



The Global Language of Business

# Regulatory Roadmap: Traceability of Medicinal Products

October 2018



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# Introduction

## Traceability of medicinal products: definition

Traceability is defined as the ability to identify and trace the history, distribution, location and use of products. A traceability system records and follows the trail as products come from suppliers, are processed and, ultimately, are distributed or dispensed as final products.

Medicinal products traceability is crucial to ensure patient safety. Over the last years, governments have been increasingly developing legislative frameworks in order to achieve drug traceability at national level.

## Roadmap purpose

This document aims to provide detailed, yet non-exhaustive, directions to support regulators before, during and after the drafting of policies in regard to the traceability of pharmaceuticals.

The reason for its creation is to help address the growing number of requests from regulators for support in aligning with the global framework of medicines identification, marking, and traceability, and to provide information from a neutral, international non-for-profit standards organisation.

## Roadmap scope

This document is intended for national and/or regional regulatory authorities, referred to as **“regulators”**, who are planning to or are currently drafting policies on pharmaceutical traceability.

The document’s scope is **pharmaceuticals** and does not include medical devices.

The following recommendations **apply primarily to secondary-level packaging**. Today, there are no implementations at primary-level packaging since, at this point, they would require longer timeframes and higher costs.

In this document, the term **“traceability systems”** encompasses various levels of traceability measures.

Fundamental to traceability is that the flow of product is accompanied by the flow of information about the product.



**“[Drug traceability] represents one more step in strengthening the institutional policy of quality of ANMAT (National Administration of Drugs, Foods and Medical Devices of Argentina), by which we improve the security of patients concerning the legitimacy, quality and efficacy of the drugs they consume.”**

**Dr Carlos Chiale,  
Director**

**ANMAT, National Administration of  
Drugs, Foods and Medical Devices  
of Argentina**



# 1. Define the status of the national healthcare market

Before starting to work on traceability requirements for medicinal products, it is crucial to **assess the local pharmaceutical market and regional trends** to ensure the requirements will meet the needs and expectations of the market.

This preliminary assessment is meant to be used internally by regulators in order to define “where and how” to target efforts for awareness and preparation.

This list of questions is non-exhaustive and some questions may not be relevant for your country. These questions aim at understanding better the size, maturity, composition of the market as well as the level of readiness for implementation of barcodes and data exchanges using GS1 global standards.

## ➔ Market analysis

- What is the percentage of large vs. local small and medium-sized manufacturers?
- What is the percentage of local manufacturers vs. global or regional manufacturers?
- What is the percentage of locally manufactured vs. imported products?
- From which country or region (e.g., European Union) are the products imported?
- What is the percentage of exported products?
- To which country (e.g., US) are the products exported?
- What is the percentage of distributors?
- What is the role of distributors in regard to importation, packaging and distribution?
- What is the percentage of pharmacies?
- Are there mainly pharmacy chains or individually-owned pharmacies?
- Does your market have primarily prescribed medicines?
- Does your market have primarily reimbursed medicines?
- How many hospitals are there?
- What is the percentage of private vs. public hospitals?

- Is there a GS1 local office (Member Organisation) in your country?
- Do third-party logistics providers (3PLs) or logistics providers manage pharmaceutical products?

## ➔ Packaging analysis

- What is the level of maturity of technology (e.g., printing capabilities, scanning) of the above stakeholders?
- What product identifiers are currently used in the country? For what purposes?
- Are there any currently existing barcoding requirements? For what purposes?
- Are there any products that are currently marked with barcodes within your market? For what purposes?
- Is there an option to mark products when received at the border or after they are received in-country?
- Are barcodes being scanned? For what purposes and where (e.g. distributors, pharmacies, hospitals)?

## ➔ Information systems analysis

- Is there any product registration and approval process? How is this information managed?
- Is there any reporting system in place to hold information about products?
- Is there any system in place to manage electronic transaction data (e.g., invoices, payment)?
- How is reimbursement or health insurance managed?

## 2. Define the regulatory objective and select the relevant traceability model

The majority of economies with existing traceability systems have clearly stated, specific **regulatory objectives**. Below is a proposed list for consideration.

### ➔ Objectives

- Improve patient safety.
- Improve supply chain efficiency.
- Improve payment monitoring.

### ➔ Traceability models

The regulator is responsible for defining the **type of system** to be used, based on the country's own needs and the existence of fully regulated legal supply chains for the distribution, storage and dispensation of pharmaceutical products. Two main types of systems are currently used around the world:

- Track and Trace
- Point of Dispense Verification

While the Point of Dispense Verification concept inherently applies to single items dispensed to the patient, the Track and Trace concept can be implemented on either batch or item level, depending on the regulatory objective.

With the **Track and Trace system**, the manufacturer or marketing authorisation holder (MAH) is required to uniquely and unequivocally identify the product. Both the manufacturer/MAH and all stakeholders of the supply chain are reporting information about this product and its movements throughout the supply chain—up to the point when these products reach points of dispense.

The advantage of this model relies on detecting in real time, a product's “irregularities” and, upon detection, ensuring an effective recall and management of inventory. Likewise, it provides visibility of the entire, end-to-end product supply chain.

The main disadvantage of a Track and Trace system is its complexity as it involves a large number of stakeholders in the supply chain that will often need to allocate resources to support the system's operation.

### The **Point of Dispense Verification system**

exempts stakeholders in the middle of the legal supply chain (e.g., wholesalers) from providing information for the majority of transactions, while the manufacturer/MAH is required to uniquely and unequivocally identify the product and share this information through a database.

Prior to the dispensation in pharmacies or healthcare institutions, the serial number on the package of the medical product, in combination with the GS1 Global Trade Item Number® (GTIN®), is validated by comparing it with the information provided by the product manufacturer/MAH.

The main advantage of a Point of Dispense system is that it involves less parties and is thus easier to implement. On the other hand, the main drawback of this system is that the detection of any abnormalities occurs at the time of dispensation and such detection is subject to the effective validation of the product at this single and last point in the supply chain. In addition, it does not provide the side benefits of a full traceability system such as detecting where counterfeit products enter the legitimate supply chain.

With both models, intermediate measures can be taken such as a point-of-dispensing check with random risk-based checks at wholesalers, or phased implementation per product type or stakeholder.

Conceptually, multiple models exist to implement Track and Trace systems while today only one model exists to implement Point of Dispense Verification. The different models are outlined in the following section.



➔ **Track and Trace systems**

**Centralised system**

Each stakeholder handling the product publishes his traceability data to a central repository or database maintained by a regulatory body.

This centralised system has been successfully implemented for example in Argentina, Turkey, South Korea, Saudi Arabia and India (for exports).

As of October 2018, Bahrain, Brazil, Egypt, Ethiopia, Jordan, Oman, Pakistan, Russia and others are considering implementing the Centralised system in the future.

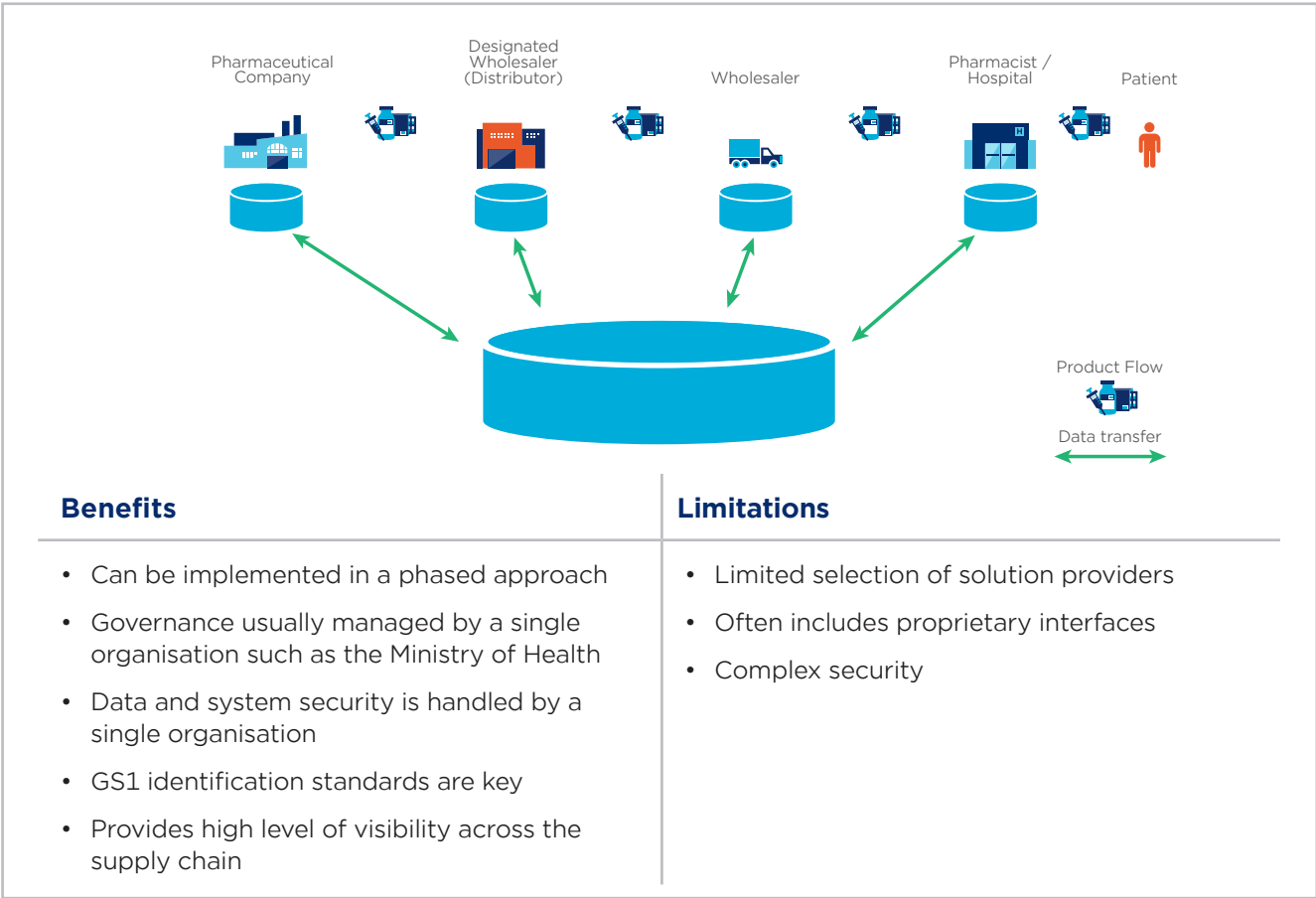


Figure 1: Centralised model with its benefits and limitations (source: APEC Supply Chain Security toolkit)





## Distributed system

In this model each stakeholder handling the product makes traceability identifiers available in a registry to enable the search capability of traceability data. This information can be stored anywhere since the registry provides the link and data-search mechanism.

As of October 2018, this system has not been implemented.

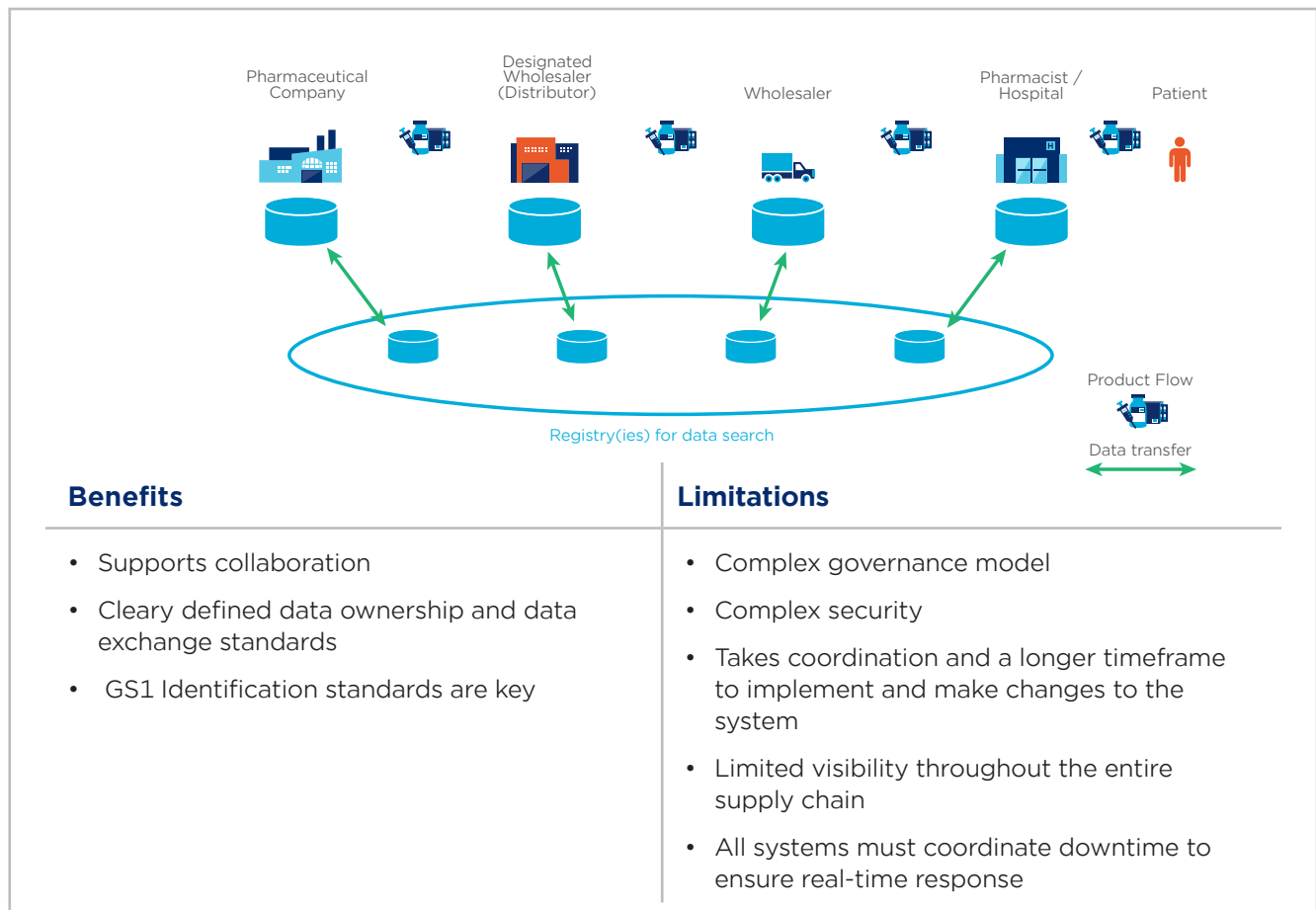


Figure 2: Distributed system with its benefits and limitations (source: APEC Supply Chain Security toolkit)

# Pharmacist+

**➔ Point of Dispense Verification system**

In Europe, a Point of Dispense Verification system with potential risk-based controls at wholesaler level, will be implemented as of 9 February 2019. In this system, the repository is designed and managed by all stakeholders though this is not inherent to the Point of Dispense Verification model.

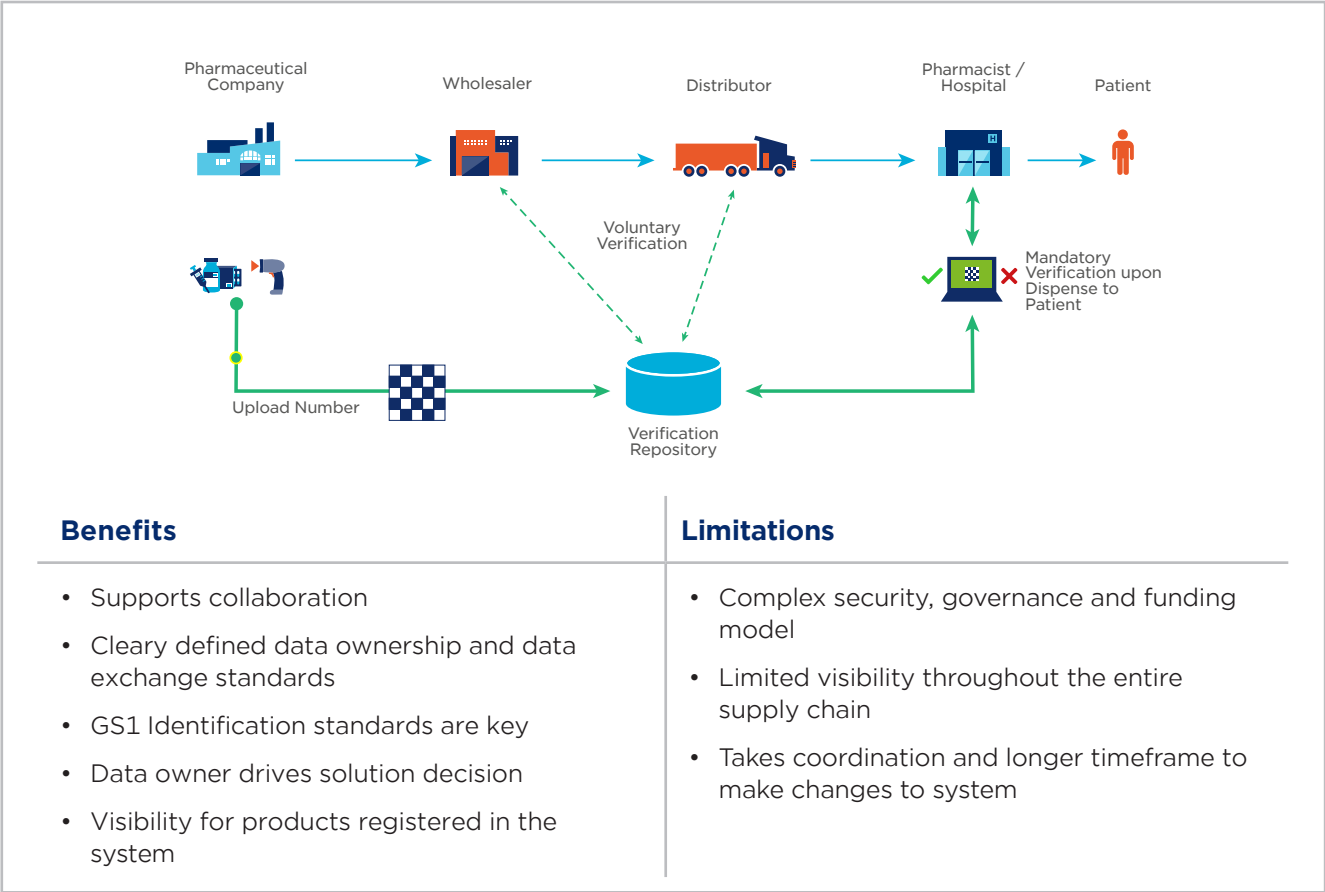


Figure 3: Point of Dispense Verification national system with its benefits and limitations (source: APEC Supply Chain Security toolkit)





## Conclusion

Figure 4 outlines the different traceability models aligned with the targeted objectives. While one of these objectives may be the main driver for developing a traceability system, as the implementation progresses, other objectives may emerge.

Objectives*	Anticipated Benefits	Centralised system	Distributed system	Point of Dispense Verification system
<b>Improve patient safety</b>	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)	✓	✓	✓
<b>Improve payment monitoring</b>	Enables efficient payment and payment monitoring processes	✓		✓
	Minimises reimbursement fraud	✓		✓
<b>Improve supply chain efficiency</b>	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	✓		

Figure 4: Objectives and traceability systems

\* Note: The objectives presented are in no particular order of importance or preference.



### 3. Define scope considering status of healthcare market and regulatory objective

The larger the number of products involved, the more complex a traceability system implementation.

The products covered by the traceability system should be **clearly defined**. Considerations for inclusion could be pharmaceuticals where instances of falsified cases have been detected, as well as products indicated for more critical pathologies, all prescription products, controlled substances, those pharmacovigilance-intensive ones, products bearing a risk management plan, high-cost products, and more.

For example, the Turkish system covers all prescription drugs, and has been gradually implemented over five years.

Alternatively, the traceability system in Argentina has been implemented by product type, initially targeting products with a high rate of adulteration and fraud on reimbursement, with a high cost as well as those indicated for cancer, HIV, haemophilia treatments and other special pathologies. This definition was assessed and discussed for more than one year before the regulation was issued. Some years after the first listing was released, other vigilance-intensive products, antibiotics, anti-Parkinson and anti-depressive products as well as psychotropic narcotics were included.

Alignment with existing practices in other countries can facilitate a timely implementation. Figure 5 provides examples of product categories that are in scope or out of scope in countries where traceability requirements are already implemented.



In scope in most of countries	In or out of scope, depending on the country	Out of scope in most of countries
<ul style="list-style-type: none"><li>• Prescribed drugs (with the exception of those listed as out of scope)</li></ul>	<ul style="list-style-type: none"><li>• Over the counter (OTC)</li><li>• Free samples</li><li>• Radiology products and contrast media-reimbursed drugs</li><li>• Cosmetics</li><li>• Food supplements</li><li>• Vaccines</li><li>• Narcotics</li><li>• IV solutions</li></ul>	<ul style="list-style-type: none"><li>• Investigational drugs</li><li>• Medicinal products intended for research and development trials</li><li>• Animal health products</li></ul>

Figure 5: Product categories in and out of scope in implementation



## 4. Define implementation approach

Collaboration between regulators and healthcare stakeholders will be very valuable when defining the implementation approach and governance model (including data management privacy).

This dialogue facilitates the alignment with business processes already implemented in the global and local supply chains, which reduces costs and complexity.

Any collaboration should be ongoing due to the changing and evolving nature of the situation. Following are some examples of collaboration efforts:

- Provide and/or sponsor workshops.
- Develop a strategy and vision with all local stakeholders (e.g., across authorities and including industry).
- Utilise real-case examples and test items (e.g., packaging configuration kits).
- Hold public consultations and hearings prior to and after completion of the policy.
- Consult with other regulators that have similar goals and have already created a successful program.
- Work with inter-governmental organisations.
- Refer to existing support documentation such as the APEC Supply Chain Security Kit. (Visit: [www.nifds.go.kr/apec/SupplyChain/APEC\\_SupplyChainToolkit\\_170317.pdf](http://www.nifds.go.kr/apec/SupplyChain/APEC_SupplyChainToolkit_170317.pdf))
- Review existing case studies and good practices and create ones from your experiences.
- Conduct pilot(s) and take lessons learned from them into account when moving forward.
- Establish a help-desk function and implementation support.
- Develop a Q&A document to provide clarification on the requirements.



### Achievable timeframe

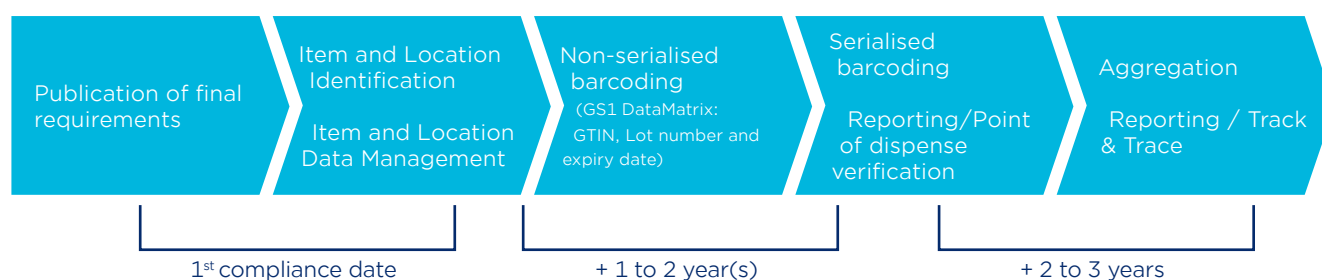


Figure 6: Example of achievable implementation timeframe

**Provisions to facilitate implementation** could include:

- Many countries are launching **pilot projects** before publishing their final requirements for traceability. This provides an opportunity to “test” the feasibility of the requirements and to assess the readiness of supply chain stakeholders. The pilot results are used as “lessons learned” to adjust the final requirements before release.
- Another step could be the application of non-removable stickers as a transition measure. These are adhesive labels with barcodes that are applied after the products are packaged. See Figure 7.

- Products already released for sale remain unchanged and can be marketed until the expiry date has been reached.



Figure 7: Examples of transitional labels with barcodes

## 5. Define data carriers and content for identification, using GS1 global standards

The use of GS1 global standards enables worldwide interoperable product identification, capture and sharing of data. This supports the efficient and cost-effective management of the healthcare supply chain globally.

The use of GS1 standards can also facilitate the harmonised implementation of regulatory requirements.

Today, around 70 economies are requiring or allowing the use of GS1 standards to implement healthcare requirements.

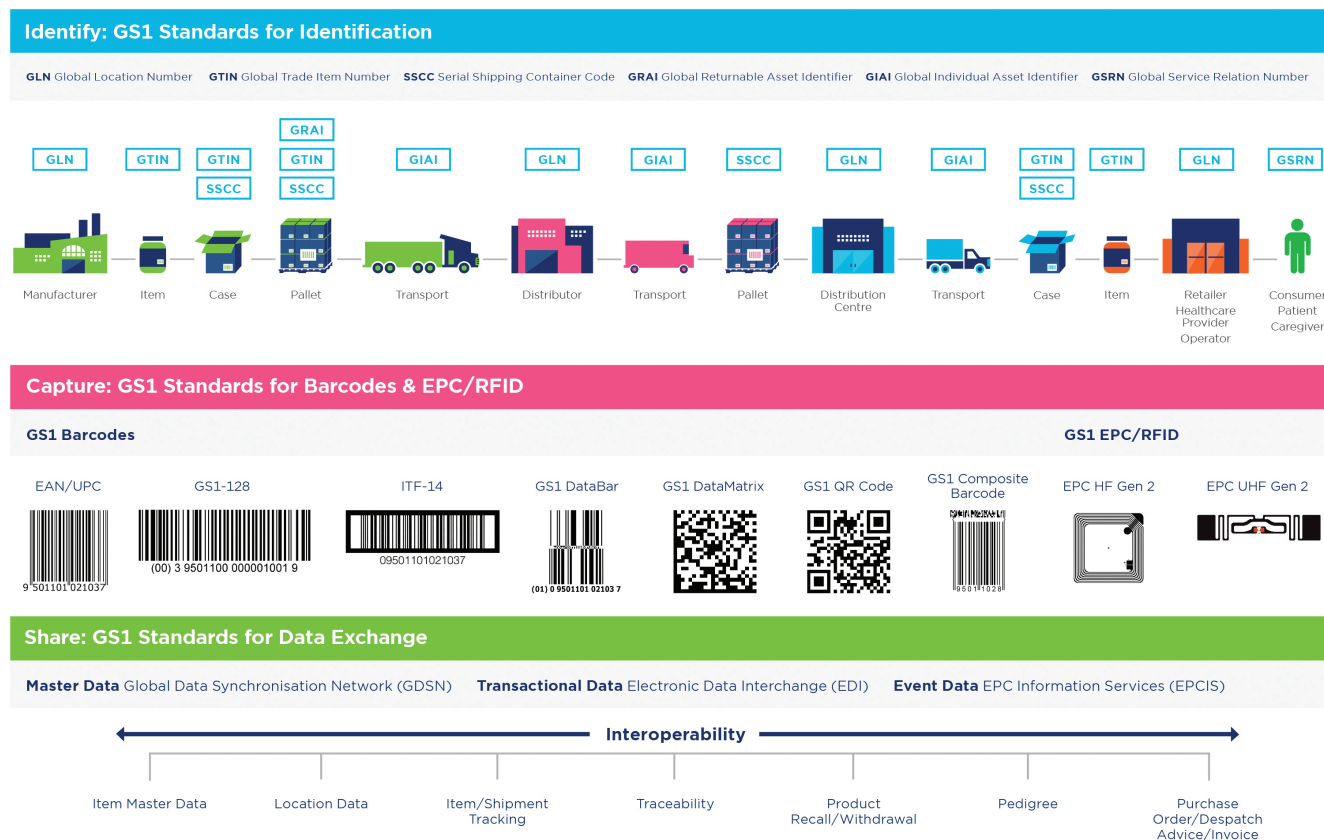


Figure 8: GS1 global standards for identification, data capture and data sharing

Most regulations for traceability around the world are aligned with global trends on identification and barcode application on secondary-level packaging: a GS1 DataMatrix barcode encoded with a GTIN, lot number, expiry date and serial number - with no specific order mandated to encode these data elements in the barcode.

## Definition of packaging levels

Today's regulatory requirements have initially focused on trade items and on secondary-level packaging for pharmaceuticals. It's important to note that to implement traceability requirements, the data carrier like a barcode should be placed on the registered packaging level, which relates to how the medicinal product is described in its marketing authorisation dossier, regardless of the commercial sellable unit.

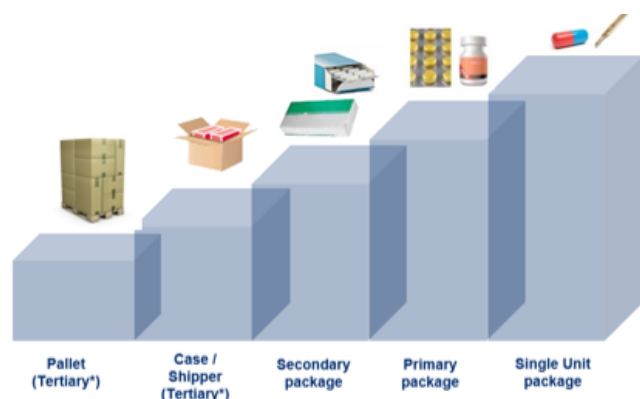


Figure 9: Levels of packaging

*\*Note: There is no globally standardised definition of "tertiary package."*

## Primary packaging

Primary packaging is the first level of packaging that is in "direct contact" with the product. In other words, it contains the product itself. This packaging level should be marked with a GS1 DataMatrix barcode, either directly on the packaging or on a label affixed to the packaging.

On primary packaging, identification and marking is not recommended today but if implemented sometimes in the future the GS1 DataMatrix barcode should only encode a GTIN or a GTIN with the batch/lot number and expiry date. It is important to note that requirements for identification and marking at the primary level of packaging is not recommended and is not implemented in any country so far.

Coding of primary packages is out of scope when considering pharmaceutical traceability requirements. However, it is mentioned here for a complete description.

## Secondary packaging

Secondary packaging (often called item level) is a level of packaging that may contain one or more primary packages, or a group of primary packages containing a single item. This packaging level should be marked with a GS1 DataMatrix barcode, either directly on the packaging or on a label affixed to the packaging.

On secondary packaging, the GS1 DataMatrix barcode should encode a GTIN with the batch/lot number and expiry date and, in the future, depending on the regulatory objective, the serial number.

## Difference between logistic units and trade items

**Trade items:** Any item—product or service—where there is a need to retrieve pre-defined information and that may be priced or ordered or invoiced at any point in the supply chain. Identify and mark a trade item with at least a GTIN in a linear barcode or in a GS1 DataMatrix barcode.

**Logistic units:** Any item of any composition that has been established for transport and/or storage that needs to be managed throughout the supply chain. Identify and mark a logistic unit with at least a GS1 Serial Shipping Container Code (SSCC) in a linear barcode. If the logistic unit is also a trade item, it can also be identified and marked with at least a GTIN in a linear barcode.

GS1 standards should be followed when defining the data carrier (e.g., linear barcode, GS1 DataMatrix barcode) and identification information (e.g., GTIN, SSCC) used on trade items versus logistic units.

## Tertiary packaging

Tertiary packaging refers to upper levels of the packaging hierarchy. A tertiary pack may be a:

- Case that contains one or several secondary packs
- Pallet that contains one or several cases

Tertiary packaging may be either a logistic unit or a trade item.

## Identification of the medicinal products

In order to establish unit-based traceability of medical products, it is essential to identify products—unequivocally and uniquely.

To this end, some regulators are mandating for traceability the use of **serial numbers** in accordance with GS1 global standards. The serial number must be associated with a specific product code (e.g., GTIN) and the product code and its associated serial number must be unique and must only be used once.

Regulators may also require the use of other product data, such as batch/lot number and expiry date.

It is important to note that in some countries, due to historical reasons, the product registration number or the product identification for social security is also required. In such cases, this data should not be included in the product identification and in the barcode but should be entered in the database.

Traceability can also be carried out on a batch/lot basis. Regarding pharmaceutical products distribution, secondary packaging should carry the identification of the manufacturing batch/lot number which, in some cases, is recorded on the commercial documents accompanying the product.

## Barcoding medicinal products

Product identification data, as defined in the previous section, should be encoded in a data carrier (e.g., barcode), which enables the automated reading of the data. Using one single barcode is essential to ensuring patient safety. Having more than one barcode symbol on a product package creates challenges in the healthcare provider environment.

It is important to enable the use of data carriers that have been previously agreed upon by the stakeholders, and that are not too costly and/or complex.

The recommended data carrier for pharmaceutical identification is **the GS1 DataMatrix** barcode for several reasons, including:

- Captures the largest amount of data in the smallest “footprint”
- Can be printed directly on the products
- Has sophisticated error detection and correction algorithms, allowing the GS1 DataMatrix barcode to be scanned even if damaged, torn or printed poorly

Even though the QR code is used for other marking purposes, such as when marketing the product, it should not be used for identification and traceability and not be printed on the package to avoid confusion and errors.

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It is important to stress that additional data carrier-related requirements, such as specific labels, serial number generation by the regulatory authority, label sizes or the definition of colour or material type will make the implementation more complex and costlier.





It is required that all information encoded on the barcodes must also be shown as HRI (human readable interpretation), adjacent to the barcode symbol.

## Printing GS1 DataMatrix barcodes

When creating and printing the GS1 DataMatrix barcode, the encoding specifications and the print quality requirements can be found in the [GS1 General Specifications](#) and should be followed. (See Appendix C: References.)

The following are additional considerations:

- **Location:** The GS1 DataMatrix barcode should be printed on one side of the secondary packaging—preferably on a flat surface. To facilitate the reading process, it should always be placed on the same face of the product packaging, where possible.
- **Barcode scanners:** The GS1 DataMatrix barcode can be read by 2D/matrix camera or image-based barcode scanners, but not by 1D/linear laser barcode scanners. Camera-based barcode scanners can also read 1D/linear as well as 2D/matrix barcodes, such as the GS1 DataMatrix barcode.

## Identification of the healthcare stakeholders

Manufacturers/MAHs should be registered in the database of their respective country's national traceability system. They should uniquely identify their company and/or specific sites each with a GS1 Global Location Number (GLN).

The same requirements apply to the stakeholders (e.g., distributors, healthcare providers) involved in the distribution and dispensing of the medicinal products.



# 6. Define data reporting and exchange processes

## Designing the exchange of traceability data

Designing the exchange of traceability data requires technical understanding of applicable standards as well as a structured methodology. Traceability processes should be analysed from a business perspective regardless of the technology used to capture and share data; this independence is crucial to the flexibility and scalability of the system later on.

The traceability situation becomes increasingly complex as the number of trading partners increases. Each party may be trading with many others, and each such trading relationship may require the exchange of information.

A core principle for managing this complexity is to **separate content from choreography**. What this means is that the content of traceability data should be designed according to a structured methodology (such as the approach described

in GS1's [EPCIS Implementation Guideline](#) - See [Appendix C: References](#)), independent of the technical means of data capture and sharing.

In addition, trading partners (or regulators, where their preference has been mandated) can decide when and how the data will move from one trading partner to another; this is called the **choreography**.

Choreography decisions include:

- Where will data reside?
- What will trigger the communication of data from one party to another?
- Will push or pull modes be used?
- What networking technology will be used?

By separating content from choreography, the choreography can adapt to changes in the size of the trading ecosystem and evolution of technology, while the design of the traceability data content stays the same.

There are many possible approaches to choreography. Many of these approaches fall into one of two broad categories:

- **Centralised choreography:** Traceability data from multiple parties in the supply chain are sent to a **shared database**. To get an overall view of the supply chain, it is only necessary to access this central database.
- **Distributed choreography:** Each party that captures traceability data keeps that information in its **own database**. There are two approaches to sharing distributed data:
  - **Query:** When another party needs an overall view of the supply chain, it must locate and request (query) all of the other parties that may have relevant information stored in their respective databases.
  - **Push:** Rather than waiting for another party to request or query for that data, the capturing party sends (pushes) its data to other parties in the supply chain that are likely to need that data. Often the push of data follows the same path as the physical or digital objects, e.g., if Party A ships goods to Party B, it also sends its traceability data to Party B.

## Master data

One of the most important and challenging areas related to the implementation of traceability, or any supply chain process, is the quality of master data.

Completeness and accuracy of product data is primarily the responsibility of the manufacturer. Each manufacturer should have an internal process to manage the data required by the regulator.

This includes:

- Data quality checks and procedures
- Data management process and policies
- Enterprise-wide data governance policies
- Roles and responsibilities that outline who has the authority to create, modify and approve the data

In a traceability model, as data is shared across all stakeholders of the supply chain, it creates an information flow that precedes the physical flow of the product. This creates a data chain-of-custody effect that requires each stakeholder in the process to share responsibility for maintaining data integrity and quality. It is important that the data required is limited to the master data effectively needed for the traceability system and is defined in consultation with the stakeholders.

Data sharing refers to a standardised method of sharing information between the source of the data and all recipients across the information supply chain. The GS1 Global Data Synchronisation Network® (GDSN®) is a standard developed by GS1 to securely share product information between organisations globally. It consists of the GS1 Global Registry® operated by GS1, which connects over 40 Certified Data Pools from all over the world. The GDSN enables manufacturers to share product data with their customers or regulators, regardless of where they are located.

When it comes to traceability, the GDSN helps establish a solid foundation of accurate product information for all stakeholders of the supply chain. This enables the manufacturers to publish their product data via a single connection to the network.

## Visibility event data

Visibility event data encompasses the “what”, “where”, “when” and “why” about an object (e.g., product, asset) in the supply chain.

Visibility data can describe:

- The origin of the object, i.e., when, where and by whom it was introduced into the supply chain as a uniquely identified product or asset
- Each business step and location where the object was observed in the supply chain
- Date and time of each observation
- Status or disposition of the object after each observation

**EPCIS** is a GS1 and ISO standard that enables supply chain partners to capture event information about supply chain events (e.g., shipped, received) and to share that information with their trading partners securely and in near real-time. Capturing and sharing visibility data, either internally or across trading partners, provides a view into the history of the manufacture, shipping, receiving and selling processes that allow for a more efficient, affordable and safe supply chain.

The stakeholders in the US would like to use EPCIS to help satisfy the traceability provisions of the US Food and Drug Administration (FDA) Drug Supply Chain Security Act (DSCSA). EPCIS has also been explicitly mentioned in FDA guidance as one possible mechanism for the interoperable exchange of pharmaceutical traceability data.

# GS1 Contacts for Support

This document has been developed to support regulators in establishing a national traceability system for medicinal products using GS1 standards. GS1 recommends the use of [GS1 General Specifications](#) (See Appendix C: References.) as the primary reference document for all technical specifications needed to meet the requirements in accordance with GS1 global standards.

The GS1 Global Office and 112 country-based GS1 Member Organisations are available to support regulators' needs for training, education and implementation.

Information on how to contact each of the GS1 Member Organisations is available: [www.gs1.org/contact/overview](http://www.gs1.org/contact/overview)

## Appendix A: Benefits of Using GS1 Global Standards

By using GS1 global standards, stakeholders throughout the healthcare supply chain can benefit in the following ways:

- Prevents counterfeiting for safer medicines
- Prevents resale of medicines
- Expedites recalls of medicines
- Prevents sale of expired medicines
- Reduces medicine shortages
- Improves process efficiencies in the supply chain
- Enables quality data for health insurances
- Provides statistics to develop policies on rational medicine use
- Enables pharmacovigilance and strategic planning

The McKinsey report, *Strength in Unity: The promise of global standards in Healthcare* concludes: "Our research also suggests that these benefits would be put at risk if the industry continues to try to manage the complexity of multiple standards rather than aligning around one."

Global healthcare leaders have a window of opportunity now to work together to align around a single set of global standards and to collaborate to drive adoption of the practices enabled by these standards."

Yet, today the "alignment around a single set of global standards" is still more of a vision versus a reality.

As the number of proprietary solutions grow so does the complexity and cost for pharmaceutical manufacturers when they must adopt different

solutions for different markets. This proprietary-based environment further creates the potential for increased costs that are then passed down the supply chain.

While there are costs associated with the implementation of GS1 standards, these would be even higher if the need existed to implement local and/or proprietary solutions for numerous markets.





## Example: Implementation costs of traceability

Typical Track and Trace Solution in Emerging Markets				
		Item	Qty	Cost (\$)
<b>Capital</b>				
<b>Equipment</b>	Primary packaging serialisation	Not required		
	Serialisation print & verify	Serialisation print & verify equipment	1	\$ 13,000-70,000
	Tamper evidence	Tamper evidence module	1	\$ 28,000-50,000
	Warehouse station	Rework station	1	\$ 7,000-17,000
	Quality assessment station	Rework station	1	\$ 7,000-17,000
<b>Serialisation software</b>	Plant software	License	1	\$ 15,000-50,000
	Line software	Included in equipment prices		\$ 0
	Integration to internal communication system of the company	If necessary	1	\$ 6,000-25,000

## Summary of needed investments

Examples of needed investments by the manufacturer in an emerging market include:

- The investment in equipment on packaging lines only accounts for a portion of the total investments required. (Estimate plus/minus 30%.)
- Physical extension of facilities may be required if not enough space exists for additional equipment.
- Project management may require additional local staff
- Aggregation may require significant investment in case packing machinery.
- A significant investment is required in IT systems.
- Artworks need to be assessed, adjusted and approved in regulatory instances.
- Master data development includes:
  - Harvesting, validating and creating GTINs
  - Setting serialisation standards
  - Harvesting, validating and creating newly required regulatory master data
  - Investing in systems to integrate master data across all impacted systems

It is important to note that standardisation is vital to keep all of the above investments under control and consistently applied. Each deviation from standards will require additional investments in IT systems, change management, artwork and master data. In addition, having different requirements across regions or between countries adds complexity in operations, increasing the risk for failure.



# Appendix B: Glossary

A glossary of key terms is provided below.

The *GS1 General Specification* should be used as a reference for terms that may not be defined below.

<b>Automatic identification and data capture (AIDC)</b>	Technologies used to automatically capture data; AIDC technologies include barcodes, smart cards, biometrics and radio frequency identification devices
<b>barcode</b>	A symbol that encodes data into a machine-readable pattern of adjacent, varying width, parallel, rectangular dark bars and pale spaces
<b>batch/lot</b>	The batch or lot number associates an item with production information that the manufacturer considers relevant for traceability of the trade item. The data may refer to the trade item itself or to items contained in it.
<b>brand owner</b>	The organisation that owns the specifications of a trade item, regardless of where and by whom it is manufactured; The brand owner is normally responsible for the management of the Global Trade Item Number (GTIN).
<b>EPCIS</b>	EPC Information Services (EPCIS) is a GS1 standard that defines a common data model for visibility data and interfaces for capturing and sharing visibility data, both within an enterprise as well as across an open supply chain.
<b>Global Trade Item Number (GTIN)</b>	The GS1 identification key used to identify trade items; The key includes a GS1 Company Prefix, an item reference and check digit.
<b>GS1</b>	A neutral, not-for-profit, global organisation that develops and maintains the most widely used supply chain standards in the world
<b>GS1-128 symbology</b>	A 1D/linear barcode symbology that leverages a subset of ISO/IEC Code 128 that is utilised exclusively for GS1 system data structures
<b>GS1 Application Identifier (AI)</b>	The field of two or more digits at the beginning of an element string that uniquely defines its format and meaning
<b>GS1 Company Prefix (GCP)</b>	<p>A globally unique string of four to twelve digits assigned to an entity and used to issue GS1 identification keys</p> <p>The first digits are a valid GS1 prefix and the length must be at least one longer than the length of the GS1 prefix. The GS1 Company Prefix is issued by a GS1 Member Organisation. As the GS1 Company Prefix varies in length, the issuance of a GS1 Company Prefix excludes all longer strings that start with the same digits from being issued as GS1 Company Prefixes.</p>
<b>GS1 DataMatrix symbology</b>	A 2D/matrix barcode symbology that is the GS1 implementation of the ISO/IEC Data Matrix barcode symbology
<b>GS1 Identification Key</b>	A unique identifier for a class of objects (e.g., a trade item) or an instance of an object (e.g., a logistic unit)

<b>healthcare primary packaging</b>	<p>The first level of packaging for the product marked with an AIDC data carrier either directly on the packaging or on a label affixed to the packaging.</p> <p>For nonsterile 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 and 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.</p>
<b>healthcare secondary packaging</b>	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
<b>healthcare stakeholders</b>	Manufacturers, marketing authorisation holders (MAH), pre-wholesalers, 3PLs, logistics providers, transportation companies, retail pharmacies, hospital, pharmacies, trade associations, regulators and patients
<b>Human Readable Interpretation (HRI)</b>	Characters such as letters and numbers that can be read by a person and are encoded in GS1 AIDC data carriers confined to a GS1 standard structure and format; The human readable interpretation is a one-to-one illustration of the encoded data. However, start, stop, shift and function characters, as well as the symbol check character, are not shown in the human readable interpretation.
<b>logistic unit</b>	An item of any composition established for transport and/or storage that needs to be managed through the supply chain; It is identified with an SSCC.
<b>serial number</b>	<p>A code, numeric or alphanumeric that is assigned to an individual instance of an entity for its lifetime. An example: microscope model AC-2 with serial number 1234568 and microscope model AC-2 with serial number 1234569.</p> <p>A unique individual item may be identified with the combined GTIN and serial number.</p>
<b>Serial Shipping Container Code (SSCC)</b>	The GS1 identification key used to identify logistic units; The key includes an extension digit, GS1 Company Prefix, serial reference and check digit.
<b>trade item</b>	Any item (product or service) upon which there is a need to retrieve predefined information and that may be priced, ordered or invoiced at any point, in any supply chain





# Appendix C: References

- McKinsey, “Strength in Unity: The promise of global standards in healthcare,” October 2012. [www.gs1.org/docs/healthcare/McKinsey\\_Healthcare\\_Report\\_Strength\\_in\\_Unity.pdf](http://www.gs1.org/docs/healthcare/McKinsey_Healthcare_Report_Strength_in_Unity.pdf)
- World Health Organization, A69/41, “Substandard/spurious/falsely-labelled/ falsified/counterfeit medical products,” 4 March 2016. [http://apps.who.int/gb/ebwha/pdf\\_files/WHA69/A69\\_41-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_41-en.pdf)
- GS1, “Recommendations on a harmonised implementation of the EU Falsified Medicines Directive using GS1 standards,” December 2016. [www.gs1.org/sites/default/files/docs/healthcare/position-papers/final\\_recommendations\\_harmonised\\_implementation\\_fmd\\_using\\_gs1\\_dec2016.pdf](http://www.gs1.org/sites/default/files/docs/healthcare/position-papers/final_recommendations_harmonised_implementation_fmd_using_gs1_dec2016.pdf)
- GS1, “GS1 General Specifications, Release 18,” Ratified, January 2018. [www.gs1.org/docs/barcodes/GS1\\_General\\_Specifications.pdf](http://www.gs1.org/docs/barcodes/GS1_General_Specifications.pdf)
- GS1, “GTIN Management Standard, Release 1.0,” Ratified, June 2016. [www.gs1.org/sites/default/files/docs/barcodes/GS1\\_GTIN\\_Management\\_Standard.pdf](http://www.gs1.org/sites/default/files/docs/barcodes/GS1_GTIN_Management_Standard.pdf)
- GS1, “GS1 Healthcare GTIN Allocation Rules, Release 9.0.2,” Ratified, December 2015. [www.gs1.org/docs/gsmf/healthcare/GS1\\_Healthcare\\_GTIN\\_Allocation\\_Rules.pdf](http://www.gs1.org/docs/gsmf/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf)
- GS1 website, Find a GDSN Data Pool. [www.gs1.org/services/gdsn/certified-data-pools](http://www.gs1.org/services/gdsn/certified-data-pools)
- GS1 website, GS1 EDI. [www.gs1.org/standards/edi](http://www.gs1.org/standards/edi)
- GS1 website, GS1 EPCIS. [www.gs1.org/standards/epcis](http://www.gs1.org/standards/epcis)
- GS1 website, GS1 GDSN. [www.gs1.org/services/gdsn](http://www.gs1.org/services/gdsn)
- GS1 website, GS1 Healthcare landing page, Enabling traceability, Healthcare traceability and GS1 standards. [www.gs1.org/traceability-healthcare](http://www.gs1.org/traceability-healthcare)
- GS1 website, GS1 Healthcare landing page, Regulatory information, Public Policy and Healthcare. [www.gs1.org/public-policy/industry-sectors/healthcare](http://www.gs1.org/public-policy/industry-sectors/healthcare)
- GS1 website, GS1 Healthcare landing page, Regulatory information, Unique Device Identification (UDIs). [www.gs1.org/healthcare/udi](http://www.gs1.org/healthcare/udi)
- GS1 website, GS1 Healthcare landing page, Regulatory information, Patient safety and pharmaceuticals. [www.gs1.org/healthcare/regulations-pharmaceuticals](http://www.gs1.org/healthcare/regulations-pharmaceuticals)
- GS1 website, GS1 Healthcare landing page, Regulatory information, Public Policy Database. [www.gs1.org/healthcare/public-policy-database](http://www.gs1.org/healthcare/public-policy-database)
- APEC Supply Chain Security Kit, March 2017 [http://www.nifds.go.kr/apec/SupplyChain/APEC\\_SupplyChainToolkit\\_170317.pdf](http://www.nifds.go.kr/apec/SupplyChain/APEC_SupplyChainToolkit_170317.pdf)







## About GS1

GS1 is a neutral, not-for-profit organisation that develops and maintains the most widely used global standards for efficient business communication. We are best known for the barcode, named by the BBC as one of “the 50 things that made the world economy”. GS1 standards improve the efficiency, safety and visibility of supply chains across physical and digital channels in 25 sectors. Our scale and reach—local Member Organisations in 112 countries, 1.5 million user companies and 6 billion transactions every day—help ensure that GS1 standards create a common language that supports systems and processes across the globe. Find out more at [www.gs1.org](http://www.gs1.org).

## About GS1 Healthcare

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

The development and implementation of GS1 standards is led by the experts who use them: pharmaceutical and medical device manufacturers, wholesalers, distributors, group purchasing organisations, hospitals, pharmacies, logistics providers, solution providers, governmental and regulatory bodies, and trade associations. Evidence available from industry implementations shows that GS1 identification, data capture and data sharing standards in healthcare deliver tangible benefit to all stakeholders. GS1 Healthcare members include more than 110 leading healthcare organisations worldwide.

For more information about GS1 standards in healthcare, go to [www.gs1.org/healthcare](http://www.gs1.org/healthcare).

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