



The Global Language of Business

GS1 Healthcare – GS1 system Introduction session

30th Global GS1 Healthcare Conference
Beijing, China

Du Han, Assistant Director, Promotion Department, GS1 China
25 October 2016

GS1 & GS1 Healthcare



GS1 – an international standards organisation



Not-for-profit
112 Member Organisations
Over one million user companies
(from SME to global companies)
Member driven
150 countries served; 20 different domains
2,700 people helping us
Over 6 billion transactions a day



GS1: The Global Language of Business



GS1 is a neutral not-for-profit organization driven by its users, that facilitates collaboration amongst trading partners, to create more efficient, safer and sustainable value chains through global standards.

GS1 is both global and local



GS1 Global Office

Identification, creation, development and maintenance of standards and our foundational architecture, coordination with other international bodies, development of training programmes...

GS1 Member Organisations

Local offices in 112 countries around the globe. Implementation of standards, local regulatory adjustments, community management and relationship management with local governments and regulatory agencies...



Our Vision:

GS1 Healthcare envisions a future where the healthcare sector integrates GS1 Standards into supply chain processes for all relevant items, locations and people to drive patient safety and supply chain efficiency improvements.

Our vision 2005



The vision of GS1 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

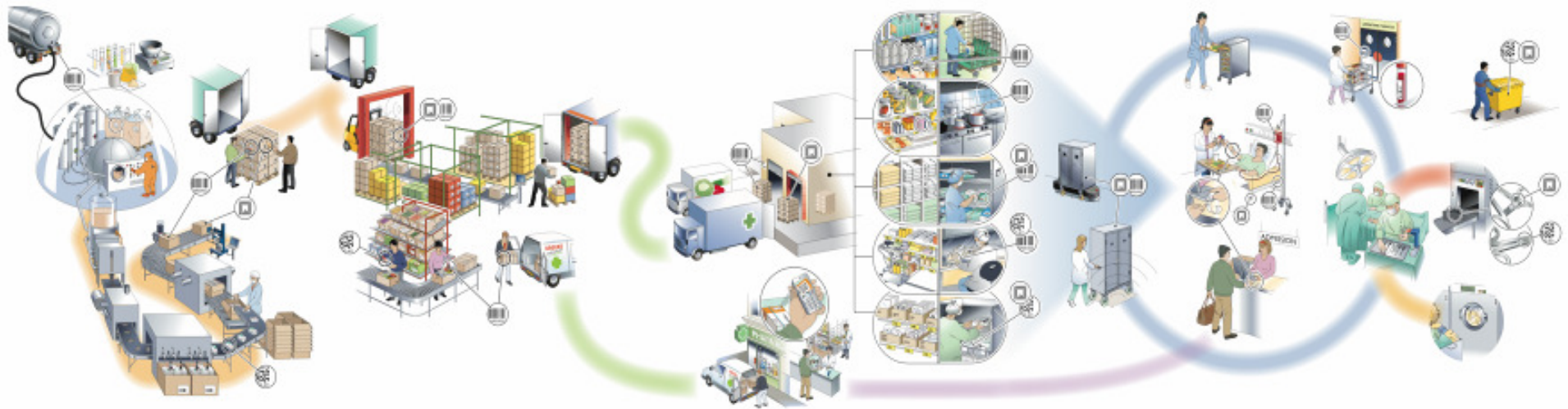


traceability



product data

Voluntary, Global Healthcare User Group



To lead the healthcare sector to the successful development and implementation of **global standards** by bringing together **experts** in healthcare to enhance **patient safety** and **supply chain efficiencies**.

5 suggested future focusses



- Unique device identification (UDI)
- Pharmaceutical traceability - serialisation and GS1 DataMatrix
- Single unit package marking - drugs
- Patient and caregiver identification
- Hospital implementation



GS1 Standards for Healthcare



GS1 Standards for Healthcare

Standards development continues, but global standards are **ALREADY available to build on:**



- AIDC Application Standards for 90% of medical products
- AIDC Application Standards for small instruments
- Healthcare extension in next GDSN release
- Global Traceability Standard for Healthcare
- GTIN Allocation Rules for Healthcare
- Guideline for plasma derivatives
- Patient and Caregiver Identification
- AI for National Healthcare Reimbursement Number (NHRN)
- eCom guidelines order to cash

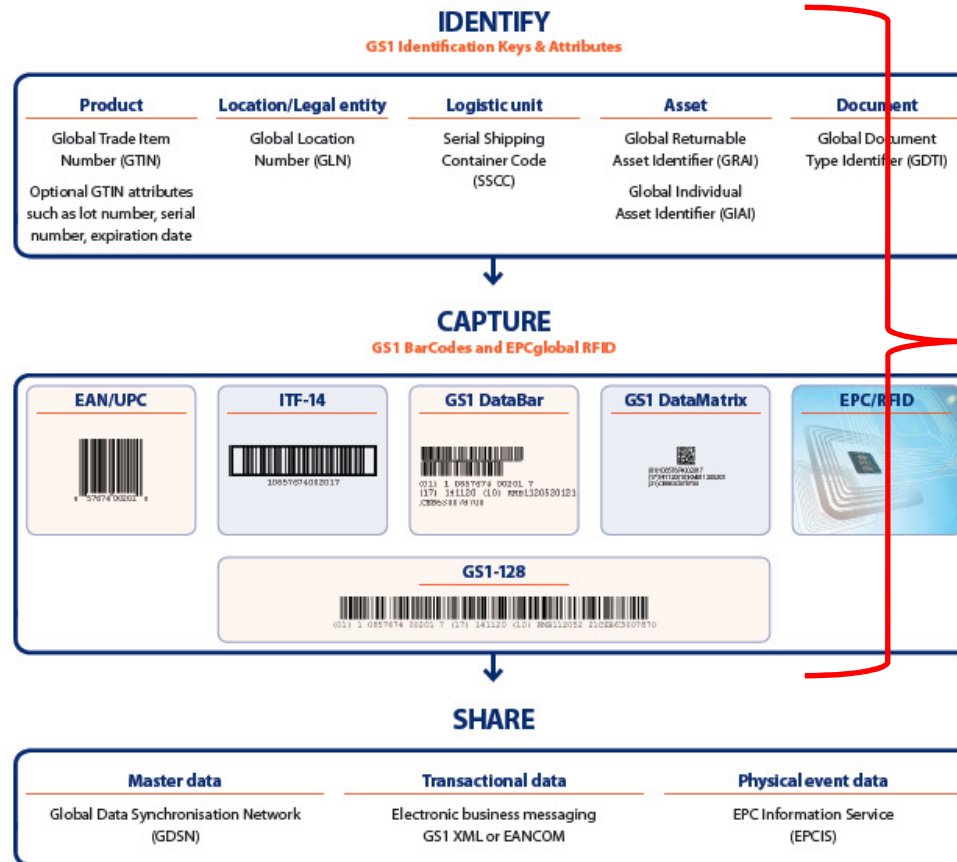
GS1 Standards in action across the entire Healthcare supply chain



Improving patient safety and supply chain efficiency



The GS1 System



The
"AIDC bits"



AIDC in Healthcare



Automatic Identification & Data Capture (AIDC)



“Automatic Identification and Data Capture (AIDC) refers to the methods of **automatically identifying** objects, **collecting data** about them, and **entering that data** directly into computer systems (i.e., without human involvement).”

Wikipedia, 2009



Healthcare AIDC Application Standards



GOAL - Define the data to carry, using specific data carriers, for every healthcare product, at every packaging level



VISION - EVERY item has ONE set of key identification data carried in ONE data carrier able to be scanned by EVERYONE at every key process step...



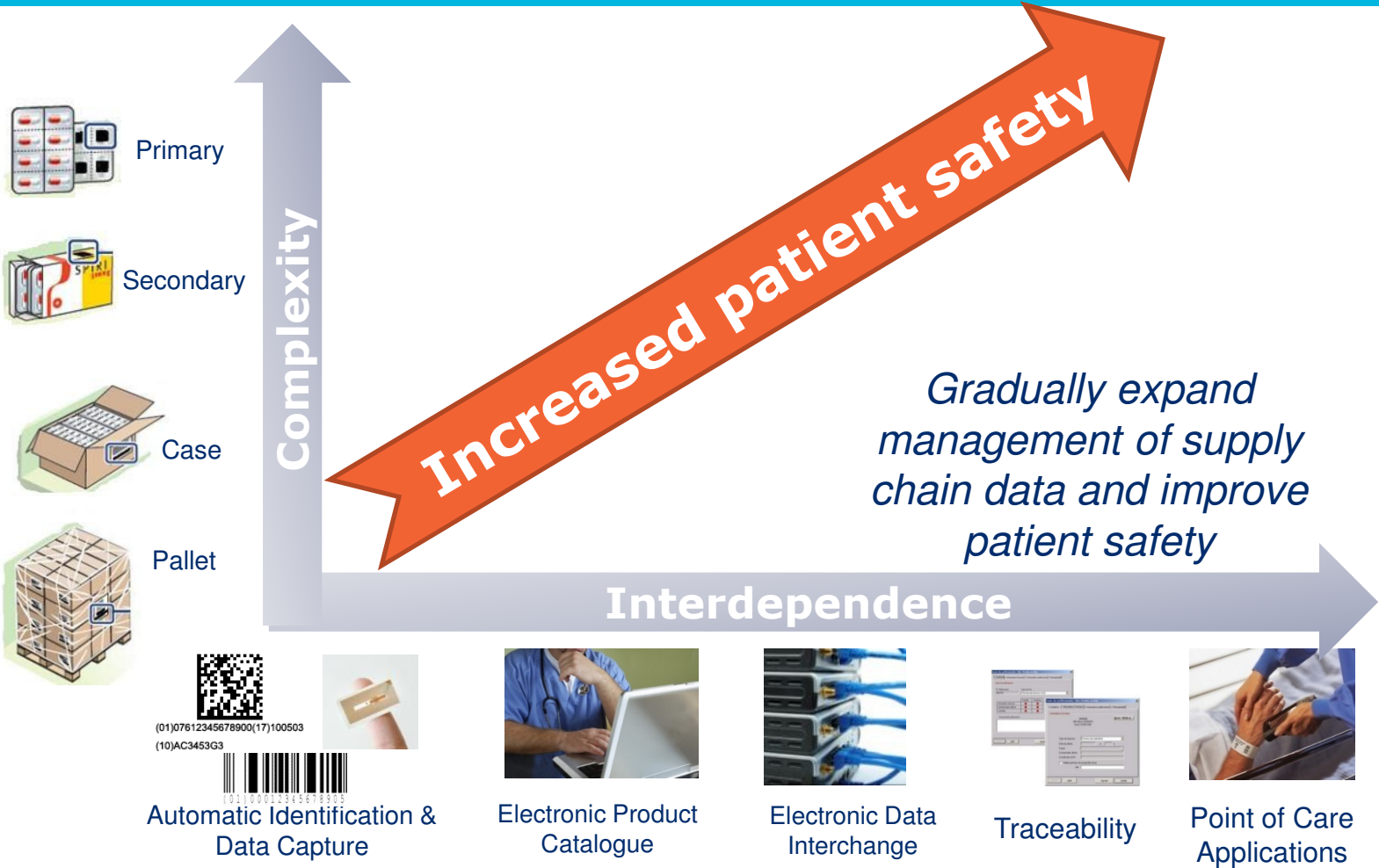
AIDC for Healthcare...Why?



- **To improve patient safety**
 - Achieve the “5 Patient Rights” / “8 Patient Rights”
 - Reduce errors
 - Ensure needed information is readily available to the healthcare practitioner
- **To increase efficiency in supply and treatment**



For a secure healthcare supply chain



Scope - All healthcare products



Pharma / Vaccine / Nutritional



Medical devices



Retail



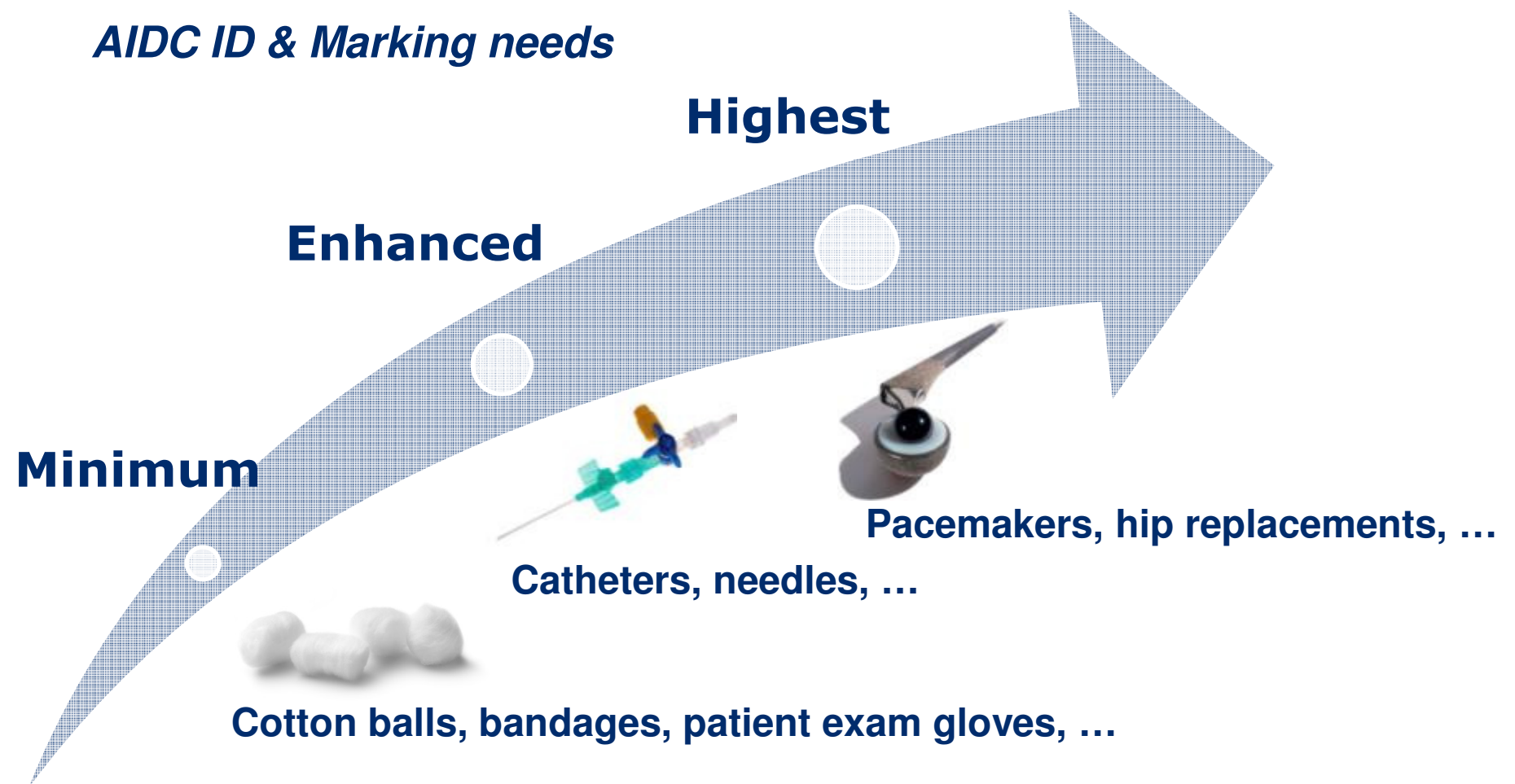
Non-retail



Scope - Data based on need



AIDC ID & Marking needs



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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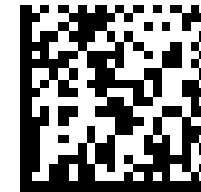
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Scope - Data & Data Carriers



Data – a few examples:

- Global Trade Item Number (GTIN)
- Expiry Date
- Batch / Lot
- Serial Number



(01)07612345678900(17)100503

(10)AC3453G3 (21)123

Data Carriers – a few examples:



(01) 0 0012345 67890 5



**GS1-128 &
GS1 DataBar**



(01)07612345678900(17)100503

(10)AC3453G3

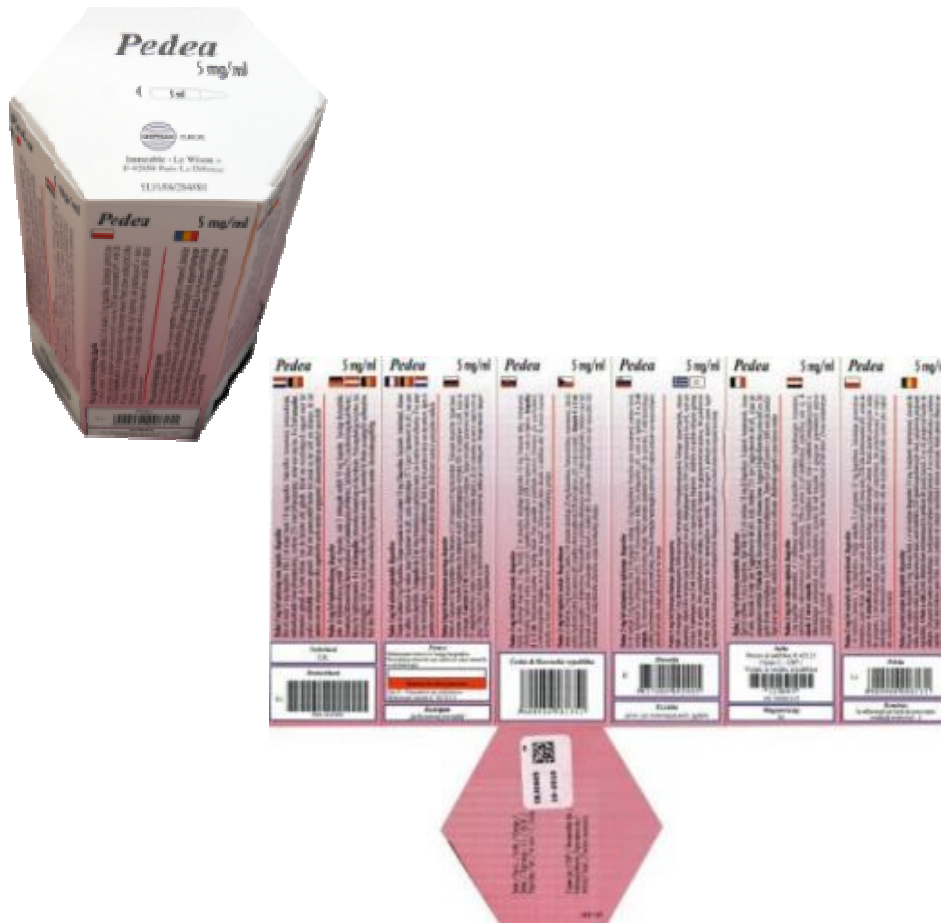
GS1 DataMatrix



EPC / RFID



Lack of standards – inefficiency & risk...



- 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

A need for global standards...



What happens when there aren't global standards?

- Inefficiencies
- Increased risk
- Lost opportunities

The Need for Global standards in Healthcare



Diverging country requirements
Manufacturing headache



“CUSTOMIZED ACTIONS MEAN COSTS!!

Harmonisation of regulatory requirements and data standards will enable efficiency of a global product offering – otherwise complexity and cost will continue to raise”

Senior Executive, MD company

...in Healthcare lack of standards can cost a life



GS1... Global AIDC standards...



**GS1 Standards ...
6+ billion 'beeps' per day**

Product identification in
Healthcare should be as
ubiquitous as it is in the
retail and grocery
industries



AIDC Application Standards... in Healthcare



Objective: develop global standards for the automatic identification and data capture for Healthcare products at all packaging levels.

Scope: Healthcare products - from finished goods at manufacture to the end of treatment at the Healthcare provider

Completed:

- Rules for HC GTIN Allocation
- AIDC Application Standard Phase 1 (covering 90% of healthcare products)
- HC AIDC Small Instrument Marking
- HC GLN Implementation Guide & Registry Strategy Recommendations
- HC AIDC Implementation Guideline
- AIDC for Blood Derivatives Guideline
- National Healthcare Reimbursement Number Application Identifier
- Patient & Caregiver ID Solution
- Multiple Bar Codes (initial work complete)
- Level below the Each

Completed (continued):

- Patient and Caregiver ID in ISO
- GTIN Non-reuse
- HC AIDC Updates
 - Custom, Configurable Trade Items
 - Clarifications on HRI, DPM application
 - HC Kit ID
 - HC Software ID

Next steps:

- Continued “maintenance” based upon implementation experience in lieu of new “Standards Development” as directed by the GS1 Healthcare Leadership Team



GS1 Standards for Healthcare



Maintenance continues, but global standards are ALREADY available to build on:



- AIDC Application Standards for 90% of medical products
 - ...includes Keys, AI's, Carriers, HRI, etc.
- AIDC Application Standards for small instruments
- Healthcare extension in GDSN release
- Global Traceability Standard for Healthcare
- GTIN Allocation Rules for Healthcare.
 - ...includes GTIN Non-reuse)
- Guideline for plasma derivatives
- Patient and Caregiver Identification
- AI for National Healthcare Reimbursement Number (NHRN)



Foundation of the GS1 System...



GS1 Identification Keys

Provide access to information held in computer files –
Information about company/location, package, product,
price, etc.



GS1 Identification Keys



Item identifier = **GTIN**

Global Trade Item Number



Logistics unit
identifier = **SSCC**

Serial Shipping Container Code



Location identifier = **GLN**

Global Location Number

And there are more ...

- Unique
- Non-significant
- International
- Secure
- Foundational



GS1 Identification Keys



- GTIN = Global Trade Item Number
Products or Services
- SSCC= Serial Shipping Container Codes
Individual Logistics Units
- GSRN = Global Service Relation Number
Recipient of services
- GLN = Global Location Numbers
Legal or Functional Entities and Locations
- GDTI = Global Document Type Identifier
Document Type
- GRAI = Global Returnable Asset Identifier
Returnable Assets
- GIAI = Global Individual Asset Identifier
Fixed Assets
- GSIN = Global Shipment Identification Number
Multiple Logistic Units for Trade (Shipper Assigned)
- GINC = Global Identification Number for Consignment
Multiple Logistic Units for Transport (Transport Company Assigned)
- GCN = Global Coupon Number
Coupons
- CPID = Component / Part Identifier
Component/Parts



The need to capture the trade item ID ... and beyond...



GS1 Keys prevail... but some users need more detailed information about that specific unit





GS1 Application Identifiers...

**GS1 Gen Spec includes 100+ "Application Identifiers"
a.k.a. "Key Attributes"**

Application Identifiers generally or commonly found in Healthcare

00	SSCC (Serial Shipping Container Code)
01	GTIN (Global Trade Item Number)
10	Lot / Batch
11	Production
17	Expiry Date
21	Serial Number
710	NHRN – Germany PZN
711	NHRN – France CIP
712	NHRN – Spain CN
713	NHRN – Brazil DRN
7003	Expiry Date + Time
7004	Active Potency
8003	GRAI (Global Returnable Assets Identifier)
8004	GIAI (Global Individual Assets Identifier)
8017	GSRN Service Provider
8018	GSRN Service Recipient
8019	Service Relationship Instance Number



The need to capture the trade item ID ... and beyond...



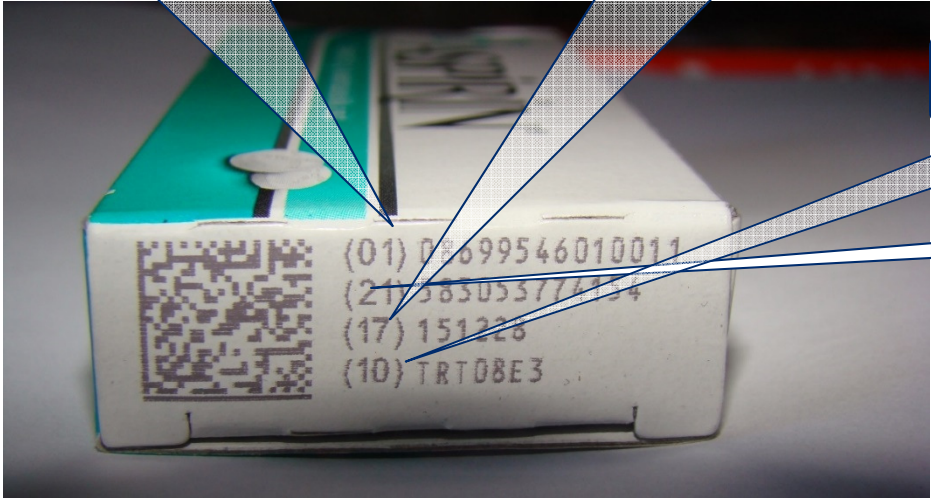
(01) 1022222333334 (17) 091231 (10) A1345B (21) 1234

GTIN

Expiry Date

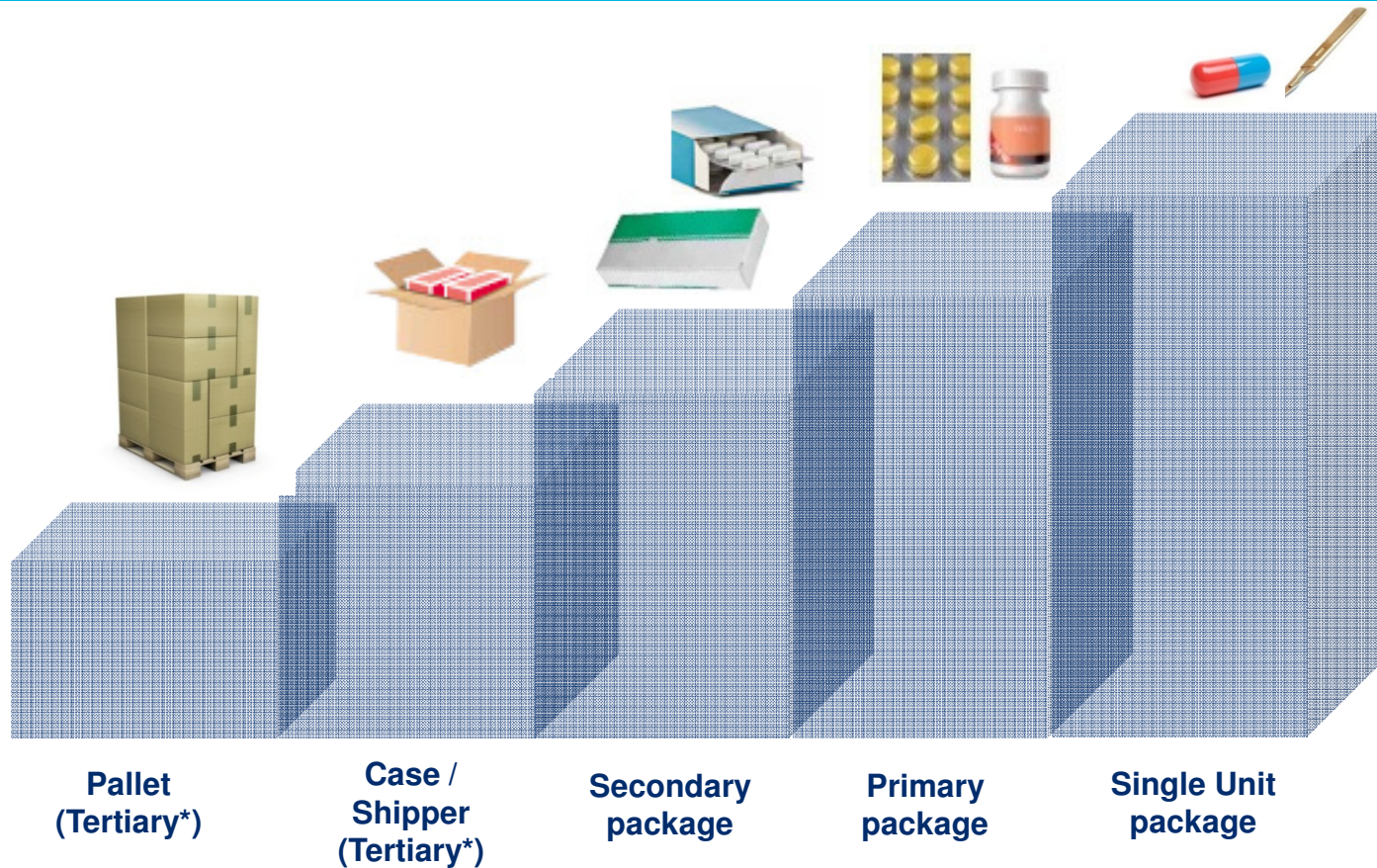
Lot/Batch Number

Serial Number



Packaging level hierarchies...

...identification at all levels...



NOTE: * - Potentially a new definition that is needed...



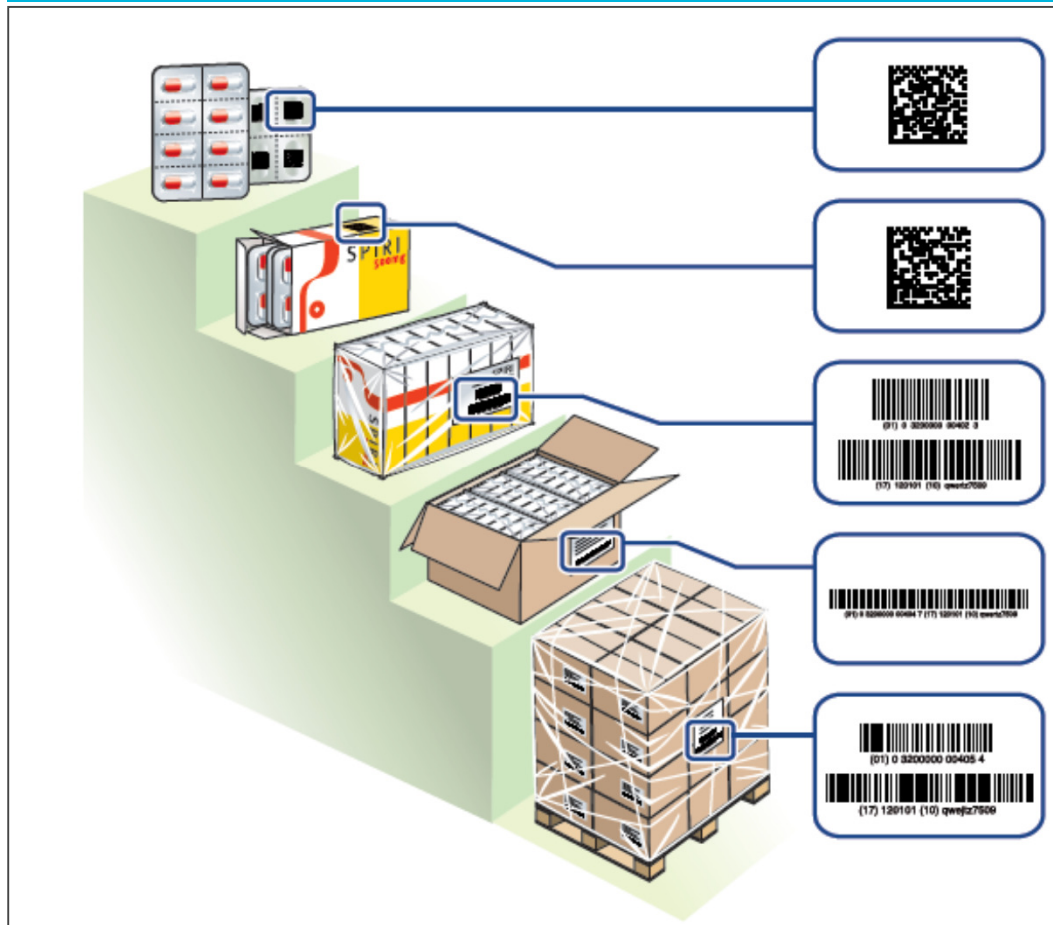
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Packaging hierarchy... Example

(Non-Retail – GTIN-13 & GTIN-14 use)



Check Digit
↓
GTIN A (GTIN-14)
29504000059273

GTIN B (GTIN-13)
9504000059279

GTIN C (GTIN-14)
49504000059277

GTIN D (GTIN-14)
69504000059271

GTIN E (pallet as a Trade Item)
(GTIN-14) 89504000059275

NOTE: Indicator Digits 1 thru 8 within the GTIN-14 are assigned to each level as determined by the manufacturer, there is no inherent significance to the number assignment. Indicator Digit 9 is reserved as per the GS1 General Specification. The last digit is the Check Digit, individually calculated for each GTIN.



Healthcare specific requirements



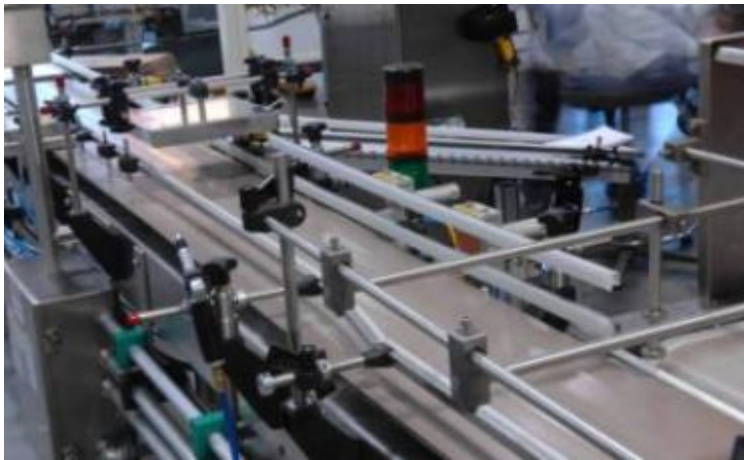
Expiration data & lot number



Small space



Direct part marking



Additional data & variable data at high production rates



Non-retail channels

Effective data capture



GS1 Data Carriers include bar codes and RFID

Scanner / Reader

Data carrier



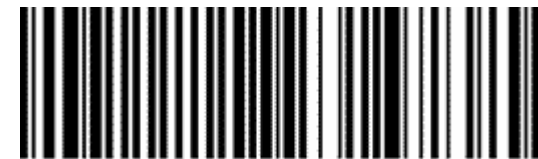
Camera-based scanner



Laser scanner



RFID Reader

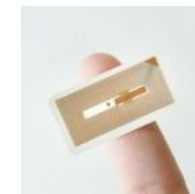


(01) 0 0012345 67890 5

Linear bar code



2-D bar code



RFID tag



Data carriers for Healthcare needs...



GS1-128 & GS1 DataBar

Preferred options if:

- ✓ package allows



Imager based bar code scanners are needed in HC !!



GS1 DataMatrix

Preferred option if:

- ✓ Large amount of data on small space
- ✓ Variable information at high production rates
- ✓ Direct part marking



EPC/RFID

Additional option

- ✓ Non-line of sight
- ✓ Large amount of data

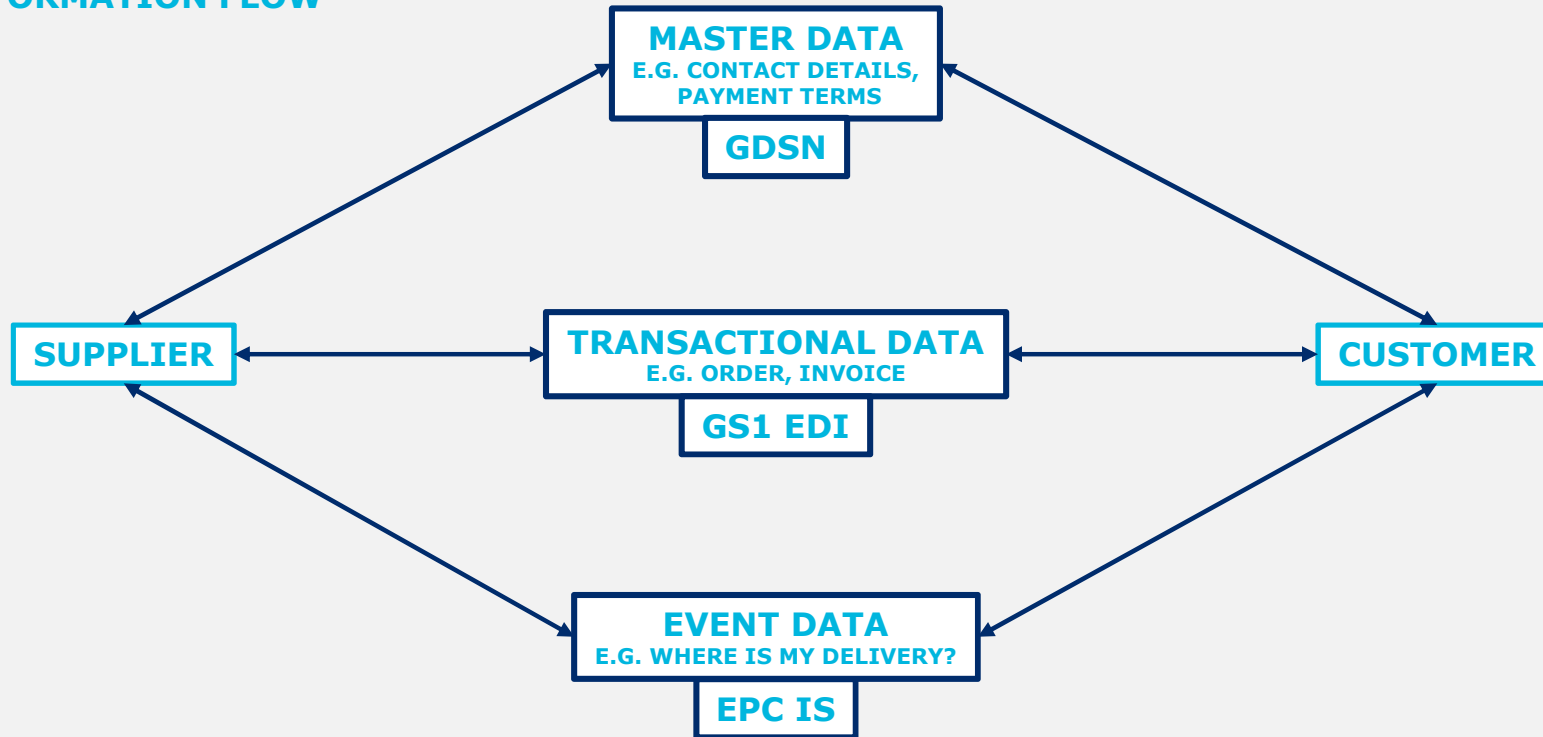
The Global Data Synchronisation Network in Healthcare



Information sharing



INFORMATION FLOW



PHYSICAL FLOW



Managing master data

How to improve?



Supplier = data source

Needs single point-of-entry

- One database to load new item data and update data on existing items

Needs security

- Authorisation access by supply chain partners

Standards-based

- Standard identification keys
- Predefined (set of) product attributes

Hospital = data recipient

Needs single point-of-truth

- One source for up-to-date, accurate data
- Continuous synchronisation

Standards-based

- Standard identification keys
- Consistently formatted information
- Complete information

GDSN for healthcare vision



All product information for every item is current, correct, and available **via a single globally-accessible network**



What is the solution?



The GS1 **G**lobal **D**ata
Synchronisation **N**etwork connects
trading partners via a network of
interoperable GDSN-certified data
pools



**Enables trading partners to share
reliable master data**



What could it mean for you?



MANUFACTURER

- Manufacturers: cost optimisation and process synchronisation



HOSPITAL / PROVIDER

- Hospitals: adequately identified medical devices and pharmaceuticals in an integrated system of information management

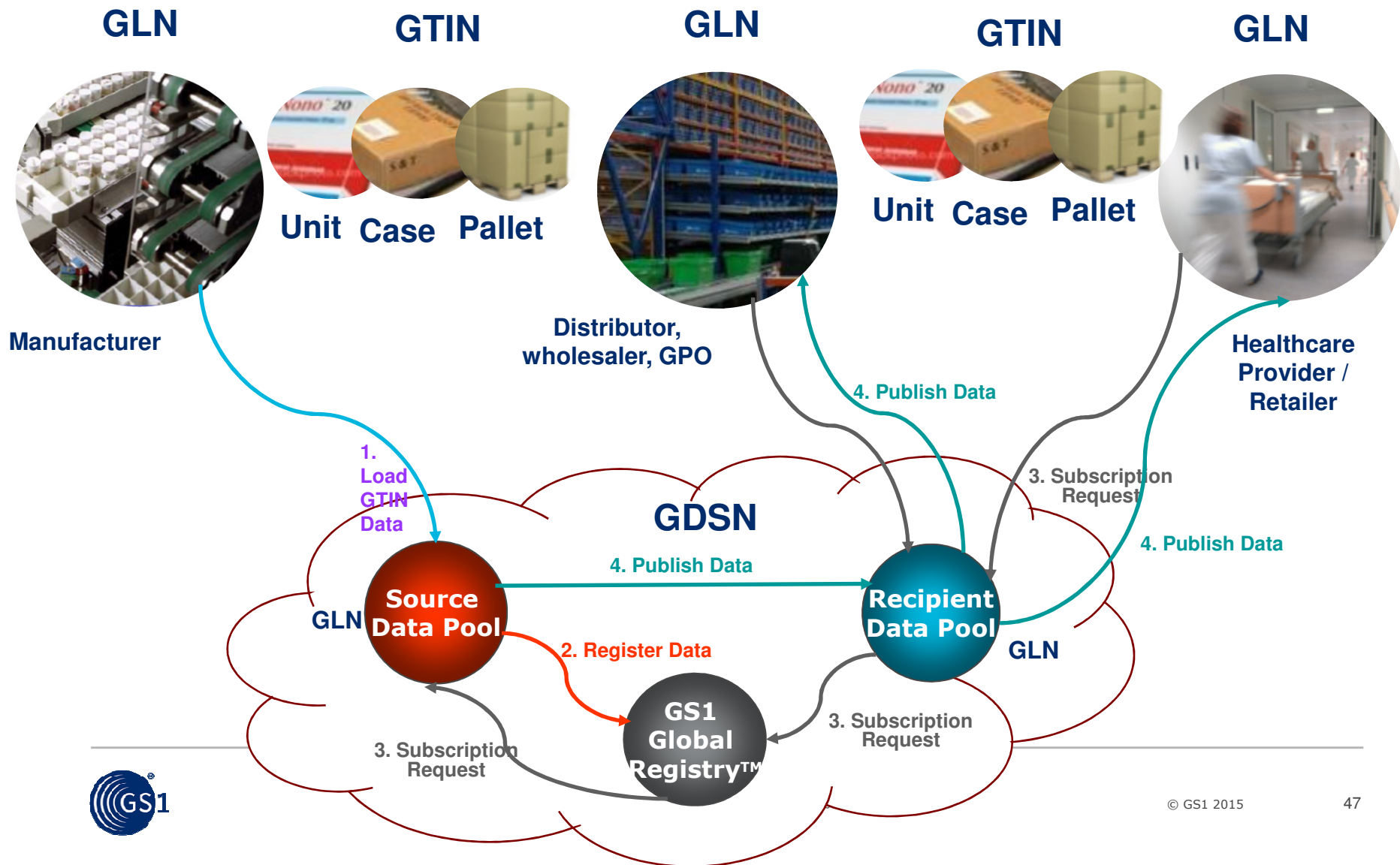


REGULATOR

- Regulators: higher levels of market surveillance, more efficient adverse event reports and quicker recall - also across borders

Global standards enable **safer and more efficient supply chain** to ensure that the **right device** is available at the **right place** and the **right time** for the **right patient**.

GDSN in action



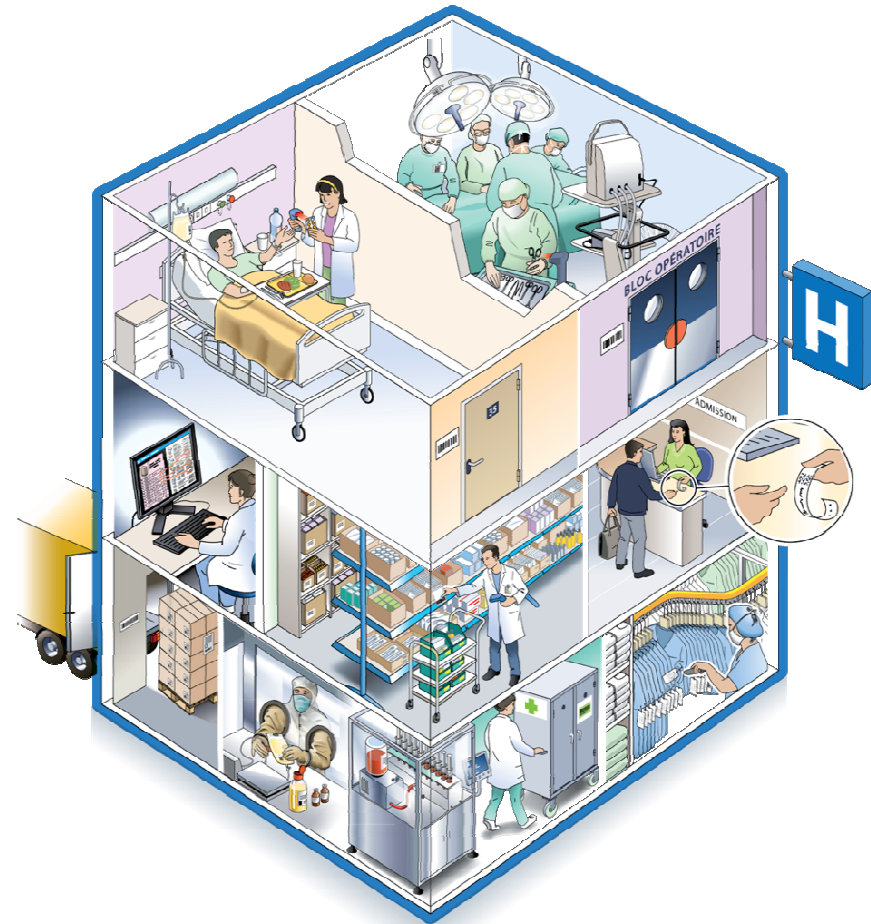
Key Business Processes in Hospitals Where GS1 Can Help



GS1 can support key business processes In hospitals



**In a hospital clinical
and supply chain
processes can be
improved by automation
and accurate data**



GS1 can support key business processes

Many products to manage

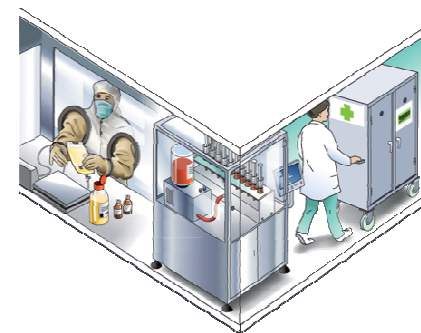
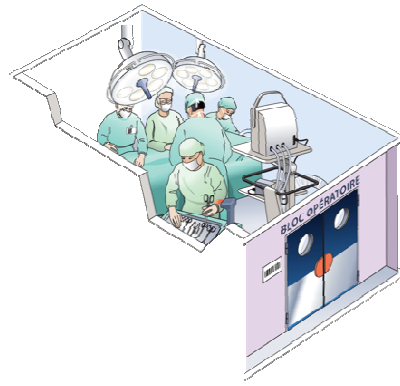
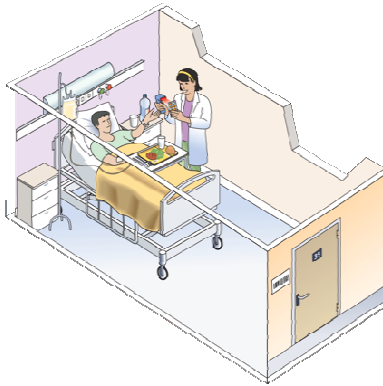


Hospitals purchase **many different kinds of products**. They **ALL** need to be identified with GS1 barcodes so they can be purchased, stocked, dispensed, billed, tracked and recalled efficiently and safely.



GS1 can support key business processes

Hospital clinical processes



Bedside scanning—
patient, caregiver,
product scanning
and verification

**Electronic Health
Records (EHR)**—
patients' records
management

Implant registry

**Instrument
management
and tracking**
(e.g., surgical
instrument tracking,
loan-set
tracking, etc.)

Product recalls

**Regulatory
compliance**

Traceability

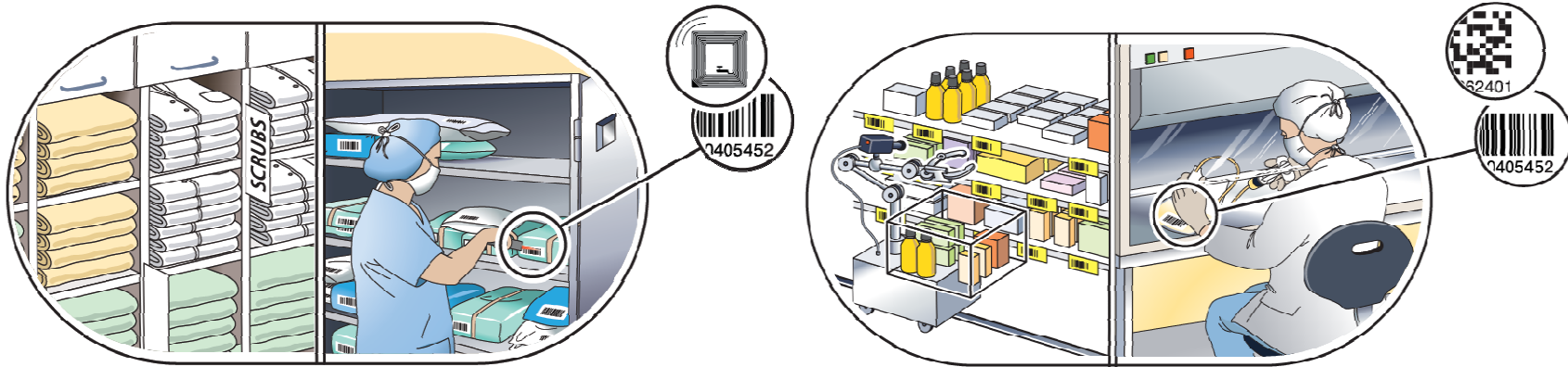
**Preparation of
patient specific
infusion solutions
and dispensing of
pharmaceuticals**

**Supporting
clinical pathways**



GS1 can support key business processes

Hospital support processes



Product recalls

Inventory
management

Asset management

Patient-level
costing

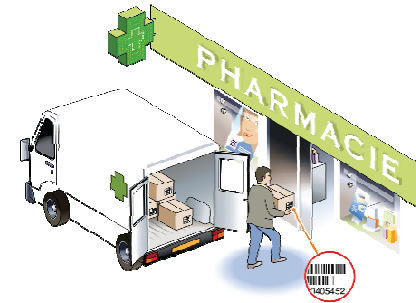
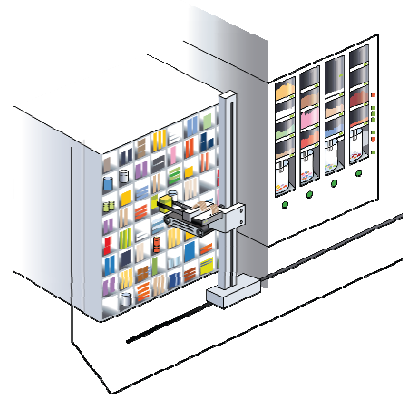
Order-to-cash
management

Catalogue
management



GS1 can support key business processes

Retail pharmacy processes



Order-to-cash

Catalogue
management

Inventory
management

Product recalls

Regulatory
compliance



Ultimately, it's all about...



PATIENT SAFETY!



Contact Information



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