GTIN identification of pharmaceutical products and medical devices

Databases must be constructed using 14 digits

The GS1 Global Trade Item Number (GTIN) is used for the unique identification of trade items worldwide[1]. GTINs can have different data structures as per GS1 Standards: GTIN-8, 12, 13 or 14; all are legitimate forms of identification in Healthcare. To safeguard the integrity of the GTIN numbering system, for all Healthcare stakeholders, databases need to be able to capture these different data structures. This means that stakeholder databases need to be constructed in such a way that they accept 14-digit Global Trade Item Numbers. This will ensure that all databases use the same GTIN.

Benefits of correct allocation and usage of GTINs

The integrity of all identification numbers, throughout the item's lifetime, is vital to maintaining uniqueness for; manufacturers, wholesalers, distributors, hospitals, regulatory bodies and other supply chain stakeholders.

The correct allocation and usage of GTINs results in benefits for all stakeholders, including:
- GTINs ensure global reach in the Healthcare supply chain. A country that promotes the use of GTINs can accept GTINs from anywhere in the world, but countries modifying GTINs or promoting national identifiers can not.
- GTINs can reduce the need for re-labelling, to meet country specific requirements, which can result in lower misidentification events, more cost-effective software solutions and fully interoperable systems, as GTINs are standardised.
- The GS1 System allows standardisation of global traceability from product manufacture to patient treatment and beyond, (including product recalls and adverse event reporting). GTINs are one enabler of the traceability process.
- GTINs, assigned to all packaging levels for automatic identification, can be used as a cross-reference to registration or reimbursement systems.
- GTINs enable realising economies of scale and cost reduction.
    - o GTINs can optimise manufacturer's production and supply chain processes, while maintaining a global reach.
    - o GTINs support optimisation of supply chain management for hospitals, pharmacy retailers, distributors and wholesalers.

Allocating the GTIN is the responsibility of the brand owner. **A GTIN must not be altered at any point in the supply chain as it compromises uniqueness** (e.g. do not store a GTIN-14 in a 13-digit field). Supply chain stakeholders using the original and correct number can recognise the product in any system, but a modified GTIN becomes unrecognisable, complicating the above processes.

---

(1) A trade item is any item (product or service) upon which there is a need to retrieve pre-defined information and that may be priced, or ordered, or invoiced at any point in any supply chain. This includes individual items as well as all their different configurations in different types of packaging.

Different GTIN data structures

As per GS1 Standards, GTINs are allocated[2] by the brand owner of the item who can choose one of the following data structures, depending on the application or use case and specific needs: GTIN-14 or GTIN-13 or GTIN-12 or GTIN-8.

	Data Structure													
	T_1	T_2	T_3	T_4	T_5	T_6	T_7	T_8	T_9	T_{10}	T_{11}	T_{12}	T_{13}	T_{14}
GTIN-14	N_1*	N_2	N_3	N_4	N_5	N_6	N_7	N_8	N_9	N_{10}	N_{11}	N_{12}	N_{13}	N_{14}
GTIN-13	0	N_1	N_2	N_3	N_4	N_5	N_6	N_7	N_8	N_9	N_{10}	N_{11}	N_{12}	N_{13}
GTIN-12	0	0	N_1	N_2	N_3	N_4	N_5	N_6	N_7	N_8	N_9	N_{10}	N_{11}	N_{12}
GTIN-8	0	0	0	0	0	0	N_1	N_2	N_3	N_4	N_5	N_6	N_7	N_8

* Indicator digit

Each identifier is globally unique and can be used anywhere in the world. **All Healthcare databases** (excluding retail point-of-sale) **must always use a 14-digit construction to allow storage of all GTIN data structures therefore, should a GTIN-8, 12 or 13 be used, leading zero's must accommodate the digit positions that are not appearing when encoded** (see table above). For example, healthcare databases for registration, traceability, distribution or reimbursement of Healthcare products must accommodate all GTIN data structures including GTIN-14.

The Indicator digit is only used in the GTIN-14 Data Structure. It takes the value of 1 to 8 for fixed measure trade items and is used for different identification levels for the trade item (e.g. the medical instrument itself, its inner pack, case, pallet). **Therefore truncating a 14-digit GTIN to a 13-digit GTIN, by removing the Indicator digit, is modifying the GTIN-14 data structure and is not valid in accordance with GS1 Standards.**

The manufacturer or supplier has the option of assigning a GTIN and symbology based on the use case to be applied:

Carrier	Example	Data	Use Case
EAN/UPC	4 512345 678906	GTIN only **GTIN-8, 12 & 13**	**Retail Point-of-Sale** Including general distribution
GS1-128	(01) 1 9501101 02091 4	All AIs[3] **GTIN-12, 13, 14**	**Point-of-Care** (Non-Retail) Including general distribution, e.g. hospital consumption unit or single unit of use, logistics, assets
GS1 DataMatrix		All AIs[3] **GTIN-12, 13 & 14**	**Point-of-Care** (Non-Retail) Direct part marking Very small items
GS1 DataBar™	(01) 0 0614141 99992 7	All AIs[3] **GTIN-12, 13 & 14**	**Retail Point-of Sale** (sunrise 2010 goal) **Point-of-Care** (Non-Retail)

(2) See GTIN Allocation Rules for Healthcare at: www.gs1.org/docs/gsmp/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf
(3) AIs (GS1 Application Identifiers) are a finite set of defined identifiers used to connect physical things and logical things to information or business messages related to them.

GS1 Healthcare - Improving patient safety worldwide

Retail and non-retail use case is a major deciding factor when choosing a symbology:

*   Products that are not sold at retail point-of-sale can use any GS1 bar code that is approved for the application (e.g. GS1-128, GS1 DataBar™, GS1 DataMatrix, EAN/UPC).
*   A product sold in one country at retail point-of-sale will dictate a GTIN-12 or 13 using an EAN/UPC bar code. The same product can also be sold at point-of-care (non-retail, healthcare application) into another country, in which case that product will still be identified with the GTIN-8, 12 or 13 using the EAN/UPC (bar code used at retail point-of-sale) to facilitate global harmonisation.

# # #

About GS1

GS1 is a neutral, not-for-profit standards organisation dedicated to the design and implementation of global standards and solutions to improve the efficiency and visibility in supply chains. GS1 is truly global with 108 Member Organisations worldwide. More than 1 million companies worldwide have adopted the GS1 System of Standards.

About GS1 Healthcare

GS1 Healthcare is a global user community consisting of all Healthcare supply chain stakeholders, including manufacturers, distributors, Healthcare providers, industry associations and regulatory authorities. 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. The vision of GS1 Healthcare is to be the recognised, open and neutral source for regulatory agencies, trade organisations and other similar stakeholders who are seeking input and direction for global standards in Healthcare for patient safety, supply chain security & efficiency, traceability and accurate data synchronisation.

For more information about the GS1 global Healthcare user group, please visit www.gs1.org/healthcare

Blue Tower
Avenue Louise 326, b10
BE 1050 Brussels
Belgium
T +32 (0)2 788 7800
F +32 (0)2 788 7899
healthcare@gs1.org
www.gs1.org
www.gs1.org/healthcare/