AIDC Healthcare

Implementation Guideline

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Document Summary

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Document Description	For the buying, selling and trading of products and services, organisations need to adhere to standards in their communications. 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 global, neutral, non-ambiguous and non-significant. 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.

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Log of Changes in Version 3

Issue No.	Date of Change	Changed By	Summary of Change
1	Dec 2010	Mike Mowad	Initial Version
2	Aug 2013	Chuck Biss	Edit in Response to WR#13-000128
3	Feb 2015	Michael Sarachman	Added new section for Human Readable Interpretation (HRI). Updated Direct Part Marking (DPM) section and Ratified

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1. Introduction

GS1 Healthcare is a healthcare-specific, global user group bringing together both large and small Healthcare stakeholders: pharmaceutical and medical device suppliers and manufacturers, wholesalers and distributors, group purchasing organisations, hospitals, pharmacies, logistic providers, governmental and regulatory bodies and industry associations. It was formed in 2007 when the GS1 EPCglobal Healthcare and Life Sciences Industry Action Group (HLS) and the GS1 global Healthcare User Group (GS1 HUG) merged into one global Healthcare user group: “GS1 Healthcare”.

The vision of GS1 Healthcare is to be the recognised, open and neutral source for regulatory agencies, industry organisations and other similar stakeholders who are seeking direction for global standards in healthcare for patient safety, supply chain security & efficiency, traceability and accurate data synchronisation. The mission of GS1 Healthcare is to lead the Healthcare sector to the successful development and implementation of global standards by bringing together experts in Healthcare to enhance patient safety and supply chain efficiencies.

Automatic Identification and Data Capture (AIDC) Standards for Healthcare trade items have been incorporated within the *GS1 General Specifications*. The result is a voluntary standard providing Healthcare industry stakeholders with a common set of data and data carriers to be applied to medical products at every packaging level, including specific guidance on selection and use of:

- Appropriate GS1 Product Identification Keys
- Additional product and production data, for example; batch/lot, expiration date, and/or serial number (where applicable)
- GS1 Data Carriers including; linear bar codes, two-dimensional bar codes and Radio Frequency Identification (RFID) tags

The Application Standard for AIDC in Healthcare was developed to target approximately 80% of the Healthcare products currently in the global marketplace. Future efforts will target additional AIDC marking needs.

These support the ability for sector-wide implementation of AIDC systems targeted to improve patient safety, reduce medication errors, facilitate anti-counterfeiting and enable effective product recalls, and adverse event reporting, while addressing inefficiencies throughout the Healthcare supply chain, and allowing stakeholders to improve and integrate their processes.

This work was completed over three (3) years by more than 100 experts from every region of the world and segment of the healthcare supply chain. This involved over 150 meetings (more than 4,500 contact hours) as the teams carefully compiled the industry’s business requirements, and designed and delivered the global GS1 solutions to meet these challenging requirements.

With the publishing of these changes in the *GS1 General Specifications*, the focus has turned to developing this Implementation Guideline. It is intended to guide the Healthcare user through the process of implementing the GS1 System for AIDC in Healthcare.

1.1. Purpose of this Document

For the buying, selling and trading of products and services, organisations 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 non-ambiguous. 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 supplementary data represented in a bar code 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 document is intended to provide guidance to readers for:

- Using a Global Trade Item Number (GTIN) in a Healthcare environment
- Recognising when additional data is required for healthcare trade item identification and traceability
- Interpreting the various AIDC marking requirements for healthcare trade items.

This implementation guide does not set or modify GS1 standards. This guideline 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* (www.gs1.org/gtinrules)
- *GS1 Traceability Standard for Healthcare* (http://www.gs1.org/healthcare)
- *GS1 Global Data Dictionary – GDD* (http://gdd.gs1.org/gdd)

Important: This document should not be interpreted as a regulatory guide for the marking or identification of products. It includes implementation guides for a variety of the more complicated issues encountered when implementing the GS1 standards outlined by this document. It seeks to increase consistency and ease of implementation by explaining the GS1 standards and providing real-world examples.

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

Note: Your local GS1 Member Organisation is the primary contact for additional information and assistance.

1.2. Who Will Use this Document?

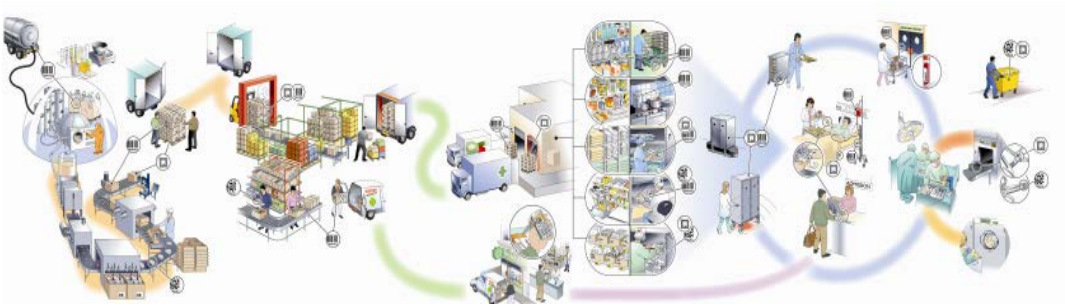
This document is intended for parties within the healthcare supply chain who are responsible for the selection of data and data carriers, the labelling of healthcare products, and parties that scan/read the data carriers.

Product identification principles as applied to the products in other industry sectors should be expanded to account for some unique characteristics in the healthcare sector, such as the risk classifications assigned to products and the need for products to be identified until point of use or throughout treatment.

This document will be used when an organisation has to define and apply a GTIN and the additional information to facilitate tracing its products throughout the supply chain. Organisations that may find this document useful include manufacturers, wholesalers, GPOs, distributors, logistic providers, retailers, hospitals and pharmacies.

The healthcare supply chain (Figure 1-1) represents the point of manufacture to end-of-treatment throughout the product lifecycle.

Figure 1-1 Healthcare Supply Chain



2. Type of Products in Scope

This section identifies example types of products with supplemental descriptions that are addressed in this document.

2.1. Pharmaceutical Products

These products are submitted for market authorisation to be sold in a country. Depending on the healthcare organisation, an authorisation code can be given by a government agency, a GS1 member organisation, or any organisation validated by the ministry of health to allocate this code.

In most countries these products can only be sold in a selected distribution channel such as pharmacies and are subject to specific regulations.

Over the Counter (OTC)

An OTC is a pharmaceutical product, drug, or medicinal specialty whose dispensing or administration does not require medical authorisation. Normally it can be used by the consumers under their own initiative and responsibility to prevent, relieve or to treat symptoms or mild diseases. Its use, in the form, conditions and authorised dosages should be safe for the consumer.

This covers healthcare items, pharmaceuticals, and medical devices that do not require a medical prescription or direct medical intervention. Typical examples include bandages, first-aid kits, mouthwash, low-strength pain-killers, etc.

Medical Prescription (Rx)

A Medical Prescription Product (Rx) (often referred to as a Pharmaceutical) is a drug, medical device, or medicinal specialty that requires a medical prescription or direct medical intervention. Typical examples include, medicated bandages, pain medication, injectables, etc. and can normally only be obtained with a prescription from an appropriate health care practitioner.

Hospital Pharmacy Production

A Hospital Pharmacy Product is a product that has to be manufactured by a hospital pharmacy for internal or multi-hospital use, thus it is not (or is no more) marketed by the pharmaceutical company that supplied the raw material. These products may correspond to the Rx or OTC category. In any case, they have to be clearly identified from the production to the bedside.

2.2. Medical Devices

Medical device means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article intended by the manufacturer to be used, alone or in combination for human beings for one or more of the specific purposes of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury
- Investigation, replacement, modification or support of the anatomy or of a physiological process
- Supporting or sustaining life
- Control of conception
- Disinfection of medical devices
- Providing information for medical purposes by means of in vitro examination of specimens derived from the human body and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

3. Healthcare Product Marking

When adopting the GS1 standards for Healthcare product marking consideration should be given to the following:

- AIDC Marking Levels
- Product Configuration
- Package Hierarchy
- Distribution Channel

The following sections will more fully describe these areas of consideration to be used by the organisation(s) responsible for selection of the AIDC marking.

Note: All products shown in this implementation guide are intended as examples. Please refer to your local regulatory or trading partner requirements for more information.

Note: All of the terms used in sections 0 and 3.3 are defined in section 3.4.

3.1. Human Readable Interpretation (HRI)

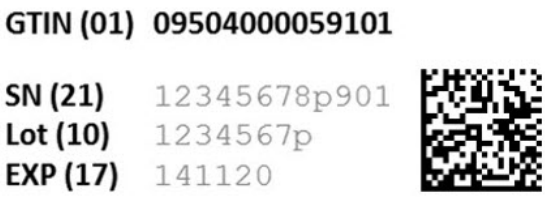
Human Readable Interpretation (HRI) is the information printed adjacent to a barcode or RFID tag that represents data carried in the bar code or tag. The rules for defining and applying HRI are described in the GS1 General Specifications, Section 4.14. Healthcare products often encounter regulatory, space, and technical constraints, so some specific rules are outlined for these products and are outlined in Section 4.14.1.

The Healthcare HRI rules enable label designers to minimize space requirements by merging HRI and non-HRI text. Doing so enables the manufacturer to display product safety information such as the lot and expiry date, without the need to display it both as HRI and in a standard label structure.

Figure 3-1 illustrates one application of this approach, combining data labels (e.g. GTIN, SN, and batch/lot) with application identifier labels [(01), (21), (10)]. This approach enables the label designer to simultaneously meet the HRI and regulatory labelling requirements without having to print this

information in two locations. Since the application identifier label is displayed next to each attribute, the data printed must follow the HRI rules, matching the data encoded in the barcode symbol.

Figure 3-1 Labelling HRI text with data labels



Regulators often require certain data attributes be represented in specific formats. This is especially true for date fields, such as expiry date. When the data format required to be displayed matches the HRI format, the AI may be used. However, as noted in the GS1 General Specifications, when it does not match, the AI must be omitted, but the data label should be used to identify the attribute. This applies to all attributes that may appear on a healthcare product label.

This is illustrated in **Figure 3-2.** In this example, the date shown in HRI is `141120`, while in non-HRI, it is represented as `20 Nov 2014`. Since these formats do not match, the non-HRI format may be used, but the application identifier label, (17), is omitted. The label formats used in the following examples are not intended to be descriptive or recommendations for meeting the requirements of the standards or local regulations. **Figure 3-3** illustrates additional examples of how HRI and non-HRI text may be combined.

Data labels are often prescribed by local regulators to ensure they are understood by the user of the product, requiring local languages to be used. Therefore, data labels that are not the same as the data titles defined in the GS1 General Specifications Section 3.2, Figure 3.2 -1, may be used to identify these data attributes as needed for each market. In addition to text labels, graphical data labels such as those defined in ISO 15223-1, may be used to identify label information, as illustrated in **Figure 3-3**.

Figure 3-2 Merging HRI and Non-HRI Text Example

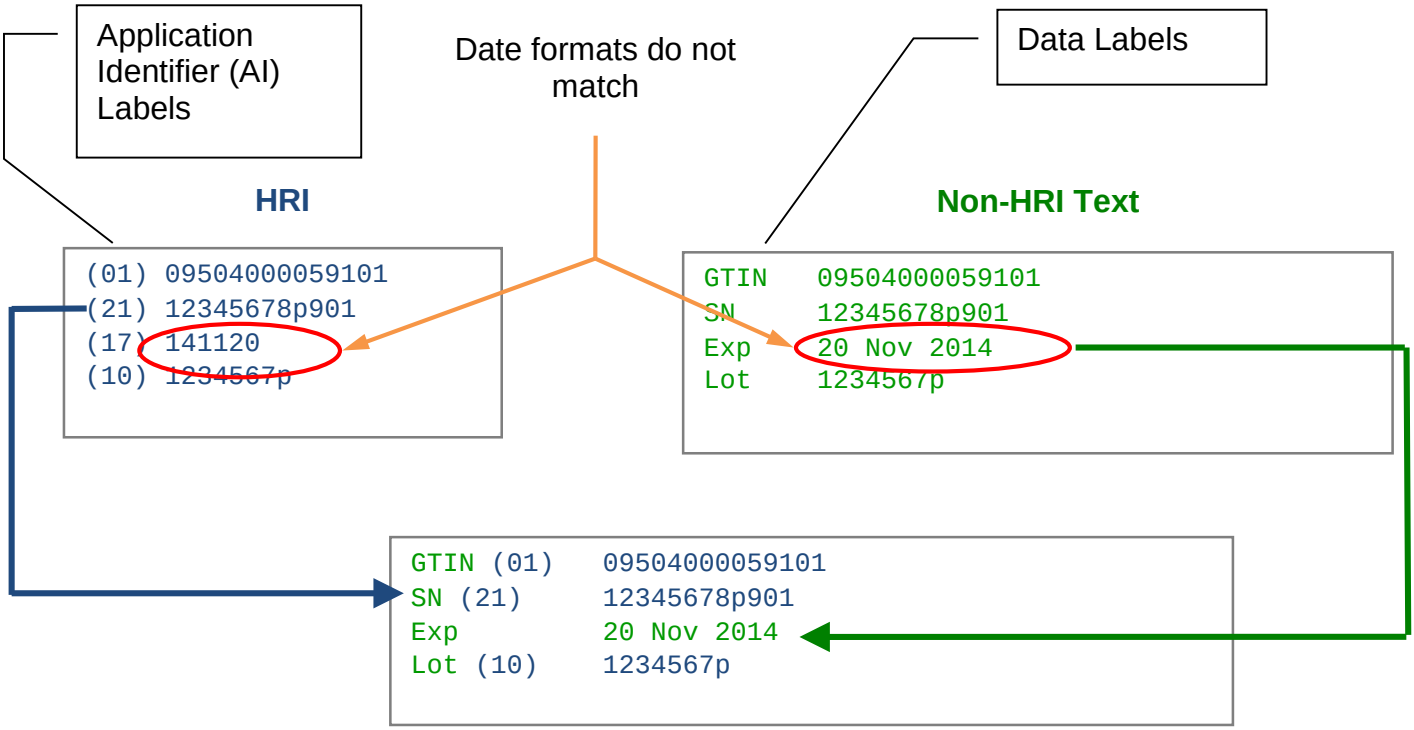
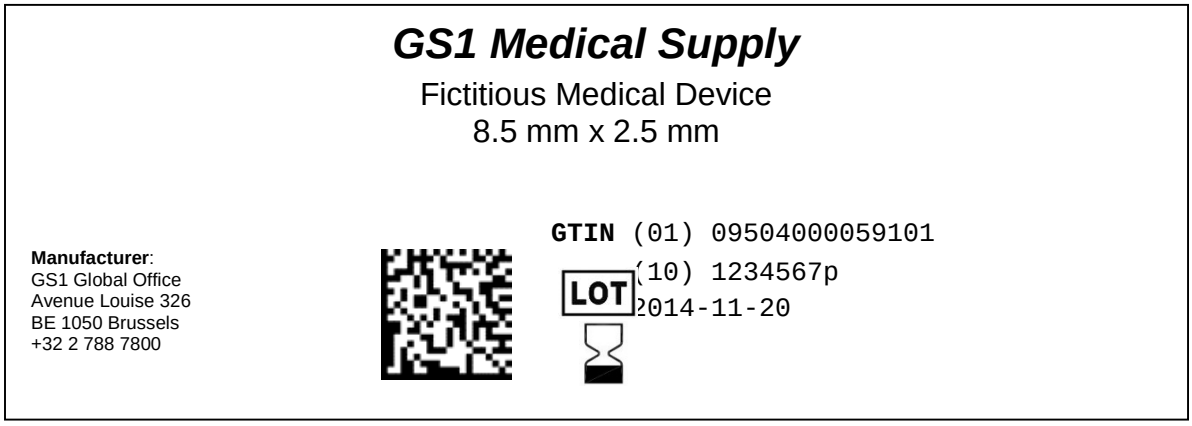


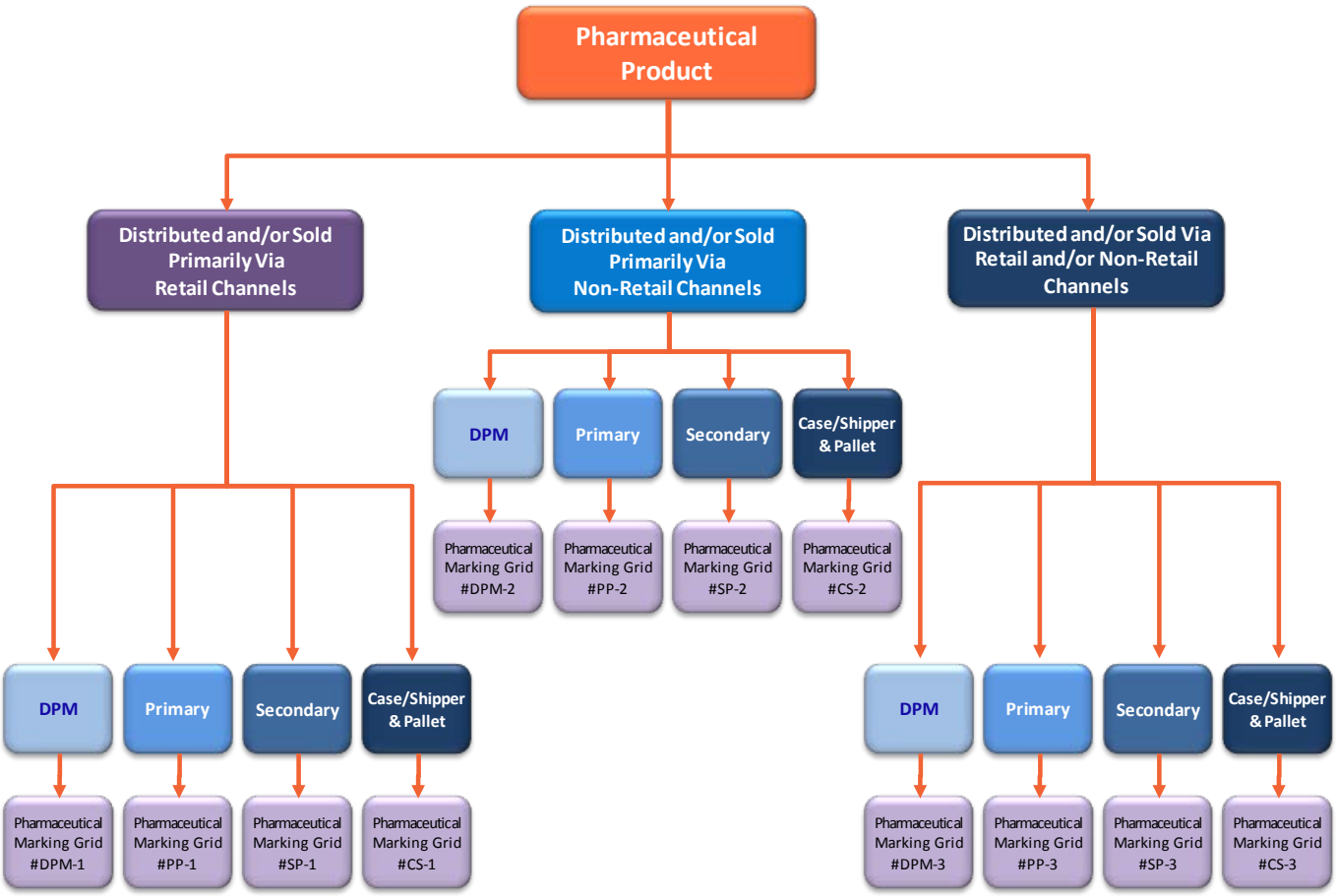
Figure 3-3 Additional HRI configuration examples



3.2. Marking for Pharmaceutical Products

The following flow diagram will assist the reader in visualizing the navigation of Healthcare AIDC Marking for Pharmaceutical Products. This should be reviewed in conjunction with the *GS1 General Specifications* and the Pharmaceutical Marking Grid (Figure 3-5). It describes the possible combinations of data content for AIDC marking of Healthcare Pharmaceutical trade items.

Figure 3-4 Pharmaceutical Products Marking



Note: These are generalised examples. Refer to the *GS1 General Specifications* for details of specific information on data content. Local Regulatory requirements for data carrier, data content, etc. may supersede the information given in the Pharmaceutical Marking Grid (Figure 3-5).

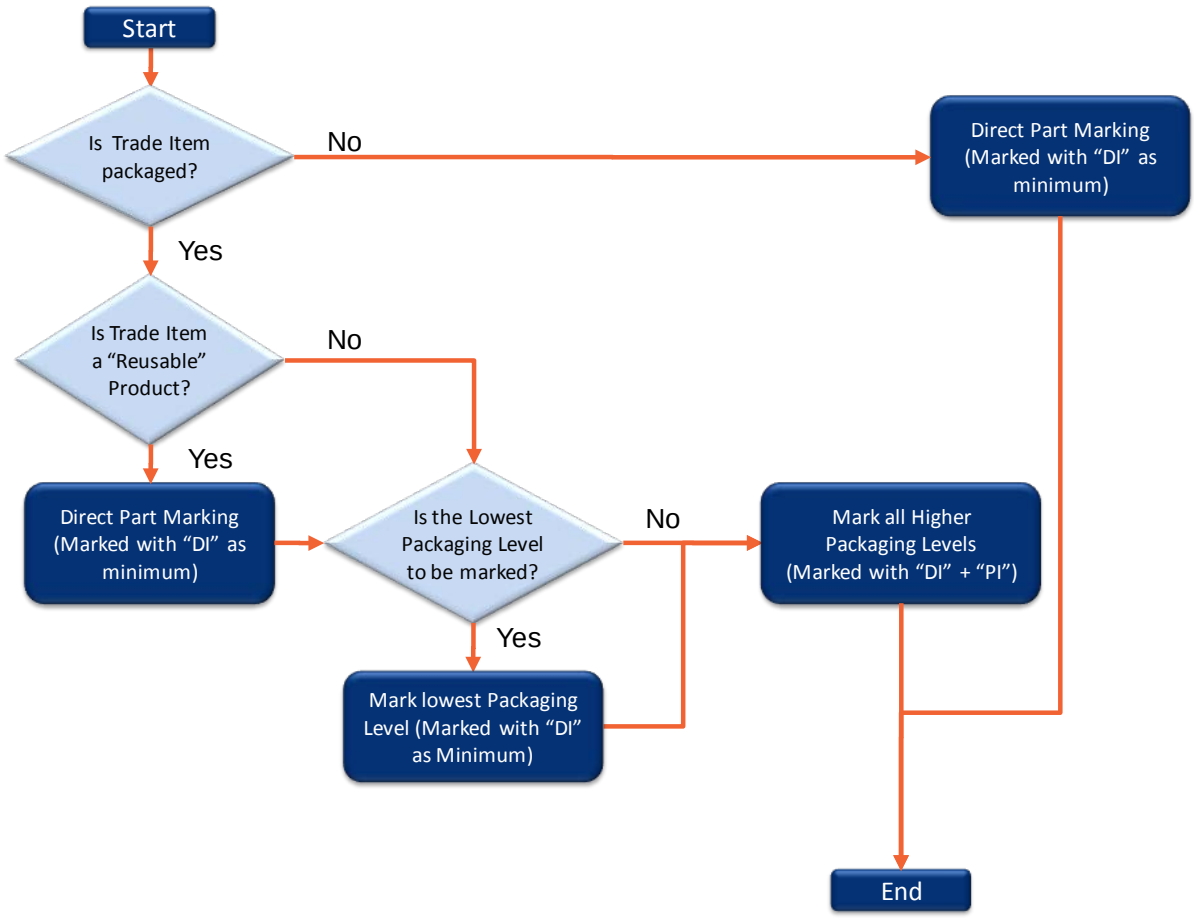
Figure 3-5 Pharmaceutical Marking Grid

	MINIMUM Level of AIDC Marking (Retail) **Pharmaceuticals Distributed and/or Sold Primarily Via Retail Channels**		**MINIMUM Level of AIDC Marking (Non-Retail)** **Pharmaceuticals Distributed and/or Sold Primarily Via Non-Retail Channels**		**HIGHEST Level of AIDC Marking** **Pharmaceuticals Distributed and/or Sold Via Retail and/or Non-Retail Channels**	
Direct Part Mark	**#DPM-1**		**#DPM-2**		**#DPM-3**	
	ENCODED DATA **Manufacturer** **Distributor / Repacker** No AIDC Data **Hospital** No AIDC Data	DATA CARRIER **Manufacturer** **Distributor / Repacker** No AIDC Carrier **Hospital** No AIDC Carrier	ENCODED DATA **Manufacturer** **Distributor / Repacker** No AIDC Data **Hospital** No AIDC Data	DATA CARRIER **Manufacturer** **Distributor / Repacker** No AIDC Carrier **Hospital** No AIDC Carrier	ENCODED DATA **Manufacturer** **Distributor / Repacker** No AIDC Data **Hospital** No AIDC Data	DATA CARRIER **Manufacturer** **Distributor / Repacker** No AIDC Carrier **Hospital** No AIDC Carrier
Primary Package	**#PP-1**		**#PP-2**		**#PP-3**	
	ENCODED DATA **Manufacturer** **Distributor / Repacker** No AIDC Data **Hospital** No AIDC Data	DATA CARRIER **Manufacturer** **Distributor / Repacker** No AIDC Carrier **Hospital** No AIDC Carrier	ENCODED DATA **Manufacturer** **Distributor / Repacker** GTIN-8; -12; -13; or -14, or EPC SGTIN (if RFID) **Hospital** No AIDC Data	DATA CARRIER **Manufacturer** **Distributor / Repacker** GS1-128, DataBar, Data Matrix, or RFID **Hospital** No AIDC Carrier	ENCODED DATA **Manufacturer** **Distributor / Repacker** GTIN-8; -12; -13; or -14, or EPC SGTIN (if RFID) **Hospital** GTIN-8; -12; -13; or -14, + Serial No. + AI(7003) for short-expiry item	DATA CARRIER **Manufacturer** **Distributor / Repacker** GS1-128, DataBar, Data Matrix, or RFID **Hospital** GS1-128, DataBar, Data Matrix, or RFID
Secondary Packaging	**#SP-1**		**#SP-2**		**#SP-3**	
	ENCODED DATA **Manufacturer** **Distributor / Repacker** GTIN-8; -12; -13 **Hospital** No AIDC Data	DATA CARRIER **Manufacturer** **Distributor / Repacker** UPC-E, UPC-A, EAN-8, EAN-13, or DataBar **Hospital** No AIDC Carrier	ENCODED DATA **Manufacturer** **Distributor / Repacker** GTIN-8; -12; -13; or -14, + Lot + Expiry, or EPC SGTIN (if RFID) **Hospital** No AIDC Data	DATA CARRIER **Manufacturer** **Distributor / Repacker** GS1-128, DataBar, Data Matrix, or RFID **Hospital** No AIDC Carrier	ENCODED DATA **Manufacturer** **Distributor / Repacker** **1st Mark:** GTIN-8, GTIN-12, or GTIN-13 **2nd Mark:** GTIN-8; -12; -13; or -14, + Lot + Expiry + Serial No, + Potency, or EPC SGTIN (if RFID) **Hospital** GTIN-8; -12; -13; or -14, + Serial No. + AI(7003) for short-expiry item	DATA CARRIER **Manufacturer** **Distributor / Repacker** **1st Mark:** UPC-E, UPC-A, EAN-8, EAN-13, or DataBar **2nd Mark:** GS1-128, DataBar, Data Matrix, or RFID **Hospital** GS1-128, DataBar, Data Matrix, or RFID
Case / Shipper	**#CS-1**		**#CS-2**		**#CS-3**	
	ENCODED DATA **Manufacturer** **Distributor / Repacker** If Trade Item: GTIN-8; -12; -13; or -14, + Lot + Expiry, or EPC SGTIN (if RFID) If Logistics Unit: AI(00) SSCC or EPC SSCC (if RFID) **Hospital** No AIDC Data	DATA CARRIER **Manufacturer** **Distributor / Repacker** GS1-128, Data Matrix, or RFID **Hospital** No AIDC Carrier	ENCODED DATA **Manufacturer** **Distributor / Repacker** If Trade Item: GTIN-8; -12; -13; or -14, + Lot + Expiry, or EPC SGTIN (if RFID) If Logistics Unit: AI(00) SSCC or EPC SSCC (if RFID) **Hospital** No AIDC Data	DATA CARRIER **Manufacturer** **Distributor / Repacker** GS1-128, Data Matrix, or RFID **Hospital** No AIDC Carrier	ENCODED DATA **Manufacturer** **Distributor / Repacker** If Trade Item: GTIN-8; -12; -13; or -14, + Lot + Expiry + Serial No, + Potency, or EPC SGTIN (if RFID) If Logistics Unit: AI(00) SSCC or EPC SSCC (if RFID) **Hospital** GTIN-8; -12; -13; or -14, + Serial No. + AI(7003) for short-expiry item	DATA CARRIER **Manufacturer** **Distributor / Repacker** GS1-128, Data Matrix, or RFID **Hospital** GS1-128, Data Matrix, or RFID
Pallet	**#P-1**		**#P-2**		**#P-3**	
	ENCODED DATA **Manufacturer** **Distributor / Repacker** If Trade Item: GTIN-8; -12; -13; or -14, + Lot + Expiry, or EPC SGTIN (if RFID) If Logistics Unit: AI(00) SSCC, or EPC SSCC (if RFID) **Hospital** No AIDC Data	DATA CARRIER **Manufacturer** **Distributor / Repacker** GS1-128, or RFID **Hospital** No AIDC Carrier	ENCODED DATA **Manufacturer** **Distributor / Repacker** If Trade Item: GTIN-8; -12; -13; or -14, + Lot + Expiry, or EPC SGTIN (if RFID) If Logistics Unit: AI(00) SSCC, or EPC SSCC (if RFID) **Hospital** No AIDC Data	DATA CARRIER **Manufacturer** **Distributor / Repacker** GS1-128 or RFID **Hospital** No AIDC Carrier	ENCODED DATA **Manufacturer** **Distributor / Repacker** If Trade Item: GTIN-8; -12; -13; or -14, + Lot + Expiry + Serial No, or EPC SGTIN (if RFID) If Logistics Unit: AI(00) SSCC, or EPC SSCC (if RFID) **Hospital** No AIDC Data	DATA CARRIER **Manufacturer** **Distributor / Repacker** GS1-128 or RFID **Hospital** No AIDC Carrier

3.3. Marking for Medical Devices

When the AIDC marking of Medical Devices is required, the following flow diagram will assist the reader in visualizing the navigation of Healthcare Marking for Medical Devices. This should be reviewed in conjunction with the *GS1 General Specifications*. Not all Medical Device trade items may require AIDC marking, as defined by regulations and/or manufacturers' processes.

Figure 3-6 Medical Devices Marking



Note: In all instances, the reader should refer to the appropriate Trade Item Application Specification section of the *GS1 General Specifications* should be referred to for detailed information and guidance on AIDC Marking.

For the purpose of this document and its related application:

- "Device/Drug Identifier", "DI" as indicated in the Decision Tree, is the identifier for the trade item and is at a minimum, the Global Trade Item Number (GTIN).
- "Production Identifier(s)", "PI" as indicated in the Decision Tree, are Expiry Date, Batch / Lot Numbers and/or Serial Numbers used for product traceability. In applying "Production Identifiers" it is the responsible entity's decision whether a product is lot or serial number controlled.
- Instances noted above of "DI" only indicate "MINIMUM Level of AIDC Marking" and instances noted above of "DI" + "PI" indicate ENHANCED and HIGHEST Levels of AIDC Marking". As the "MINIMUM Level of AIDC Marking" may in some cases include no AIDC marking as an option,

the appropriate Trade Item Application Specification section of the *GS1 General Specifications* should be referred to for detailed information and guidance about requirements and options.

- "Direct Part Marking" can be realized by various technologies that leave a permanent mark.
- Technical and practical feasibility of using a marking technology at the respective pack level (or direct on the product itself) is a prerequisite (e.g. sufficient space, substrate or packaging material suitability, etc.).

3.4. AIDC Marking Levels

The AIDC marking of healthcare products uses a graduated system of marking; Minimum, Enhanced and Highest. The identification solution for each of these levels may differ between the category of "pharmaceuticals" (which includes biologics, vaccines, controlled substances, clinical trial pharmaceuticals and therapeutic nutritional products) versus the category of "medical devices" (which includes all classes of medical devices) and may also differ by configuration or packaging level (trade items direct marked, primary packaging, secondary packaging, case/shipper, pallet, logistics unit).

Consideration should first be given to the data to be included in the data carrier. Decisions will take into account different levels of AIDC Marking. The three levels of AIDC Marking are designated Minimum, Enhanced and Highest based on information need.

3.4.1. MINIMUM Level of AIDC Marking

A level within a graduated system of AIDC trade item marking that provides a GTIN with no attribute information; it is used with products that do not require a high level of traceability control. Marking at this level includes the GTIN at a minimum.

3.4.2. ENHANCED Level of AIDC Marking

A level within a graduated system of AIDC trade item marking, it provides GTIN plus attribute information. This includes products that require a higher level of traceability control. Marking at this level includes the GTIN, Batch or Lot Control Numbers, and the Expiration Date (when applicable).

3.4.3. HIGHEST Level of AIDC Marking

A level within a graduated system of AIDC trade item marking, it provides GTIN, serialization, and potentially other attribute information. This includes products that require the highest level of traceability control. Marking at this level includes a GTIN, Serial Number and Expiration Date (when applicable).

3.5. Product Configurations

Consideration should next be given to where on the product the data will be carried. Decisions will take into account different levels of product configuration.

3.5.1. Direct Part Marking (DPM)

Direct part marking (DPM) refers to a process of marking a symbol directly onto an item without packaging using an intrusive or non-intrusive method instead of applying a label or using another indirect marking process. Information related to applying DPM to health care products is described in the GS1 General Specifications, beginning with Section 2.1.1.8.

Figure 3-7 Example Direct Part Marking

3.5.2. Primary Package

The primary package is the first level of packaging for the product marked with a data carrier either on the packaging or on a label affixed to the packaging.

Primary package configurations may consist of:

- sterile packaging
- non-sterile packaging
- single item
- group of items
- combination of items for a single therapy (kit)

Figure 3-8 Primary Package examples:

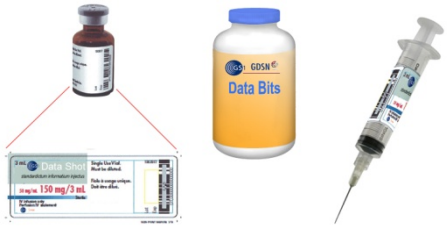
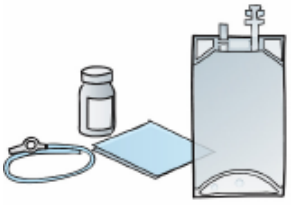


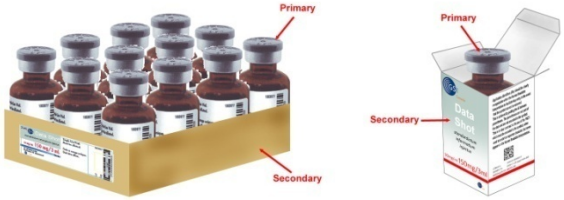
Figure 3-9 Kit example



3.5.3. Secondary Package

Secondary packaging configurations consist of packages containing one or more single items in their Primary Packaging

Figure 3-10 Secondary Package examples:



3.5.4. Case / Shipper and Pallet

These are packaging configurations that may be used as either trade items or logistic units. Case / shippers may contain one or more items in their Primary Packaging and/or Secondary Packaging. Pallets may contain one or more case / shippers.

Note: Only fixed configuration Pallets and Shippers may be identified with a GTIN.

Figure 3-11 Case / Shipper Example

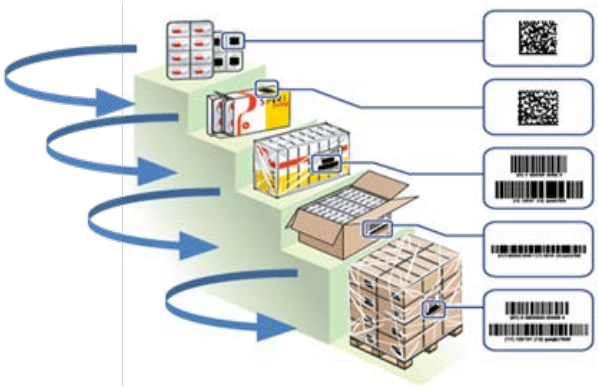
Figure 3-12 Pallet Example

3.6. Package Hierarchy

Consideration should be given to the hierarchy of packaging. Each level of the package hierarchy presents different printing challenges in labelling (e.g. space, substrate, production line speed, etc.). Each level also presents differing data information requirements: GS1 Identification Key or GS1 Identification Key plus additional data.

The GS1 System provides a variety of Data Carriers that will meet the combination of printing and data needs. This section will offer illustrations and examples.

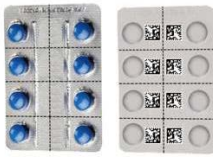
Figure 3-13 Package Hierarchy Illustration



Note: Pallets can be marked with either GTIN (following *GS1 Healthcare GTIN Allocation Rules*) or Serial Shipping Container Code (SSCC) identifiers (which is defined in Section 4.2).

Table 3-1 provides examples of the different symbologies, coding options and information attributes for each packaging level and the associated label size.

Table 3-1 Package Hierarchy Examples

	Healthcare Product	GS1 Key *	Additional data	Encoded information and GS1 Data Carriers
Primary packaging (one pill in the blister cell)		GTIN "1"	Lot ABC Expiry date 31-Dec-2010	(01)07665431234566(17)101231(10)ABC Suggested GS1 Data Carriers: GS1 DataMatrix, GS1 DataBar or (01)07665431234566 Suggested GS1 Data Carriers: GS1 DataMatrix, GS1 DataBar
Secondary packaging** (two blisters in one box)		GTIN "2"	Lot ABC Expiry date 31-Dec-2010	(01) 07665433456781(17)101231(10)ABC Suggested GS1 Data Carriers:GS1 DataMatrix, GS1-128, GS1 DataBar
Multi-pack (7 boxes) This is only an example of another packaging level		GTIN "3"	Lot ABC Expiry date 31-Dec-2010	(01)07665431234887(17)101231(10)ABC or (01)17665431234563(17)101231(10)ABC Suggested GS1 Data Carriers:GS1 DataMatrix, GS1-128, GS1 DataBar
Case (8 multi-packs)		GTIN "4"	Lot ABC Expiry date 31-Dec-2010	(01)07665431234573(17)101231(10)ABC or (01)27665431234560(17)101231(10)ABC Suggested GS1 Data Carriers:GS1-128, GS1 DataMatrix

* For information on GS1 Keys refer to the *GS1 General Specifications*.

** Secondary Packages in some countries is sold through retail point of sale (refer to Figure 3-5).

Note: Regulatory requirements may specify the data carrier(s) to be used. As these examples do not cover all possible scenarios, please refer to the *GS1 General Specifications* for more detailed information.

3.7. Distribution Channel

Consideration should be given to the channel (such as Retail Point-of-Sale) through which the products are intended to be distributed to aid in the selection of the data and data carrier. A product may belong in more than one channel depending on the target market(s). Please refer to the *GS1 General Specifications* more information on distribution channels and target markets.

Note: Specific sectors have requirements or restrictions with regards to the symbologies that may be deployed (e.g. Retail Point-of-Sale).

4. GS1 Identification Keys and Additional Data used in this Document

When marking Healthcare products, GS1 Identification Keys are used to identify trade items and logistic units. Additional data may be associated with the GS1 Identification Keys through the use of GS1 Application Identifiers (AI's). Following are the GS1 Identification Keys and Application Identifiers that are contained in the *GS1 General Specifications* for use in Healthcare AIDC applications. It is not a requirement to use multiple forms of product identification (GTIN, Global Returnable Asset Identifier (GRAI), etc.) on the same package.

Note: The Identification Keys which are shown in this section are examples of what are typically used in the Healthcare industry, other types of Identification Keys may be used.

Note: Refer to the GS1 Global Data Dictionary for the latest approved definitions.

4.1. Global Trade Item Number (GTIN)

The GS1 Key for unique product identification is the Global Trade Item Number (GTIN) which is assigned AI (01). 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 responsible entity who is normally responsible for the allocation of the GTIN.

A company receives a GS1 Company Prefix by joining a GS1 Member Organisation. This gives the company the ability to create GTINs and access to the GS1 standards.

Note: Refer to the *GS1 General Specification*s and *GS1 Healthcare GTIN Allocation Rules* (http://www.gs1.org/gtinrules) for the GTIN Structure.

4.2. Serial Shipping Container Code (SSCC)

The GS1 Key for uniquely identifying a logistic unit is the SSCC, which is assigned AI (00). The SSCC can provide a link between the physical logistic unit and information pertaining to the logistic unit that is communicated between trading partners using Electronic Data Interchange (EDI).

Note: Refer to *GS1 General Specifications* for the SSCC structure and rules of use.

4.3. Global Returnable Asset Identifier (GRAI)

The GS1 Key for uniquely identifying returnable assets is the GRAI which is assigned AI (8003). GRAIs identify reusable packages or transport equipment of a certain value, such as a tote, a gas cylinder, or cold chain container. The GRAI enables tracking as well as recording of relevant data. A GRAI can be used to identify identical returnable assets (as an asset type) and when paired with an optional serial number can be used to uniquely identify individual assets within that asset type.

Note: Refer to the *GS1 General Specifications* for the GRAI Structure

4.4. Global Individual Asset Identifier (GIAI)

The GS1 Key for uniquely identifying individual assets is the GIAI, which is assigned AI (8004). The GIAI enables tracking as well as recording of relevant data.

Note: Refer to *GS1 General Specifications* for the GIAI Structure

Note: Refer to the GS1 Global Data Dictionary for the latest approved definition

4.5. Batch/Lot - AI (10)

If you require additional data to identify Batch or Lot Number, the GS1 Application Identifier (10) is used and typically assigned at the point of manufacture. This additional data is alphanumeric with a variable length of up to 20 characters.

4.6. Expiration Date - AI (17)

If you require additional data to identify an Expiration Date the GS1 Application Identifier (17) (often referred to as expiry date, use by date or maximum durability date) is used. This indicates the limit of consumption or use of a product (e.g., for pharmaceutical products it can indicate the possibility of an indirect health risk resulting from the ineffectiveness of the product after the date). It is expressed as year, month and day (**YYMMDD)**.

Note: The Expiration Date data string can only specify dates within a certain range. Please refer to the *GS1 General Specifications* for additional information on structure and range.

4.7. Expiration Date and Time - AI (7003)

When the exact expiration date and time is critical to patient safety, the Application Identifier (7003) is used. Date is expressed as year, month and day **(YYMMDD)** and time is expressed in hours and minutes **(HHMM)**. Examples might be customised pharmaceuticals in a hospital or public pharmacy with an expiration time within a single day.

Note: The Expiration Date and Time data string can only specify dates within a certain range. Please refer to the *GS1 General Specifications* for additional information on structure and range.

4.8. Serial Number - AI (21)

If Healthcare products are to be individually tracked and traced using a Serial Number, Application Identifier (21) can be used. This additional data is alphanumeric with a variable length of up to 20 characters.

4.9. Active Potency – AI (7004)

If use of a Healthcare product requires recording of active potency, then AI (7004) can be used to indicate that the additional data field contains an active potency. The active potency of certain biologics, such as haemophilia products, varies by batch from the nominal potency of the trade item and is measured in International Units (IUs).

Note: Refer to *GS1 General Specifications* for more information about Active Potency

5. GS1 Data Carriers

The Healthcare specific sections of the *GS1 General Specifications* refer to the following data carriers.

Note: The following examples were chosen to represent the Healthcare industry and may not be applicable to all industries (see the GS1 Healthcare Marking Decision Tree in section 3). Refer to *GS1 General Specifications* for more information on GS1 symbologies.

Note: The following examples are not meant to be all inclusive of the various forms and formats that the encoded data may take in the data carriers shown (e.g. a data string which contains GTIN plus attribute data in a GS1-128 may be encoded as a single symbol or multiple symbols).

5.1. EAN/UPC

UPC-A, UPC-E, EAN-13, and EAN-8 Bar Codes can be read omni-directionally. These symbols should be used for all items that are scanned at the Point-of-Sale.

Figure 5-1 EAN-13 (example of EAN/UPC Symbology)

5.2. GS1-128

A subset of the Code 128 Bar Code Symbology, its use is exclusively licensed to GS1. This extremely flexible symbology encodes Element Strings using Application Identifiers.

Figure 5-2 GS1-128 Bar Code Symbol Example

5.3. ITF-14

A specific application of the Interleaved 2 of 5 bar code symbology, ITF-14 symbols carry ID numbers only on trade items that are not expected to pass through the Point-of-Sale. ITF-14 Symbols are better suited for direct printing onto corrugated fibreboard.

Figure 5-3 Bar Code Symbol example

5.4. GS1 DataBar

A family of linear symbologies used within the GS1 System. In most cases this family implicitly encodes the GTIN in Application Identifier (01) and in the case of GS1 DataBar Expanded explicitly encodes Element Strings using Application Identifiers.

Figure 5-4 GS1 DataBar Limited example

(01)15012345678907

5.5. GS1 DataMatrix

A two-dimensional bar code symbol that supports GS1 System data structures, including the Function 1 Symbol Character. Implementation of GS1 DataMatrix should be done as per the approved GS1 System application guidelines. This extremely flexible symbology encodes Element Strings using Application Identifiers.

Figure 5-5 GS1 DataMatrix example

(01)03453120000011(17)091125(10)ABCD1234

5.6. Radio Frequency Identification (RFID)

Radio-frequency identification (RFID) is the use of a RFID tag applied to or incorporated into a product or item for the purpose of identification and tracking using radio waves. Radio-frequency identification comprises interrogators (also known as readers), and tags (also known as labels) and a computer network. At present, RFID as a data carrier is not recommended for Healthcare product identification.

EPC is GS1's standard for RFID applications. For more information please refer to the *GS1 General Specifications*, or EPCglobal Standards documentation at: http://www.gs1.org/epcglobal.

Figure 5-6 Radio Frequency Identification (RFID) illustration

5.7. Data Carrier Selection

Selection of the appropriate GS1 Data Carrier is based in part upon the trade item to be marked and its use within the supply chain. For assistance in selecting the proper GS1 Data Carrier refer to the *GS1 Symbology Operational Environment Decision Tree* found in the *GS1 General Specifications*.

6. Implementation Procedures

6.1. Who will identify a product?

Management of product identification is the responsibility of the person or persons within the healthcare supply chain who are responsible for the AIDC marking of healthcare products, assets and / or logistics units, such as:

- Manufacturer
- Wholesaler / Distributor / Re-packager
- GPOs
- Logistics providers
- Hospital / Pharmacy

6.2. Practical Steps to Implement GTINs using Bar Codes

The following steps are informative in nature and intended to help new implementations. Review these to see how they apply to your organisation and your existing implementation of GS1 standards.

Before a GTIN implementation project is commissioned, executive support will be necessary. A statement of work should be developed to clearly describe the purpose, scope, goals, objectives, deliverables, and cost of implementation. An important consideration should be the analysis of the current master data, including the development of rules for configuration management and inter-changeability. The GTIN will need to be mapped to the master data in a logical standardised fashion. Master data should be cleaned before GTIN assignment. Corporate standards and policy should be developed to regulate how the organisation will allocate GTINs moving forward and at what phase of product development lifecycle they get assigned. Systems for allocation of the GTIN (e.g. Enterprise Resource Planning or ERP) and governance of master data creation are essential to ensure GTIN allocation is in accordance with the GS1 System.

Step 1: Commission a Project

- Scope which products will be identified and bar coded
- Create a project team including a Manufacturing, Finance, Engineering, Logistics, Quality, Information Technology, Regulatory and other departments as appropriate
- Look at the time scales involved

- Look into existing bar code production capabilities
- Analyse how you currently identify products

Step 2: Engage with GS1

Are you already a member of GS1?

If you are already a member you should identify which products have already been allocated a GS1 GTIN. If there are multiple company prefixes from one or more countries, it is the responsible entity's responsibility to manage and use the company prefixes appropriately or according to company strategy - or consult one of your local GS1 organisation for guidance.

Not a member of GS1?

If you are not a member of GS1, you will need to join your local GS1 Member Organisation (membership policies are detailed in *GS1 Operational Manual* - available through local GS1 MOs). Once you have joined, you will be provided with a GS1 company prefix. This will allow you to create Global Trade Item Numbers (GTINs), Serial Shipping Container Codes (SSCC), Global Location Numbers (GLNs) and other GS1 Identification Keys.

The complete identification number you create is a non-significant number, which means that the individual digits in the number do not relate to any classification or convey any specific information. The simplest way to allocate your numbers is sequentially.

Step 3: Product Commitment

Identify which products you wish to allocate GTINs. This product range may be impacted by target markets or discontinued items. Special care must be taken to ensure that all possible configurations be considered prior to allocations of a unique identifier (GTIN).

Step 4: Allocate GTINs according to the GS1 Healthcare GTIN Allocation Rules

To manage your GTINs accurately you should undertake the following:

- Allocate a unique Global Trade Item Number (GTIN) for each product and for each packaging level, referring to the *GS1 Healthcare GTIN Allocation Rules* (www.gs1.org/gtinrules).
- Register the GTINs in a database linking the number to the product name, description and its hierarchy.
- The GTIN should never be duplicated or re-used even if the product becomes obsolete.
- Build in a quality process for GTIN allocation for new products to ensure that duplication does not occur.
- Build an automatic check digit calculator into your system.

Step 5: Define Product Marking

The information that will be carried in the bar code and the type of symbology is determined by a number of factors. The following questions can be used in determining the information that should be carried in the bar code.

Use the information in Section 3 and answer the following questions to guide you in marking Healthcare products.

- What is the distribution channel for each product? Will the product cross the retail point-of-sale?

  Define the marking depending on product risk level, the target market, the regulatory requirements and customer expectations. Ask your local regulatory staff to provide guidance.

- Beside product identification (GTIN), is additional information (batch/lot, expiry date, etc.) required?

Step 6: Select Carrier(s) as appropriate

If the product is going to be sold at retail point-of-sale or is going to be used in a robotic dispensing system you will need to choose one of the GS1 bar code displayed in section 5. By doing this consider the target market and the customer's expectations.

Depending on the available space on the product, existing regulations and customer's requirements, you will choose either a linear bar code or 2D symbol.

Step 7: Implement

- **Evaluate printing software and devices**

  When choosing or using existing printer software, check your ability to produce your selected GS1 symbol(s) in accordance with the *GS1 General Specifications*.

  The position of the bar code on the packaging will need to be checked to see that it meets the requirements of the *GS1 General Specifications*. Any final labelling or wrapping should also be examined to ensure that the bar codes remain visible and able to be scanned.

- **Evaluate your symbol quality**

  It is good practice to assign the role of Symbol Quality Manager in your organisation (and create an internal bar code verification process that includes the equipment and techniques to test in accordance with ISO/IEC 15415 and 15416) to ensure your bar codes consistently meet the quality standards as specified in the *GS1 General Specifications*.

  In first stages, your code can be checked by your local GS1 Member Organisation; this can later be done with a bar code verifier, which is used to check the quality of the symbols printed. In case of in-line printing a continuous quality control process is recommended.

Note: Unit package markings introduce technical challenges that may not allow printing as small as the *GS1 General Specifications* permits.

Step 8: Communicate

Communicate to the relevant parties (i.e. trading partners, regulators, etc.) your product identification plans (i.e. new labelling, data carrier, data content, etc.).

6.3. Additional Considerations

In some instances, it may be necessary to perform a Technical Feasibility Study before implementing GTINs within your business. This could include one or more of the following steps

- Is the packaging material suitable to carry a bar code (particularly at single use medical device on primary pack level)?
- Are artwork changes necessary to support additional information in a bar code symbol?
- What is the correct size of the bar code that could be used (can depend upon factors such as package type, available space, print method, symbology, type of validated ink, etc.)?
- What is the impact on the production/packaging throughput?
- Are we meeting Quality System and Regulatory requirements? – All quality system requirements and processes should be considered in the implementation.

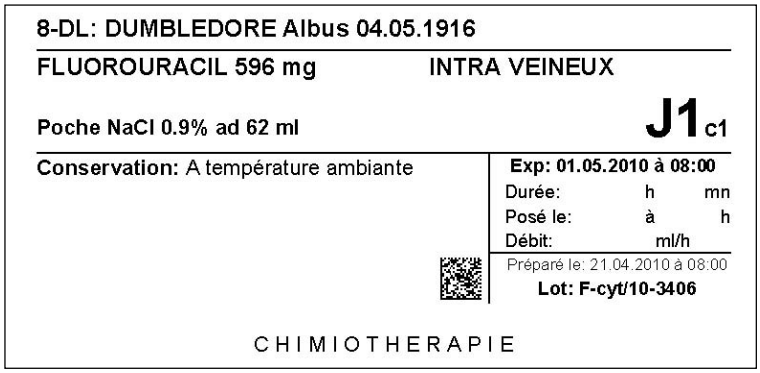
7. Use Cases

7.1. Hospital of Geneva: Cytostatics Identification

Items	Answer
Name of organisation	Hôpitaux Universitaires de Genève
Type	University Hospital
Number of beds	2167
Number of FTE medical staff	6241
Number of FTE of non-medical staff	2108
Pilot / Implementation	Implementation
Contact (Project lead)	Dr Pascal Bonnabry
Domain of implementation	Pharmacy, manufacturing and administration of oncology products
Department	Pharmacy
Products	Cytostatics
Project description	Integration of drug administration in daily processes
Hard- and Software used	Nice ID-Gen, Cyto (Software made by NICE Computing, Lausanne for University Hospitals Geneva and Lausanne). Lap-tops and wired image scanners.
Standards and carriers	GS1 System, GS1 DataMatrix
Major objective, vision	Objective is to secure full traceability of drugs down to the administration to the patient. An initial trial has been made with RFID 13.56 MHz tags, but demonstrated the limited benefit of RFID. Initially, PDAs have been used. Wireless connection was more difficult to stabilise with this small hardware, therefore mobile Lap-tops have been preferred.
Volumetric	-
Project scope global or local?	Local scope; a phased implementation of GS1 tools in the hospitals.
Expected ROI	ROI was not a primary target. See presentation.
ROI budget / quality / technical / regulatory / auditing	See presentation
Short term (12-18 months)	
Long term (+18 months)	
Project launch	2005
Project end	2007
Implementation start	2007
Project team Y/N	Yes
Staffing of project team	Representatives of pharmacy, support, medical informatics, GS1
Role of external project team staff	Technical coaching.
Cost of project : monetary, human resources, ICT	n/a
Difference to budget (monetary)	n/a

Items	Answer
Differences to objectives / vision	Difficulties occurred with RFID and with Wireless connections. RFID has been replaced by GS1 DataMatrix. Difficulties with Wireless connection stability have been overcome by using laptops instead of PDA.
Sources of differences	-
Is project included in Organisation's development plan	No
Detail of phases : initialisation / installation / roll out / deployment	Modelisation of new processes; modification of existing programs, tendering and development of software to produce GS1 data structures and bar code images ; tests with users ; tests « in vitro » ; small scale roll out, deployment.
What slowed down the project	Difficulties around RFID
Key for success	Nurses have been enthusiastic
Pre-requisite for deployment	-
Presentation available	Yes
Conclusion	A good base for expanding to other product groups (narcotics, blood derivatives, etc.)
Advises for similar projects	Users (nurses) support is key to progress.

Figure 7-1 Cytostatics Identification



7.2. University Hospital of South Manchester: Identification of Instruments

Items	Reponses
Company Name	University Hospital of South Manchester
Company type	NHS Healthcare Hospital
Number of employees	81 within the CSSD department, 5,200 within the hospital
Number of active item references	40,000 are being scanned
Number of items following the GS1 standards	100% (instrumentation apart) Those outside the 100% are the single use instruments where the marking is on the packaging not the instruments.

Items	Reponses
Experience (reflection, pilot, realisation, …)	Traceability and marking have been an everyday concern for years Realisation phase Proactively
Contact Name (local Project Manager)	Caroline Robinson – Customer Contract Manager
Concerned Activity	Medical Devices
Concerned Market	Hospitals
Products / Instruments	40,000 being scanned single use products
Main Objective / motivation for that experience of activity	Patient safety & general cost benefits.
Description Internal item code all levels with GTIN associated to the different levels Code generation Orders taking Production transfer to distribution	The central Data Base department in Derby UK contains certain GS1 company codes. They open these code in “TrakStar for automatic generation of the item codes by the local department Marketing asks for the GTIN per instrument, tray, trolley) at the item creation. All item are codified where possible before being distributed Customers can receive orders with Synergy internal code, GTIN; Currently the delivery notes bear the internal Synergy codes. A product is marked with the GTIN where needed and is taken out of the production line to carry out this process. GTIN, Expiry Date, Batch Number are immediately entered / registered in TrakStar for Distribution (GS1-128 bar code)
Software and Material	TrakStar is the central ERP used by all Synergy generic printer is the IT label generator We can have automatic printers at production levels
Standards and supports used	GS1 System : EAN-13 on tray, GS1-128 on single use, GS1 DataMatrix on instruments, (GTIN & GIAI)
Implementation of DataMatrix	Marking data for Data Matrix implementation: Decision taking delay : About 6 months Prompter: Official decision making in University Hospital of South Manchester to get all instruments marked with a GTIN inserted using a data matrix was Director of Estates and Facilities (Trust Decontamination Lead) Flows and traceability optimisation Starting date: May 2007 End planned date : Nov 2007 but ongoing due to new lines being phased into production. Marking technique : thermo transfer or inkjet directly on the production lines
Company Name	University Hospital of South Manchester
Company type	NHS Healthcare Hospital
Number of employees	81 within the CSSD department, 5,200 within the hospital
Number of active item references	40,000 are being scanned
Number of items following the GS1 standards	100% (instrumentation apart) Those outside the 100% are the single use instruments where the marking is on the packaging not the instruments.

Items	Reponses
Experience (reflection, pilot, realisation, …)	Traceability and marking have been an everyday concern for years Realisation phase Proactively
Contact Name (local Project Manager)	Caroline Robinson – Customer Contract Manager
Concerned Activity	Medical Devices
Concerned Market	Hospitals
Products / Instruments	40,000 being scanned single use products
Main Objective / motivation for that experience of activity	Patient safety & general cost benefits.
Description Internal item code all levels with GTIN associated to the different levels Code generation Orders taking Production transfer to distribution	The central Data Base department in Derby UK contains certain GS1 company codes. They open these code in “TrakStar for automatic generation of the item codes by the local department Marketing asks for the GTIN per instrument, tray, trolley) at the item creation. All item are codified where possible before being distributed Customers can receive orders with Synergy internal code, GTIN; Currently the delivery notes bear the internal Synergy codes. A product is marked with the GTIN where needed and is taken out of the production line to carry out this process. GTIN, Expiry Date, Batch Number are immediately entered / registered in TrakStar for Distribution (GS1-128 bar code)
Software and Material	TrakStar is the central ERP used by all Synergy generic printer is the IT label generator We can have automatic printers at production levels

Appendix A: Glossary

The following glossary was updated for the Nov 2014 publication of this document. Please refer to the glossary in the GS1 GDD (http://gdd.gs1.org/GDD/public/searchableglossary.asp) for the latest version.

Term	Definition
Active Potency	Represents the measured actual (“Active”) potency of a biologic such as haemophilia products.
brand owner	When not applied in Healthcare, the party that is responsible for allocating GS1 System numbering and bar code symbols on a given trade item. The administrator of a GS1 Company Prefix.
Data label	An abbreviated description of an attribute that may or may not be the same as the data title. It may be used instead of the data title when a specific format is required.
Enhanced Level of AIDC Marking	A level within a graduated system of AIDC trade item marking that provides GTIN plus attribute information.
Electronic Product Code (EPC)	An identification scheme for universally identifying physical objects (e.g. trade items, assets, and locations) via RFID tags and other means. The standardised EPC data consists of an EPC (or EPC Identifier) that uniquely identifies an individual object, as well as an optional Filter Value when judged to be necessary to enable effective and efficient reading of the EPC tags
EPCglobal	The GS1 global standards system that combines RFID (radio frequency identification) technology, existing communications network infrastructure and the EPC (Electronic Product Code).
General Retail Consumer Trade Item	A retail consumer trade item identified with a GTIN-13, GTIN-12 or GTIN-8 utilising omnidirectional linear bar codes that can be scanned by high-volume, omnidirectional scanners.
GS1 Identification Key	A numeric or alphanumeric data field defined by GS1 to ensure the global, unambiguous uniqueness of the identifier in the open demand or supply chain
Highest Level of AIDC Marking	A level within a graduated system of AIDC trade item marking that provides GTIN, serialisation, and potentially other attribute information.
Human Readable Interpretation (HRI)	Characters, such as letters and numbers, which can be read by persons 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.
Levels of AIDC Marking	A graduated system of AIDC marking. The graduated system is defined as minimum, enhanced and highest levels of AIDC marking.
Minimum Level of AIDC Marking	A level within a graduated system of AIDC trade item marking that provides GTIN with no attribute information.
Omnidirectional Linear Bar Code	A linear bar code symbol designed to be omnidirectionally read in segments by suitably programmed high-volume Omnidirectional Point-of-Sale (POS) scanners.
Point-of Sale (POS)	Refers to the retail checkout where omnidirectional bar codes must be used to enable very rapid scanning or low volume checkout where linear or 2D matrix bar codes are used with image-based scanners.

Term	Definition
Primary Packaging	The first level of packaging in direct contact with the product and marked with a data carrier either on the packaging or on a label affixed to the packaging. 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.
responsible entity	In Healthcare, the party responsible for the safety and effectiveness of the medical product at a moment in time in its lifecycle, according to the approved regulatory file (including labelling) and regulatory/legal/professional obligations associated with the medical product (e.g. Brand Owner, Repackager, Hospital Pharmacy, etc.).
Secondary Packaging	A level of packaging marked with an AIDC carrier that may contain one or more primary packages or a group of primary packages containing a single item.
Serial Shipping Container Code	The GS1 Identification Key used to identify logistics units. The key comprises an Extension digit, GS1 Company Prefix, Serial Reference, and Check Digit.
Short Life Items	An item, preparation or reconstituted product with limited use / shelf life, such as in healthcare a cytotoxic medicine, that has undergone some manipulation, such as addition of a diluent, in order to make it administrable to a specified patient.
Traceability	The ability to trace the history, application or Location of that which is under consideration.
SKU	Stock Keeping Unit

Appendix B: Supply Chain Roles and Definitions

- **Responsible entity** – The party that is responsible for allocating GS1 System numbering and bar code symbols on a given trade item. The administrator of a GS1 Company Prefix;
  - and /or the party that is the ultimate authority for the trade item.
  - and / or the owner of the product specifications.
  - and /or responsible for placing a traceable item into commerce.
- **Supplier** - The party that produces, provides, or furnishes an item or service.
- **Manufacturer** – The Party that produces the Item.
- **Logistic provider -** A logistics provider is a person or entity that provides logistics services for part or all of the supply chain management functions for other entities (manufacturers or suppliers). Third Party logistics providers are typically specialised in integrated warehousing and transportation services that can be customised according to the demands and delivery requirements of their customers. A logistics provider does not hold proprietary rights over the product they store or distribute.
- **Distributor** - Party distributing goods, financial payments or documents.
- **Wholesaler** - Seller of articles, often in large quantities, to be retailed by others
- **Hospitals –** Organisation dedicated to care of patients. Hospitals are mostly “bar code readers” but for their own production (cytostatics, compounding, etc.) are “bar code markers”.
- **Point of care**: Place where medicine or medical devices will be used to care for a patient.
- **Retail Point of Sales** - Retail in this document is a generic term referring to stores that trade non-healthcare items and healthcare items in some countries.
- **Pharmacy/Drug Store** – Specialised store (can be a retail point of sale in some countries) where healthcare products are stored and dispensed to patients under a pharmacist responsibility. A pharmacy may produce specific compounds according medical prescription.

Appendix C: Frequently Asked Questions (FAQ)

Question	Answer
How many GTINs do we need?	Assign one GTIN to each product offering (defined product configuration) at each level of packaging (SKU); each SKU has only one GTIN. When assigning GTINs to specific product offerings, please refer to the *GS1 GTIN Healthcare Allocation Rules*.
How many digits are there in a GTIN?	GTINs may have 14, 13, 12 or 8 digits. *GS1 General Specifications* provide full guidance on how to generate GTINs
Which identifier do we need to start with?	This guide focuses on GTIN allocation as a priority. The others GS1 Identification Keys are mentioned in section 3 to be used depending on need.
Which additional information is needed for which product (e.g. batch number, expiry date)?	See Section 3.4 and Section 4 to determine correct assignment of necessary additional information to be used. If further information is required contact your local GS1 Member Organisation.
How determine the different levels of marking?	AIDC marking is organised in levels which are described in this document.
How can be built the check digit?	See *GS1 General Specifications* or contact your local GS1 Member Organisation.
What information is encoded in the data carrier when an item is a medical device in one country and a medicine in another country?	The objective is to have a single GTIN with additional information in the data carrier when possible. Regulatory requirements supersede the recommendations, and possibly impact labelling.
How do we label combination products, i.e., medical device and drug?"	The product should be labelled in accordance with its market approval authorization, i.e., drug or medical device.
How do we determine the GTIN for a kit (or set) of products?	A grouping of products may be defined to be a kit (or set). For detailed information on determining GTINs for Kits, refer to the *GS1 Healthcare GTIN Allocation Rules* (www.gs1.org/1/gtinrules).
Which data carrier is needed for which product, and which product hierarchy?	These are explained in section 3.
How can we integrate the GTIN into our ERP System? What kind of modification do we have to manage?	The Enterprise Resource System (ERP) must be able to manage a GTIN for each level of the product hierarchy. At each level of the hierarchy, the database should be able to link the GTIN's of the higher and lower levels (parents/children). For more information, contact your solution provider/ERP specialist and your local GS1 Member Organisation.
How can we start this project?	See "Steps to implement GTIN"
Who should be the project leader?	Consider this as a strategic project when choosing the project leader. This means that he/she should benefit from strong management support, know the products, the sector, and the customers and the GS1 System. Additional skills such as a technical background in both systems/packaging engineering and Information Technology are an asset.
What about the organisation in a multi-site configuration, when implementation is decentralised?	The implementation strategy should be defined at company / organisation level; implementation requires local skills and the benefit of local GS1 Member Organisation support.

Question	Answer
Is AIDC implementation a local or global decision?	Good practice recommends this decision to be global, with involvement of local actors.
Who should be involved in the project inside the company?	The project should be managed by a group. The group could include, depending on the organisation: Packaging Engineers; Financial Controller, Regulatory and Quality Teams, Legal Counsel, Supply Chain Distribution, Accounts Payable, Public Relations (internal), Information Systems (business & operational), Information Systems Implementation Analyst, Group Purchasing Representative, Primary Distributor Representative, Marketing, Customer-facing Teams (e.g., Call Centre, Catalogue, etc.). This, of course, depends on the structure of the company or organisation.
Do we need to involve our trading partners?	Yes, your business partners must be informed about your project; some of them may be part of pilot phase.
What are the main steps of the project?	See “Steps to implement GTIN”
For a global company, who decides to adopt GS1 standards? What are the drivers?	As this is a strategic decision, which requires a strong management support in the mid- to long term, the decision belongs the global management. Sometimes, local regulations/ circumstances drive to global adoption.
How long does the implementation take and which part is the most time consuming?	The existing framework impacts the resources (human and financial) and the duration of an implementation. For smaller companies with a limited portfolio, it may take few months. For larger companies, depending on the portfolio and structure, it may take few years.
Who is the GS1 contact (in case of a global company for example)	The GS1 contact can be established where the main office is located or in the country where the implementation will start.
What can we expect from GS1 in terms of support, training, etc.?	GS1 Member Organisations provide local support and training to their members.
What kind of improvements can we expect?	The identification of products can lead to a traceability system ensuring patient safety, facilitate recalls and improve business processes and logistic. Several users have optimised their processes, which has led to short term Return on Investment (ROI).
How do we deal with traceability questions and recalls?	Refer to the *GS1 Traceability Standard for Healthcare* **Note:** Government regulations will always supersede any suggestions put forward in GS1 documentation.