



GS1 Standards in the Medicines Supply Chain Implementation Guidance

GS1 standards to improve traceability of medicines in the healthcare supply chain

Release 2.0, Ratified, Oct. 2019

Document Summary

Document Item	Current Value
Document Name	GS1 Standards in the Medicines Supply Chain Implementation Guidance
Document Date	Oct. 2019
Document Version	2
Document Issue	0
Document Status	Ratified
Document Description	GS1 standards to improve traceability of medicines in the healthcare supply chain

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Log of Changes

Release	Date of Change	Changed By	Summary of Change
1.0	July 2018	Ann Luyckx	First draft version
1.1	May 2019	Peter Adam	Second draft version
1.2	Sept 2019	Patrick Ponsaerts	Community Review Draft
2.0	Oct. 2019	Patrick Ponsaerts	Ratified

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1 Introduction

1.1 Purpose of this document

The purpose of this document is to provide guidance for the implementation of GS1 standards to improve the traceability of medicines in the healthcare supply chain and for all products who follow an identical process in the supply chain. The result is a voluntary standard providing healthcare supply stakeholders with a common set of data and data carriers to be applied to medicinal products at each packaging level. The document has been prepared by GS1 Belgium & Luxembourg and has been reviewed by the participants of the GS1 Belgium & Luxembourg working group on traceability of medicines in the healthcare supply chain.

For the buying, selling and trading of products and services, organizations need to adhere to standards in their communications with each other. The GS1 System is a set of standards that through its implementation, facilitates an efficient supply chain worldwide due to uniquely identified products, logistic units and locations. These standards are intended to be global, neutral, and unambiguous. They facilitate product and data flow between supply chain partners such as suppliers, manufacturers, wholesalers, logistic providers, transporters, hospitals, etc. They help automatic data capture and data management, increase data flow, reduce cost and secure the supply chain.

The GS1 System uses identification numbers and additional data represented in a barcode format or in RFID tags to track and trace products in the supply chain. These numbers are also exchanged via electronic messages to be automatically integrated and stored in databases. They are the key to access a set of information that may be used for traceability.

This guidance is intended to be used in conjunction with applicable GS1 standards, including but not limited to the:

- GS1 General Specifications (<http://www.gs1.org/genspecs>)
- GS1 Healthcare GTIN Allocation Rules (<https://www.gs1.org/1/gtinrules/en/healthcare>)

! Important: This document should not be interpreted as a regulatory guide for the identification of medicines. Government regulations will always supersede any suggestions put forward in GS1 documentation.

✓ Note: The reader should refer to the latest published version of these standards when using this guide.

1.2 Who will use this document

This document is intended for parties within the healthcare supply chain who are responsible for the identification, the data carriers and the labelling of medicinal products, and for parties that scan/read the data carriers of these medicinal products.

This document will be used when an organization has to define and apply a Global Trade Item Number (GTIN) and/or a Serial Shipping Container Code (SSCC) and additional information to facilitate tracing its medicinal products throughout the supply chain. Organizations that may find this document useful include manufacturers, wholesalers, global purchasing organizations (GPOs), distributors, logistic providers, hospitals and pharmacies.

2 Medicines Supply Chain

2.1 Overview

To ensure quality and safety at a high level of performance and efficiency from the manufacturer to the patient, the flow of medicinal products and patient data must be managed through the entire supply chain and the flow of information linked to these physical flows must be overseen. This is enabled by using the GS1 system of standards across the healthcare supply chain.

2.1.1 Product flow

Each packaging level of the medicine is assigned with a global trade item number (GTIN) and marked with batch/lot number and expiration date.

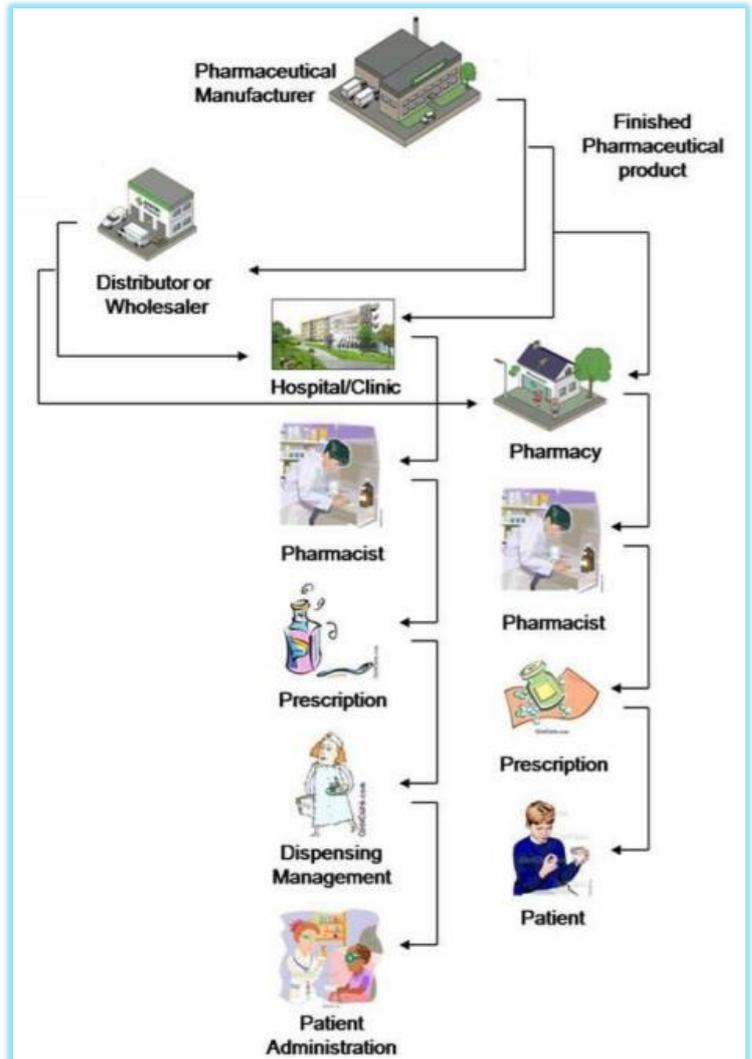
Ordered products are picked and logistic units are created and made ready for shipping. The logistic units are marked with a Serial Shipping Container Code (SSCC). Traceability can be achieved by connecting the SSCCs with the identity of the goods recipient (GLN, Global Location Number), the identities of the products (GTIN) and batch/lot numbers.

Product arrivals can be managed using the identity of the logistic units (SSCC).

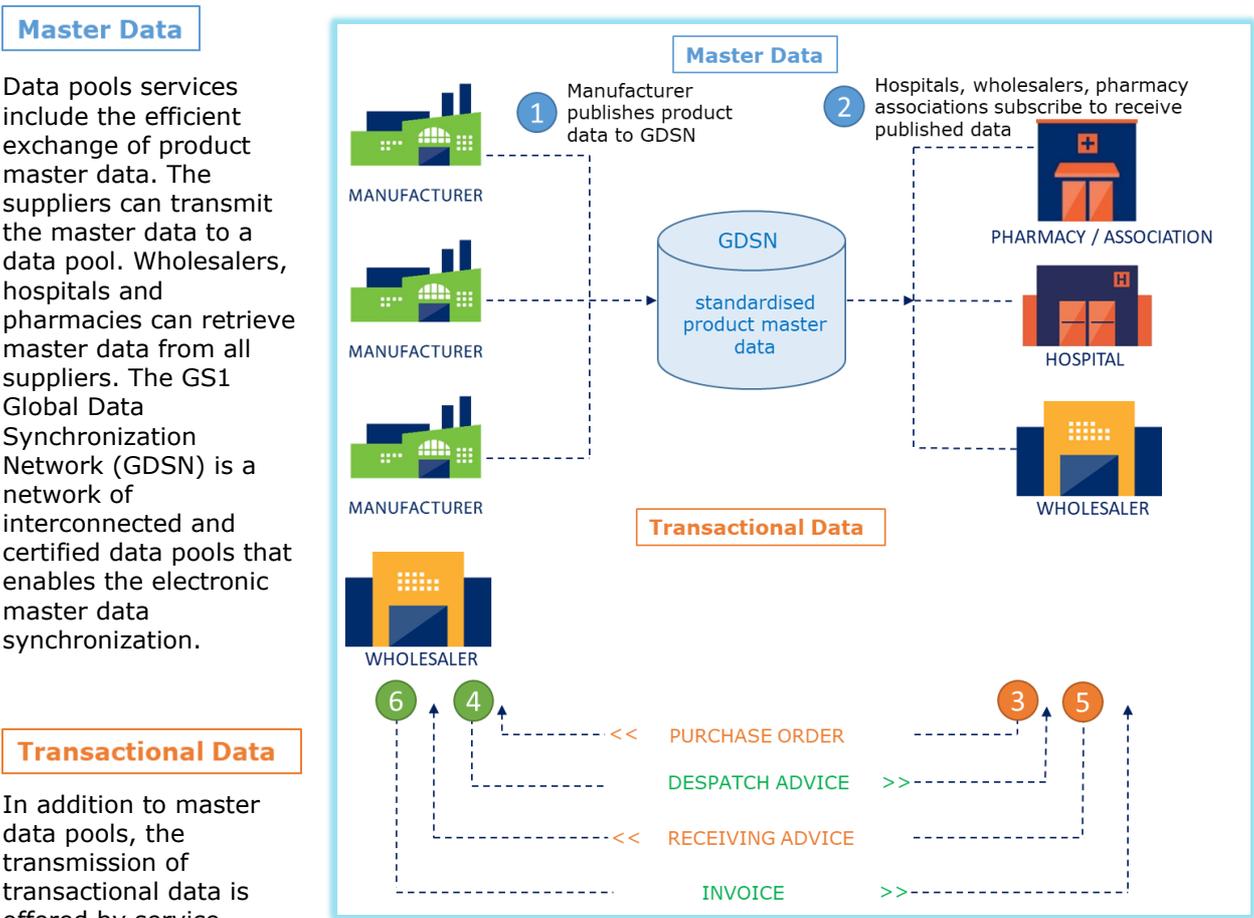
During storage, physical stock management can be optimized using the global trade item numbers (GTIN) and batch/lot numbers of the products and the identities of the logistic units (SSCC).

The internal processes in the hospitals and pharmacies should provide traceability up to the patients. Products are identified by their global trade item number (GTIN) and lot/batch number and are recorded in the patient's medical chart or records to ensure the complete safety and traceability.

If required by legislation a serial number must be added in the different steps.



2.1.2 Data flow



Master Data

Data pools services include the efficient exchange of product master data. The suppliers can transmit the master data to a data pool. Wholesalers, hospitals and pharmacies can retrieve master data from all suppliers. The GS1 Global Data Synchronization Network (GDSN) is a network of interconnected and certified data pools that enables the electronic master data synchronization.

Transactional Data

In addition to master data pools, the transmission of transactional data is offered by service providers, for example ordering platforms, electronic invoicing, transport (dispatch advice) and delivery (receiving advice) messages. An efficient and effective supply chain management can only be achieved if all partners use unique references (SSCC, GTIN and GLN).

2.2 Product configurations

For the identification of medicinal products, consideration should be given to the selection of the identification key and the use of variable data elements e.g. expiration date. Each level of package hierarchy presents differing identification requirements:

- a GS1 Identification Key: Global Trade Item Number (GTIN), Serial Shipping Container Code (SSCC)
- the additional data: e.g. batch number, expiration date, serial number

Each level also presents different data carriers and printing requirements in labelling (e.g. space, substrate, production line speed, etc.).

The relationship between the different packages levels (GTINs) should be managed by the brand owner and communicated to the trading partners. When using GDSN for the exchange of master data the hierarchy of the package levels will be exchanged automatically.

2.2.1 Primary Packages

Identification of, and the use of barcodes on, primary packages such as vials, pre-filled syringes or solid forms in blister cavity are important conditions for successful point of care verification, registration in electronic health records and contribute to automatic traceability up to the patient.

Identification and labelling effort of primary packages should be undertaken when existing packages provide enough space and if the process is technically possible. If packaging modifications would be necessary, labelling with barcodes should be considered each time packaging redesign is required.

Primary packages are in direct physical contact with the product. The following illustrations provide examples of common primary packaging forms for medicinal products. Each primary package is identified with its own GTIN (see section 4) and with the production information lot/batch and expiration date (see section 4). The recommended data carrier is the GS1 DataMatrix (see section 5).

■ Examples:



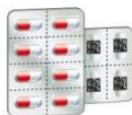
Single vials, or combinations of vials and their diluent, each identified with its own GTIN.



Ampoules.



Pouches.



Blister packs, identification of each cavity having the same GTIN.



Pre-filled syringe.

2.2.2 Secondary Packages

Secondary packages of medicines should be identified with their own GTIN (see section 4) together with the production information expiration date and batch/lot number (see section 4). This identification data should be encoded in the GS1 DataMatrix data carrier (see section 5). This identification and labelling lead to a product traceability system ensuring patient safety, facilitate recalls and improve business processes and logistics.

Secondary packages of medicinal products can be subject to carry a Unique Identifier (UI) according to legislation(s). Upon the above-described data elements, a random serial number (serialization) should be attributed to each secondary package (see section 4).

✓ Note: only one identification and barcode should be visible on the outer package to avoid confusion during scanning.

Secondary packages contain one or more items in their primary packaging.

- Examples:



Blisters in a box.



Bottle(s) in a box.

2.2.3 Kits

A kit is a combination of different components intended for one specific healthcare purpose and is supplied as a single trade item. A kit should be identified with its own GTIN (see section 4).

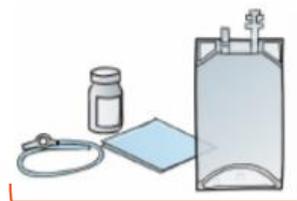
The responsible entity that defines the kit contents, specifications and labelling is the responsible organisation and therefore allocates the GTIN to the kit.

The additional information batch/lot number and expiration date associated with the kit (see section 4) should be added together with the GTIN. The recommended data carrier is the GS1 DataMatrix (see section 5).

Kits containing medicinal products can be subject to carry a Unique Identifier (UI) according to legislation(s). Upon the above-described data elements, a random serial number (serialization) should be attributed to each secondary package (see section 4).

Adding, removing or changing kit components requires a new GTIN. Please refer to the GS1 Healthcare GTIN Allocation Rules (<https://www.gs1.org/1/gtinrules/en/healthcare>).

- Example:



The GTIN of the kit must be different than the GTINs of the individual components.

2.2.4 Multipacks

Multipacks are composed of several single packs having the same GTIN, the same lot/batch number and the same expiration date. A multipack is intended for the convenience of logistic operations and handling.

If a multipack is a trade item (it can be priced, ordered or invoiced at one or more points in the supply chain) it should be identified with its own GTIN (see section 4) together with the additional information expiration date and batch/lot number (see section 4). The recommended data carrier is the GS1 DataMatrix (see section 5).

If a multipack is a trade item for the end-user, the individual boxes should have the required text 'can't be sold separately' or equivalent. *These multipacks could be subject to carry a Unique Identifier (UI) according to legislation(s). In that case, a random serial number (serialization) should be added on each multipack (see section 4).*

- Examples:



Bundle of packs



Carton with packs

2.2.5 Cases/Shippers

Cases / shippers may contain one or more items of lower package levels.

Fixed configurations of cases/shippers can be priced and/or ordered and/or invoiced at any point in the supply chain. These trade items should be identified with their own GTIN together with the additional information expiration date and batch/lot number (see section 4).

Shippers without a fixed configuration and established for transport and/or storage that needs to be managed through the supply chain should be considered as logistic units. Logistic units are any combination of trade items packed together for storage and/or transport purposes, for example a case or a pallet. Logistic units are identified with an SSCC (see section 4).

The recommended data carrier is the linear barcode GS1-128 (see section 5).



2.2.6 Pallets

Pallets may contain one or more cases or shippers.

Usually pallets are considered as logistic units and they should be identified with an SSCC. A logistic unit is an item of any composition established for transport and/or storage that needs to be managed through the supply chain.

Pallets with a fixed configuration might be trade items (i.e. they can be priced and/or ordered and/or invoiced at any point in the supply chain) and should be identified with a GTIN.

The data carrier for a SSCC and a GTIN on a pallet is the linear barcode GS1-128 (see section 5).



2.3 Traceability System

To achieve supply chain safety and integrity stakeholders in the medicines supply chain should be able to retrieve and manage traceability information from any point in the supply chain. The adoption of globally interoperable standards enhances the efficiency of the supply chain and supports the traceability system. The necessary components are:

- Identification of trade items, logistic units, locations, patients
- Alignment of master data
- Exchange of transactional data
- Record of traceability data

It is not necessary to use the global standards for the internal traceability processes within an organization. However, it is recommended that the organization explore the opportunity to harmonize internal and external traceability practices, processes and standards to reap greater benefit.

✓ Note: Technologies for data recording depend on the internal information system(s) of the organization e.g. Enterprise Resource Planning (ERP) software.

The steps that should be followed:

2.3.1 Pre-actions

- Determine how to assign, collect, share, and keep traceability data.
- Determine how to manage links between inputs, internal processes, and outputs.

2.3.2 Actions before the physical flow

- Create Global Location Number(s) (GLN) for your organization and assign GLNs for locations that are required for traceability.
- Assign Global Trade Item Number (GTIN) to trade items.

- Assign Global Returnable Asset Identifier (GRAI) to assets that need to be traced as relevant, e.g. transportation boxes for medicines from wholesaler to pharmacy.
- Exchange master data with trading partner. Master data elements should be aligned between trading partners before starting to order and deliver the products. For example: GTIN, description of the product, height, weight, etc... The best practice is to use a GDSN certified data pool, where the master data exchange is standardized, electronic and automatic.

2.3.3 Actions during the production process

- At production: assign additional identification to medicines:
 - o a batch/lot number and expiration date.
 - o if the medicine is a serialized product: add a serial number.
- Label the products as soon as created. The label should remain on the product throughout its intended useful life.
- The label should:
 - o contain the GTIN and the additional data in a data carrier. The recommended data carriers are the GS1-128 barcode and the GS1 DataMatrix. The choice will depend on the package level and/or legal requirements (see section 3).
 - o show the human readable information (HRI).
- Assign, if realizable during the production process, a SSCC (Serial Shipping Container Code) to logistic units and create a logistic label, using the GS1-128 barcode.

2.3.4 Actions at dispatch

- If not assigned during the production process, a SSCC (Serial Shipping Container Code) should be assigned to logistic units and a logistic label should be created, using the GS1-128 barcode.
- Collect, record and link internal data from dispatching step.
- Share the transactional data. The best practice is to use the DESADV EDI.
- Store all data collected. The length of time of retention of data should be in line with local regulatory requirements.

2.3.5 Actions at reception

- Scan and capture the identification of the trade item or logistic unit. If current labels received from suppliers do not enable automatic data capture, trading partners can contact their suppliers in order to invite them to use GS1 global standards for identification and data capture for their own benefits (automation at the dispatch) as well as for traceability reliability (data capture by the customer on receipt).
- Collect data from the supplier. DESADV is the best practice today.
- Link and store all data collected at reception. The length of time for retention of data should be in line with local regulatory requirements.

3 Implementation by stakeholder

3.1 Manufacturer

For the purpose of this document “Manufacturer” refers to supply chain partners who provide finished goods to downstream partners (e.g. wholesalers, distributors, hospitals).

Actions at implementation of static information for each medicinal product:

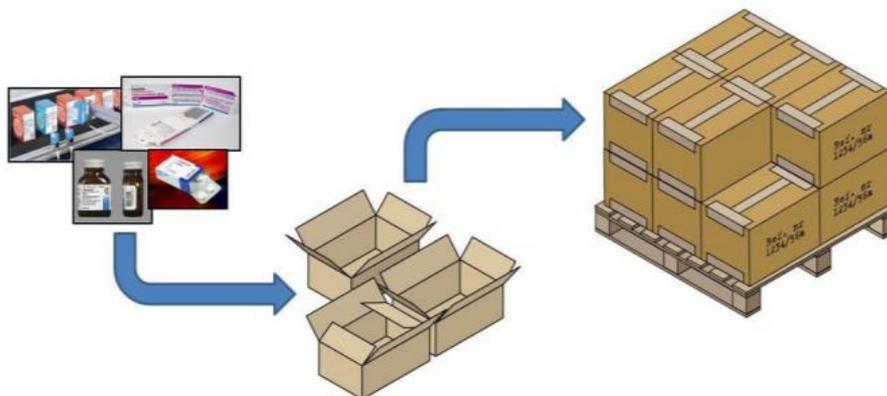
- Assign a GTIN to any package level of each medicine.
- Store product master data in a product master database, linked to the related GTIN.
- Share the product master data with the customer. This can be done through a GDSN certified data pool if both manufacturer and customer are connected.

Actions at production and labelling:

- Identify each level of products with the GTIN and additional data (batch/lot, expiration date and, if required, a serial number).
- Encode the product identification into the GS1-Datamatrix (primary and secondary packages and/or multipacks) or GS1-128 barcode (higher package levels).
- If the trade item is also the logistic unit a unique SSCC can already been assigned to it.

Actions at the warehouse/shipping location:

- An order is received from a wholesaler/distributor or a hospital for a quantity of one or more branded pharmaceutical products. For each ordered trade item, the GTIN should be specified in the order form.
- The products, usually packed in cartons, are picked and grouped in a shipping case or onto a pallet.
- When (a part of) the order is complete, assign a Serial Shipping Container Code (SSCC) to the logistic unit (shipping case or pallet). The globally unique SSCC enables traceability of this shipping unit from leaving the warehouse until arrival at the wholesaler/distributor or hospital.
- Link the SSCC with the essential information such as GTINs, quantity, batch/lot number, expiration date and, if required by the wholesaler or hospital, the serial numbers of the shipped goods.
- When the material physically leaves the manufacturer's site, send an electronic dispatch advice to the customer to provide him with the relevant information. The dispatch advice should contain at least the SSCC, the GTINs with their respective count, lot or batch number, expiration date and, if required by the wholesaler or hospital, the serial numbers.



3.2 Wholesaler/Distributor

For the purpose of this document “Wholesaler/Distributor” refers to supply chain partners who are engaged in wholesale distribution of products to downstream partners.

Actions at implementation of static information for each medicinal product:

- Collect the product master data of each medicinal product. This can be done through a GDSN certified data pool if the supplier and the wholesaler/distributor have agreed to synchronize data via the GDSN. Integrate the master data into the internal system(s).

Actions at goods reception:

- The wholesaler/distributor has received all important shipment information in advance from their upstream supply chain partner (e.g. manufacturer).
- Scan the Serial Shipping Container Code (SSCC) on the shipping unit. The data will automatically be matched with the electronic information received.
- Complete a visual check of the shipment and move the shipping unit into the warehouse.
- As long as the shipping unit is not unpacked the SSCC can be used to trace the original shipping unit within the warehouse. Discard the SSCC once the content of the original shipping unit is handled (unpacked, stored).
- Track the products in the warehouse by use of the GTIN of the package. A barcoded expiration date supports effective warehouse management in line with the first-expiration- first-out (FEFO) principle.

From this point onwards, tracking of the medicines leaving the warehouse must be done at the user package level. The reference for tracking products is the GTIN and the lot number.



The wholesaler/distributor receives an order for a quantity of medicines from a pharmacy (public or hospital). The medicines are grouped into a carton or shipping box.

Actions at the warehouse/shipping location:

- When (a part of) the order is complete, assign a SSCC to the shipping unit (carton or box or pallet). The globally unique SSCC enables traceability of this shipping unit from leaving the warehouse until arrival at the pharmacy or hospital or work with the identifier on the delivery tote.
- Link the SSCC with the essential information such as GTINs, quantity, batch/lot number, expiration date and, if required by the hospital, the serial numbers of the shipped medicines.
- When the material physically leaves the wholesaler’s or distributor’s site, send an electronic dispatch advice to the customer to provide him with the relevant information. The dispatch advice should contain at least the SSCC, the GTINs with their respective count, lot or batch number, expiration date and, if required by the hospital, the serial numbers.

3.3 Public Pharmacy

The identification level of medicines is likely to have been made upstream in the supply chain, for example, by the manufacturer. However, consideration should be given to items in a public pharmacy that do not comply with the global standards and a decision is taken by the pharmacy to apply the appropriate identification.

Actions at implementation of static information for each medicinal product:

- Collect the product master data of each medicinal product. This can be done through a GDSN certified data pool if the supplier and the pharmacy (or pharmacy association) have agreed to synchronize data via the GDSN. Integrate the master data into the internal system(s).

The public pharmacy has received all important shipment information in advance from their upstream supply chain partner (e.g. wholesaler/distributor).

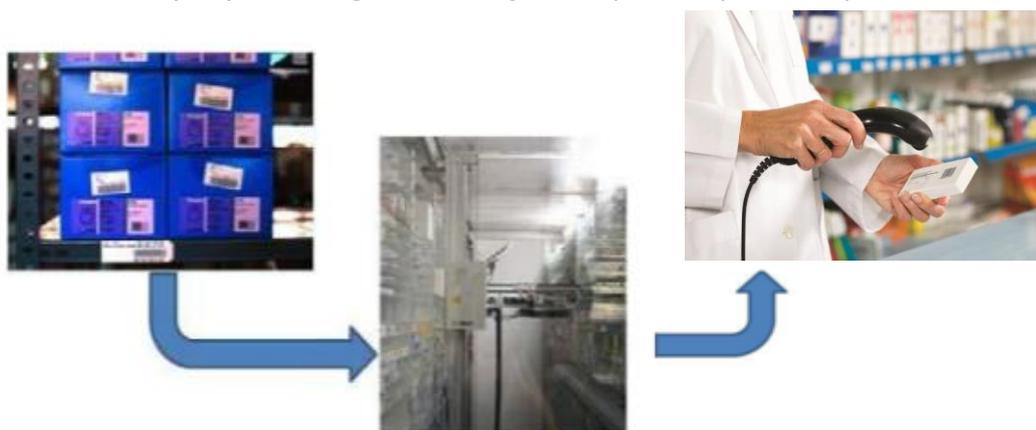
Actions at goods reception:

- Scan the SSCC on the shipping label. The data will automatically be matched with the electronic information received.
- Complete a visual check of the received goods.
- Suspend the SSCC and move the products into the store or stock.
- Track the products in the store and stock by use of the GTIN on the package. A barcoded expiration date supports effective store and stock management in line with the first-expiration- first-out (FEFO) principle.

A patient is requesting a medicine (with or without prescription) at the public pharmacy. Tracking of the products leaving the public pharmacy must be done at the user package level. The reference for tracking products is the GTIN and the lot or batch number (and the serial number if legally required).

Actions at dispense of the medicine to the patient:

- Scan the GS1 DataMatrix barcode on the product just prior to giving the product to the patient. The barcode contains the GTIN, batch or lot number, expiration date and, if legally required, a serial number. Scanning can be associated with the electronic prescription and the medication information can be recorded into the Electronic Patient Record (EPR). Scanning can also adjust the pharmacy inventory.



3.4 Hospital

The identification level of medicines is likely to have been made upstream in the supply chain, for example, by the manufacturer. However, consideration should be given to items in the hospital that do not comply with the global standards and a decision is taken by the hospital to apply the appropriate identification that does comply.

Actions at implementation of static information for each medicinal product:

- Collect the product master data of each medicinal product. This can be done through a GDSN certified data pool if the supplier and the hospital have agreed to synchronize data via the GDSN. Integrate the master data into the internal system(s).

The hospital has received all important shipment information in advance from their upstream supply chain partner (e.g. manufacturer or wholesaler/distributor).

Actions at goods reception:

- Scan the SSCC on the shipping label. The data will automatically be matched with the electronic information received.
- Complete a visual check of the received goods.
- Suspend the SSCC and move the goods into the stock or the hospital pharmacy.
- Track the goods within the hospital by use of the GTIN on the package. A barcoded expiration date supports effective stock management in line with the first-expiration-first-out (FEFO) principle.

Actions at the hospital pharmacy for identification of single dose units that do not carry a barcoded GTIN:

- Assign a GTIN, based on the hospitals GS1 company prefix.
- Take the supplier’s batch/lot number and optionally the supplier’s expiration date. The supplier’s expiration date can be taken when there is no integrity change of the medicinal product during the preparation of the single dose units.
- Encode the identification in a GS1 DataMatrix, print and apply the barcode label.
- Scan the items to record the information in the hospital pharmacy database.

A prescription from a ward medication is delivered to the hospital pharmacy using an electronic prescription entry system. The prescription document can be uniquely identified with the GS1 identifier Global Document Type Identifier (GDTI), encoded in a GS1-128 barcode or GS1 DataMatrix. The prescription should be related to the Electronic Patient Record (EPR).

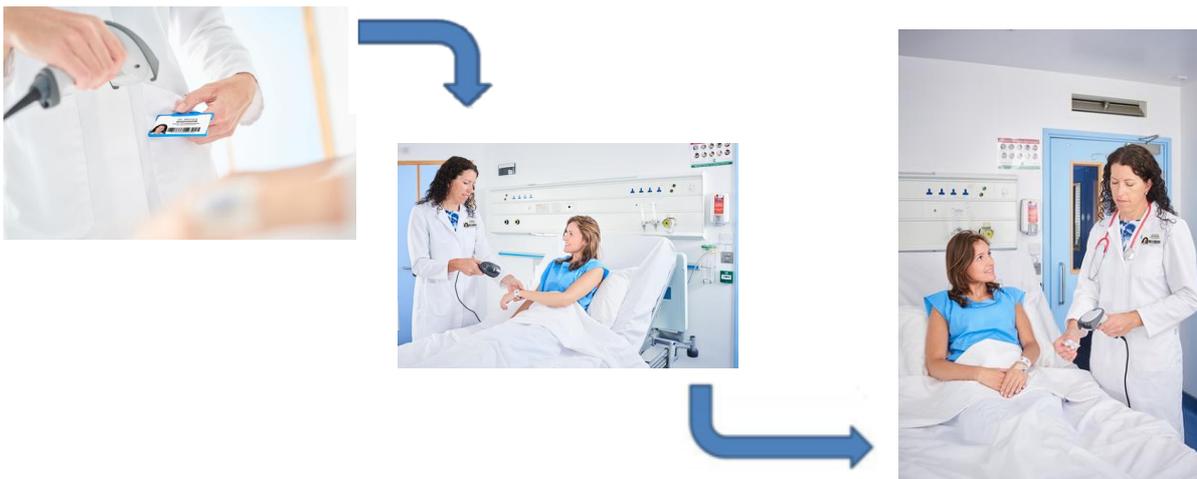
Actions at the hospital pharmacy when delivering medicines to the ward:

- Scan the GS1 DataMatrix just prior to dispatching the medication to the ward. The hospital pharmacy inventory will be adjusted.
- Scan the barcode on the prescription document to associate the medication to the prescription and to the Electronic Patient Record (EPR).



Actions at administration to the patient: bedside scanning

- Prior to the administration, scan the patient’s wristband for positive patient identification, scan the single dose unit GS1 DataMatrix and scan the caregiver’s identification. The GS1 identification key Global Service Relation Number (GSRN), encoded in a GS1 DataMatrix, can be used for the identification of patients and caregivers. The bedside scanning, in combination with the Hospital Information System (HIS), makes an automatic check of the relation between the medication and the patient possible. This procedure reduces medication errors and ultimately enhances patient safety. The patient’s medication should be automatically recorded (with TDOS: time, date and operator stamp) in the Electronic Patient Record, resulting in an optimal traceability up to the patient.



4 GS1 standards for identification of medicines and logistic units.

When marking the different package levels of medicines, GS1 Identification Keys are used to identify trade items and logistic units. Additional data, e.g. lot number and expiration date, may be associated with the GS1 Identification Keys. The GS1 Identification Keys can be encoded in the data carriers GS1-128 barcode or GS1-DataMatrix (see section 5) together with the additional data by using the GS1 Application Identifiers (AI’s).

If legislation requires human readable interpretation, “Characters, such as letters and numbers, which can be read by persons are encoded in GS1 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.”

see links below for exact application of the rules:

FAGG : https://www.fagg-afmps.be/sites/default/files/content/POST/MAH/119-nl-etikettering_van_geneesmiddelen.pdf

EMA : https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-2/c/2009_01_12_readability_guideline_final_en.pdf
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/draft-quality-review-documents-recommendations-pack-design-labelling-centrally-authorized-non_en.pdf

Following are the GS1 Identification Keys and Application Identifiers that are contained in the GS1 General Specifications for use in Healthcare AIDC applications.

4.1 Global Trade Item Number (GTIN)

The GS1 Key for unique product identification is the Global Trade Item Number (GTIN). GTINs are used to identify “trade items” (i.e., products and services that may be priced, ordered or invoiced at any point in the supply chain). They are assigned by the brand owner. Each package level in an item hierarchy must have a unique GTIN.

The structure of a GTIN is based on the GS1 Global Company Prefix (GCP). A company receives a GS1 Global Company Prefix (GCP) by joining a GS1 Member Organization. Different formats of GTINs can be used. In this document the GTIN-13 and GTIN-14 formats will be described. The GTIN-13 starts with the GCP followed by a unique trade item code attributed by the company up to a 12-digit number. The 13th digit is the check digit. The GTIN-14 starts with a digit between 1 and 9, the so-called indicator. The indicator is followed by the GCP and the trade item code up to a 13-digit number. The 14th digit is the check digit.

✓ Note: the check digit can be calculated by using the check digit calculator:

<https://www.gs1belu.org/nl/tools/bereken-het-controlecijfer>

<https://www.gs1belu.org/fr/outils/calculer-le-chiffre-de-contrôle>

On consumer packages, the GTIN-13 is used for identification. On lower or higher package levels, a GTIN-13 or GTIN-14 can be used.

! Important: only for applications that require a uniform 14-digit format, a leading zero should be added to the GTIN-13. Examples are the coding of GTIN-13 in a GS1-128 barcode or a GS1 DataMatrix and the use of the Global Data Synchronization Network (GDSN) for the exchange of master data between trading partners and/or regulatory agencies.

The GTIN-13 and GTIN-14 are composed of numeric characters

GTIN-13: the total length without leading zero is 13 digits

the total length with leading zero is 14 digits

GTIN-14: the total length is 14 digits; a GTIN-14 never starts with a zero.



 For applications that require a uniform 14-digit format, a leading zero should to be added to the GTIN-13.

 Indicator digit (from 1 to 8; 9 is for products with variable weight and/or dimensions)

 Start of GS1 Global Company Prefix

 Additional digits of the GS1 Global Company Prefix

 Depending on the length of the Global Company Prefix: additional digits of the GCP or part of product code

 Depending on the length of the Global Company Prefix: additional digits of the product code or start of the product code.

 Check digit

The Application Identifier (01) is used to assign a GTIN when it is encoded into a GS1-128 or GS1-DataMatrix data carrier. Application Identifier (01) is always followed by the GTIN data field with a fixed length of 14 numerical characters. This means that a leading zero should be added to a GTIN-13, manually or automatically by the barcode creator software.

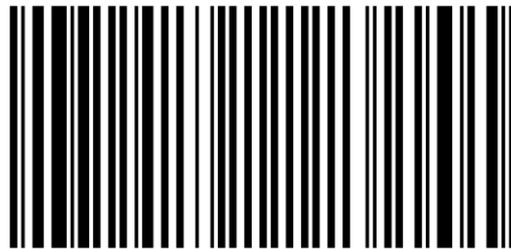
■ Examples:

GTIN-13 (541000007834) encoded in the GS1-DataMatrix:



(01) 0 5410000 00783 4

GTIN-14 (1541000007831) encoded in the GS1-128 barcode:



(01) 1 5410000 00783 1

✓ Note: Refer to the GS1 General Specifications (<https://www.gs1.org/standards/barcodes-epcrfid-id-keys/gs1-general-specifications>) and GS1 Healthcare GTIN Allocation Rules (<https://www.gs1.org/1/gtinrules/en/healthcare>) for the GTIN structure.

! Important: the GTIN should never be duplicated or re-used even if the product becomes obsolete.

4.2 Batch/Lot

If the production data batch or lot number is required, the GS1 Application Identifier (10) is used to assign the batch or lot number when it is encoded, together with a GTIN, into the GS1-128 or GS1-DataMatrix data carrier. The format of the batch or lot number is alphanumeric with a variable length of up to 20 characters.

■ Data string:

$(01)N_1N_2N_3N_4N_5N_6N_7N_8N_9N_{10}N_{11}N_{12}N_{13}N_{14}(10)X_1...X_{\leq 20}$

with (01) the application identifier for GTIN

N numeric characters, fixed length of 14 digits for the GTIN (add a leading zero when using a GTIN-13)

(10) the application identifier for batch/lot number

X₁...X_{≤20} alphanumeric characters, with variable length up to 20 characters for the batch/lot

4.3 Expiration Date

If the expiration date is required, the GS1 Application Identifier (17) is used to assign the expiration date when it is encoded, together with the GTIN, into the GS1-128 or GS1 DataMatrix data carrier. The format of the expiration date is numeric with a fixed length of 6 digits expressed as year, month and day (YYMMDD).

- Data string:

`(01)N1N2N3N4N5N6N7N8N9N10N11N12N13N14(17)N1N2N3N4N5N6`

with (01): the application identifier for GTIN

N: numeric characters; fixed length of 14 digits for the GTIN (add a leading zero when using a GTIN-13), fixed length of 6 digits for the expiration date expressed as YYMMDD.

(17): the application identifier for expiration date

4.4 Serial Number

If medicinal products are subject to serialisation, Application Identifier (21) should be used to encode the serial number, together with the GTIN, into the GS1 DataMatrix data carrier. The serial number is alphanumeric with a variable length of up to 20 characters.

- Data string:

`(01)N1N2N3N4N5N6N7N8N9N10N11N12N13N14(21)X1...X≤20`

with (01) the application identifier for GTIN

N numeric characters, fixed length of 14 digits for the GTIN (add a leading zero when using a GTIN-13)

(21) the application identifier for serial number

X₁...X_{≤20} alphanumeric characters, with variable length up to 20 characters for the serial number

- Example:

4 data-elements encoded in the GS1 DataMatrix:

GTIN-13: 5410000007834

Expiration date: June 14, 2022

Batch / lot number: ABC123

Serial number: 2Q47P



(01) 0 5410000 00783 4

(17) 220614

(10) ABC123

(21) 2Q47P

✓ Note: concatenation is often used. Concatenation is advantageous because it means that the symbol's double start, symbol check and stop characters are only needed once, and the space required for the symbol is smaller than when separate barcodes are used to encode each element string. It also improves scanning accuracy, allowing for single scanning rather than multiple scanning. The various element strings are transmitted from the barcode reader as a single full

string. The GTIN is always put first then the AI's with fixed length followed by the AI's with variable length. AI's with variable length need a function 1 separator unless placed at the end of the string

More technical information on concatenation:

https://www.gs1.org/sites/default/files/docs/barcodes/GS1_General_Specifications.pdf

Pages 445-449

4.5 Serial Shipping Container Code (SSCC)

The GS1 Key for uniquely identifying a logistic unit is the Serial Shipping Container Code (SSCC). The SSCC can provide a link between the physical and information flow pertaining to the SSCC that is communicated between trading partners using Electronic Data Interchange (EDI).

The structure of the SSCC is a numeric code with a fixed length of 18 digits. The SSCC starts with a digit between 0 and 9, the so-called extension digit. This extension digit is followed by the GCP and the serial reference of the logistic unit up to a 17-digit number. The 18th digit is the check digit.

✓ Note: the check digit can be calculated by using the check digit calculator:

<https://www.gs1belu.org/nl/tools/bereken-het-controlecijfer>

<https://www.gs1belu.org/fr/outils/calculer-le-chiffre-de-controle>

The SSCC is composed of numeric characters, with a fixed length of 18 digits



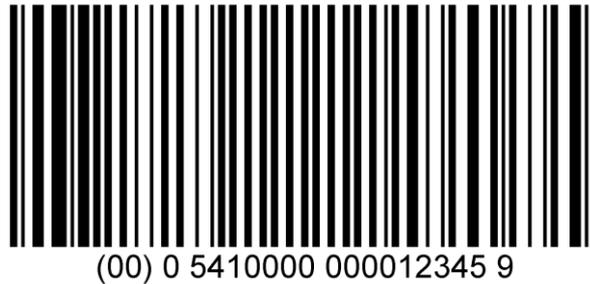
-  Extension digit (between 0 and 9)
-  Start of GS1 Global Company Prefix
-  Additional digits of the GS1 Global Company Prefix
-  Depending on the length of the Global Company Prefix: additional digits of the GCP or part of the serial reference of the logistic unit
-  Depending on the length of the Global Company Prefix: additional digits of the serial reference of the logistic unit or start of the serial reference of the logistic unit
-  Check digit

The Application Identifier (00) is used to assign a SSCC when it is encoded into a GS1-128 data carrier.

✓ Note: Refer to GS1 General Specifications for the SSCC structure and rules of use (<https://www.gs1.org/standards/barcodes-epcrfid-id-keys/gs1-general-specifications>).

■ Example:

SSCC (054100000000123459) encoded in the GS1-128 barcode:



The label on a logistic unit carries the SSCC in a GS1-128 barcode. The label should also show the SSCC in text format with the use of the data title SSCC. At the top of the label additional free text information can be added, e.g. sender information.

■ Example: logistics label

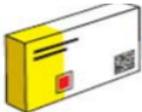


4.6 Overview identification keys, variable data and their application on each package level

Table 1: Overview of the identification keys and the variable data

GS1 Application Identifier	Data Description	Format	Additional information
01	Global Trade Item Number (GTIN)	N2+N14	For trade items only
10	Batch or lot number	N2+X ₁ ...X ₂₀	Variable length
17	Expiration date	N2+N6	Expressed as YYMMDD
21	Serial number	N2+X ₁ ...X ₂₀	Variable length
00	Serial Shipping Container Code (SSCC)	N2+N18	For logistic units only

Table 2: Overview of GS1 Identification on each package level

Package level	Healthcare product	GS1 key (AI)	Additional data (AI)	Suggested GS1 Data Carrier*
Primary packaging		GTIN"A" (01) (GTIN-13 or GTIN-14)	Batch/Lot (10) Expiration date (17)	GS1 DataMatrix
Secondary packaging		GTIN"B" (01) (GTIN-13)	Batch/Lot (10) Expiration date (17) Serial number (21), if required by legislation	GS1 DataMatrix
Multi-packs		GTIN"C" (01) (GTIN-13 or GTIN-14)	Batch/Lot (10) Expiration date (17) Serial number (21), if required by legislation	GS1-128 GS1 DataMatrix if required by legislation
Case/Shipper		For fixed configurations (trade items): GTIN"D" (01) (GTIN-13 or GTIN-14)	Batch/Lot (10) Expiration date (17)	GS1-128
		and/or SSCC (00), if logistic unit		GS1-128
Pallet		SSCC (00)		GS1-128
		and GTIN"E" (01), if the pallet is a trade item	Batch/Lot (10) Expiration date (17)	GS1-128
		If the boxes on the pallet are cases / shippers, each with their own SSCC no additional identification is used. Reception is done at the level of the cases / shippers.		

*Description of the data carriers in section 5

5 GS1 data carriers used in the healthcare sector

The recommended GS1 data carriers for automatic identification of medicines are the linear GS1-128 barcode and the two-dimensional GS1 DataMatrix. Depending on the package level, the available space on the product, existing regulations and sector requirements either the linear GS1-128 barcode or the 2D symbol GS1 DataMatrix is chosen (see section 4.6). It is good practice to evaluate the quality of the data carrier, in accordance with ISO/IEC 15415 and 15416, and to ensure your barcodes consistently meet the quality standards as specified in the GS1 General Specifications. In first stages, your local GS1 Member Organization can check your codes.

5.1 GS1 DataMatrix

The GS1 DataMatrix is a two-dimensional barcode symbol and is derived from ISO/IEC DataMatrix. It supports the GS1 System data structures, including the Function 1 Symbol Character. This extremely flexible data carrier encodes element strings using the GS1 Application Identifiers. The GS1 DataMatrix can encode large amounts of data in small areas and employ "error detection" and "error correction".

Implementation of GS1 DataMatrix should be done as per the approved GS1 System application guidelines (https://www.gs1.org/sites/default/files/docs/barcodes/GS1_DataMatrix_Guideline.pdf).

The size of a GS1 DataMatrix is dependent upon the amount and format (numeric or alphanumeric) of the encoded information, the choice of form (square or rectangular) and the size of the X-dimension. The X-dimension is the length of one of the sides of the symbol elements in the GS1 DataMatrix. The specification of the X-dimension for regulated healthcare trade items is related to the scanning environment (https://www.gs1.org/sites/default/files/docs/barcodes/GS1_General_Specifications.pdf):

Scanning environment of the medicines	X-dimension (mm)		
	Minimum	Target	Maximum
Hospital/Nursing homes	0.254	0.380	0.990
Public pharmacy	0.396	0.495	0.990

■ Example:

Secondary package with GTIN, serial number, expiration date and lot number encoded in the GS1DataMatrix



5.2 GS1-128

GS1-128 barcodes can hold GS1 identification keys (GTIN, SSCC) and additional information (batch/lot number, expiration date, etc.). This extremely flexible data carrier encodes the element strings using the GS1 Application Identifiers. GS1-128 barcodes must be distinguished from Code 128 barcodes by the use of Function Code 1 (FNC1), immediately after the start character.

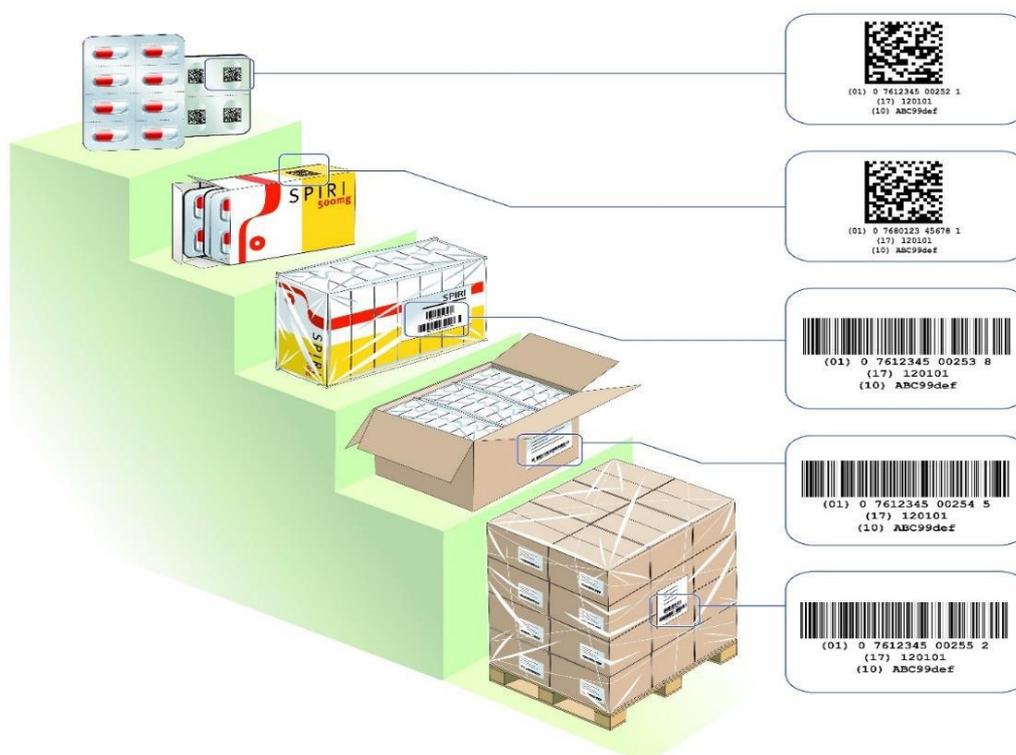
Implementation of GS1-128 should be done according to the GS1 General Specifications (https://www.gs1.org/sites/default/files/docs/barcodes/GS1_General_Specifications.pdf).

The size of the GS1-128 barcode is dependent upon the amount and format (numeric or alphanumeric) of the encoded information, the size of the X-dimension and the height. The X-dimension is the width of the smallest bar of the GS1-128 symbol. The specifications of the X-dimension and the height for regulated healthcare trade items is related to the scanning environment:

Scanning environment of the medicines	X-dimension (mm) / minimum height (mm)		
	Minimum	Target	Maximum
Hospital/Nursing homes	0.170 / 12.70	0.495 / 12.70	0.495 / 12.70
Public pharmacy	0.264 / 12.70	0.330 / 12.70	0.660 / 12.70
Logistic environment (cases, shippers, pallets)	0.495 / 31.75	0.495 / 31.75	0.940 / 31.75

5.3 Example of GS1 data carriers for each package level

When an identification is attributed to a product, the producer must transmit the product information linked to this number as well as the packaging hierarchies.



✓ Note: Traceability after theft.

With an end-to-end system such as in the EU, the stolen packs cannot be identified, and therefore cannot be blocked. With an e-pedigree like in the US it's possible.

Aggregation databases are a solution, but in that case there is a greater risk of serial codes being hacked, and the 1/10000 guess correction is lost. Protecting the serial codes is therefore very important.

When exchanging data digitally it is very important to ensure sufficient digital security to prevent harvesting of original unique codes. These stolen codes could be used to market false medicines with correct codes.

6 Appendix

6.1 Acronym decoder

AI	Application Identifier
AIDC	Automatic Identification and Data Capture
DESADV	Dispatch Advice message
EDI	Electronic Data Interchange
EPC	Electronic Product Code
FNC1	Function Code 1
GCP	Global Company Prefix
GDTI	Global Document Type Identifier
GLN	Global Location Number
GPO	Global Purchasing Organization
GTIN	Global Trade Item Number
GSRN	Global Service Relation Number
HIS	Hospital Information System
HRI	Human Readable Information
OTC	Over The Counter medicinal products
RFID	Radio Frequency Identification
Rx	Medical Prescription Product
SSCC	Serial Shipping Container Code
TDOS	Time, date, Operator Stamp
UI	Unique Identifier

6.2 Resources

General Specifications

<https://www.gs1.org/standards/barcodes-epcrfid-id-keys/gs1-general-specifications>

Healthcare GTIN Allocation Rules

<https://www.gs1.org/1/gtinrules/en/healthcare>

GS1 Global Traceability Standard for Healthcare (GTSH) Implementation Guideline

https://www.gs1.org/sites/default/files/docs/healthcare/gs1_global_traceability_healthcare_implementation_guideline_i1_0_1_2015-07-13.pdf

Questions on the content of this publication? Contact the Healthcare helpdesk of GS1 Belgium & Luxembourg: tel +32 (0)2 290 57 73 or Healthcare@gs1belu.org

