader model
Operates across an unlimited number of organisations and supply chains nationally, regionally and globally	**Coverage**	Operates within the confines of the IT-jurisdiction of the Enterprise
Business leverage and Risk Management across an entire industry sector, centralised or decentralised risk **coordination**, industry wide impact	**Enablement**	Business leverage and Risk Management within the Enterprise only, centralised risk **control**, impact only inside Enterprise
Scalable at national, regional and global levels	**Scalability**	Scalable only within the Enterprise
• Regulation (national, regional, global) • Global standards and protocols • Supply chain transparency (participants and consumers) • Supply chain efficiencies requirements	**Drivers**	Enterprise priorities
• Onboarding of participant organisations • Information sharing between organisations • Collection of levies and fees • Maintenance, support and functional expansion via a NPC • Compliance across organisations to agreed standards	**Coordinate**	• Access • Desktop support • Maintenance, support and functional expansion via IT department • Compliance within enterprise

Peggy Staver
Pfizer

"Given the increased complexity of global supply chains and the proliferation of pharmaceutical serialisation mandates we are seeing today, it is critical that we have a common means by which to identify, capture and share key product attributes and distribution information about our medicines. Standards-based solutions such as those developed by GS1, help to ensure interoperability of the solutions being deployed to enhance patient safety, improve supply chain transparency and efficiency, and deter pharmaceutical counterfeiting, theft and diversion. GS1 provides a forum for dedicated industry stakeholders to work side-by-side to address issues impacting the potential safety of the patients we serve."

Grant Courtney
GSK

"Seven years ago, the prospect of serialisation was a daunting one, with the potential for every country to introduce market specific requirements; making it almost impossible for multi-national organisations to respond to the level of complexity this would have introduced. GS1 has worked tirelessly with industry and legislators to ensure the use of GS1 standard are adopted, which will ultimately help us protect our patients and reduce the risk posed by fake products."

Voices of our customers

"A lack of interoperability is the source of considerable additional time and effort. What should be simple becomes complex simply because trading partners don't leverage standards." ~ *Healthcare*

"Achieving greater adoption of GLN upstream is necessary. It is currently a major stumbling point to achieving end-to-end visibility." ~ *Foodservice*

"GLN and GTIN are key enablers, but more needs to be done to standardize data generated upstream for use down through the entire chain." ~ *Solution Provider*

"GS1 standards are perceived to be crucial. But, there is a general lack of in-depth understanding of the GS1 organization and GS1 standards." ~ *Healthcare*

Thank You