NHS Supply Chain

Data Standards - Supplier Product Coding

Supplier Requirements and Guidance

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Purpose

GS1 is NHS Supply Chain's preferred data coding standard for product. This document sets out the requirements on suppliers of medical devices and clinical consumables in relation to this policy and provides information and guidance. It is aligned to our In-Hospital Services Inventory Management Systems deployment programme and should be seen in this wider context.

Introduction

Improving data on medical devices across the NHS system is a key contributor to improving patient safety through greater and more rapid traceability.

At present medical device data is not routinely collected in a consistent manner or standardised digital format. Current processes are often paper based and lack standardisation and validation which means that tracing medical devices is time consuming and laborious and linking devices to patient outcomes difficult.

The adoption of global standards, such as GS1, for product identification enhances the traceability of medical devices and other products used in an episode of patient care.

The GS1 data standards provide a common foundation and consistent format and enables the unique identification, capture and sharing of information automatically. When data describing medical devices is captured electronically it can be easily associated with a patient and provides accurate information about which devices have been used in their care.

This electronic data capture for product forms part of the NHS England Scan4Saftey programme methodology to capture data for person (patient and caregiver), product, place and procedure.

Access to this data electronically in a standard format enables it to be interrogated and performance of medical devices can be monitored, patient outcomes measured and any potential issues with devices can be identified faster and more easily allowing clinicians to intervene and if necessary, prevent harm before it happens.

Benefits to Suppliers, the NHS and NHS Supply Chain

Implementing a policy on the adoption of GS1 standards for product coding will support our **vision** to make it easier to put the patient first, by saving clinical time required for product and patient recall and aligns to our **purpose,** to help the NHS to save lives and improve health through greater traceability of medical devices supporting better patient outcomes.

Benefits will be realised by multiple stakeholders and those of significant value to our suppliers include:

- **Data relating to product safety** will be captured and will be used to inform better patient outcomes and drive the adoption of innovative products;
- **Reduced transaction** costs due to fewer price-based invoice queries and reduced supply chain disputes by provision of accurate and timely order, delivery and invoice information, as the whole supply chain will be using the same product identifiers;
- **Greater efficiency** and visibility of product throughout the supply chain reducing wastage, lowering the costs of product recall;
- **Enabling compliance** with forthcoming UK traceability regulatory requirements, and existing market obligations, for example in the EU and USA;
- **Standardised data** enabling increased automation in the flow of product data between NHS Supply Chain, NHS organisations and their trading partners.

Using GS1 standards as the foundational data in our Inventory Management System deployment programme to trusts will also enable other benefits to suppliers such as:

- reduction in inventory levels through more accurate and timely information leading to improved demand forecasting and inventory planning;
- improved visibility of and reduced reliance on consignment stock;
- reduction in wastage due to improved expiry date management;
- saving in time and increased efficiency and reliability in production, storage, picking, shipping and reporting using barcode scanning;
- improved product traceability delivering faster, and lower cost, product recall processes through more accurate and timely information about product locations within the supply chain;
- improved patient safety through transparency of expiry dates;
- more effective monitoring of customer contractual requirements through accurate and comprehensive information relating to orders, deliveries and invoices.

Scope

All medical devices, as defined by the MHRA here**,** are in scope and are subject to the requirements detailed in this document.

To support patient level costing, inventory management processes and product recall in a hospital, clinical consumables are also included in the scope of these requirements.

Requirements

1. Allocate GTINs/UDI-DIs at all packaging levels and at unit of use level if the item is not packaged separately.
2. Include GTINs/UDI-DIs in relevant data submissions to NHS Supply Chain, including product data for NHS Supply Chain's catalogue. Further detail will be provided in due course relating to other procurement documents.
3. For medical devices include UDI compliant barcodes at all levels of packaging, including unit of use if packaged and labelled individually. There should not be multiple barcodes per unit as this can lead to scanning errors.
4. For Clinical Consumables include product identifier (GTIN) compliant barcodes at all levels of packaging.

Guidance

As GS1 is the preferred coding standard for NHS Supply Chain the information that follows is specific to GS1 standards. If you use an alternative standards body, you will need to follow their guidance.

NHS Supply Chain is currently reviewing its procurement documentation and further detail will be made available in due course as to how these requirements will be incorporated, however for some tenders it is likely that they will form part of the evaluation criteria and this data population will be a condition for products being listed in the catalogue.

To meet the requirements of this policy the actions listed below should be taken in accordance with the Supplier Adoption Timeline (pages 9 and 10).

1. **Allocate GTINs at all packaging levels and at unit of use level if the item is not packaged separately.**

To be able to use GS1 identifiers and access the help that is available, suppliers must become a member of the not-for-profit non-governmental organisation GS1. Many suppliers to the NHS will already be members of GS1 somewhere in the world. To join GS1 or find out if your company is already a member contact the GS1 UK healthcare team at healthcare@gs1uk.org or visit the GS1 UK website at www.gs1uk.org**.**

Allocate a Global Trade Item Number (GTIN) to your products at each level of the packaging hierarchy from unit of use through to carton/case.

The (GTIN) is the GS1 identifier used to uniquely identify any product or service. This is a static identifier that is equivalent to a UDI Device Identifier (UDI-DI). GTINs are numeric and end with a check digit. They can be eight, twelve, thirteen or fourteen digits long and are known as GTIN-8, GTIN-12, GTIN-13 and GTIN-14 respectively.

The check digit calculation is specified at http://www.gs1.org/barcodes/support/check_digit_calculator where an online check digit calculator is also available. Alternatively, users can create, manage and store their GTINs online using the GS1 UK Numberbank. More details are available from GS1 UK at healthcare@gs1uk.org.

The most used GTIN is the GTIN-13 which is a 13-digit fixed length number, starting with a GCP followed by an item reference allocated by the product's brand owner and finally a check digit.

The number of item reference digits depends on the length of the prefix as shown in the following table:

GS1 Company prefix	Item reference	Check digit	Complete GTIN
5012345	98765	1	5012345987651
506097389	009	6	5060973890096

GTIN-14s may be used to identify specific packaging configurations, such as multipacks or outer cases and other packaging groupings. They are derived from the GTIN-13 used to identify the lowest product configuration contained in the outer case by adding an extension digit as a prefix to the GTIN-13 and then recalculating the check digit. The extension digit can take any value from 1-8, and simply creates a different item number for a different packaging configuration.

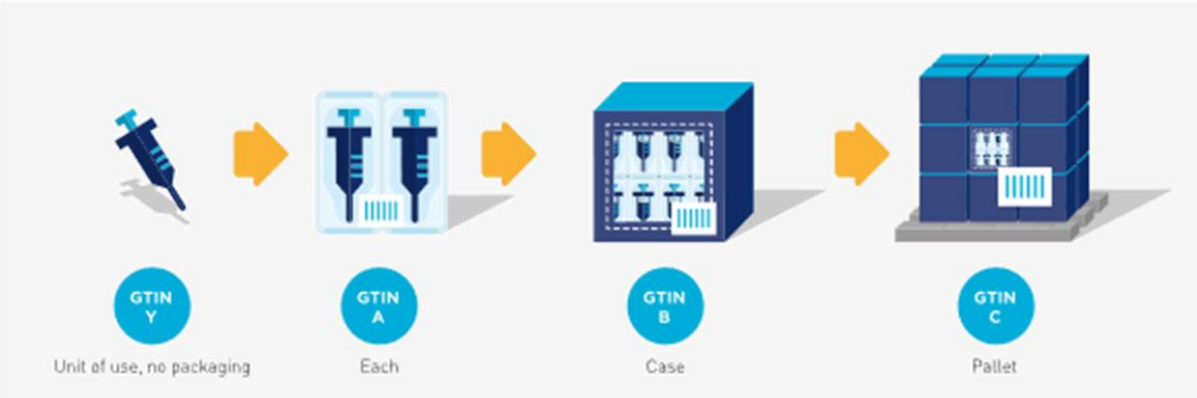
The extension digit 9 is reserved for identifying outer cases of products, which are priced on their weight or other continuously variable measure; examples include cases of meat or fish.

GTIN-13s may also be used to identify outer cases. It is the choice of the brand owner whether to use a GTIN-13 or a GTIN-14 on their outer cases.

For additional detail please refer to the GS1 General Specifications.

GTINs and the packaging hierarchy

It is important that different levels within the packaging hierarchy (e.g., unit of use, each, case or pallet) are assigned different GTINs. The brand owner should allocate GTINs to the single unit, or unit of use, plus all other levels that are priced or ordered.



Source: GS1 Healthcare GTIN Allocation Rules Standard

Managing GTINs

Brand Owners/Legal Manufacturers are responsible for properly allocating and maintaining the GTINs for their products to enable trading partners to distinguish products effectively for regulatory, supply chain and patient safety purposes. GTINs may directly impact patient safety since in some healthcare applications the GTIN may be used to check and subsequently record that the correct medication and/or equipment is administered.

It is important to implement a process for allocating and managing GTINs into your product quality management system. This should include ensuring that duplicate GTINs are not created and that the check digit is calculated correctly. A new GTIN should be allocated when a product changes significantly. The GS1 GTIN Allocation Rules for Healthcare provide more specialised guidance for healthcare products and services.

Internal SKUs and GTINs

GTINs should be referenced in all external communication with NHS Supply Chain and NHS customers, including invoices, purchase orders and Advanced Shipping Notifications (ASNs). However internal SKUs can be mapped or “anchored” to GTINs thus enabling internal systems and staff to continue to use internal SKUs if this is more convenient. Suppliers should still be able to use GTINs when discussing issues with NHS Supply Chain or NHS customers.

2. Include GTINs in all relevant data submissions to NHS Supply Chain

GTINs at individual level should be included in all data submissions to NHS Supply Chain. This includes catalogue data and further detail will be provided in due course relating to other procurement documents.

Once unique product information has been provided to NHS Supply Chain, the supplier is responsible for keeping all relevant data updated in a timely manner. We will monitor GTIN quality and content in our catalogue and will be seeking regular feedback from our customers on data challenges that they experience, which in turn, working with GS1 UK, we will feedback to our suppliers for remedial action where necessary.

3. For medical devices include UDI compliant barcodes on all levels of packaging

To ensure the scanning process is as efficient as possible it is important that correctly formatted and legible barcodes are used on product packaging and the UDI barcode is obvious and clear. The ISO UDI symbol should be placed next to/near the UDI barcode when the label/packaging contains non-UDI barcodes. Any barcodes for internal use should be separate and not near the UDI barcode. This is to facilitate the most straight-forward scanning process for hospital staff, as packaging from lots of manufacturers with varied labels and barcodes will need to be managed daily.

Print a GS1 compliant barcode label that includes the UDI, both a GS1 device identifier (GTIN/UDI-DI) and the product's production information (UDI-PI, expiry date, lot/batch, or serial number). The UDI label should be applied to all levels of packaging including the lowest level/unit of use in accordance with the Supplier Adoption Timeline and the requirements specified in the EU MDR.

Please note: This will be reviewed when the UK MDR are published.

Implementing product barcodes

GS1 identifiers can be encoded into a variety of GS1 standard barcodes and RFID tags which are recognised throughout the healthcare supply chain. Currently linear GS1-128 or 2D GS1 DataMatrix barcodes are most used.

Information to be barcoded

The information to be carried in a traded item barcode is its device identifier (e.g., GTIN) and its production identifiers, such as expiry date, batch/lot number or serial number; this will enable forthcoming UK UDI regulatory requirements to be met.

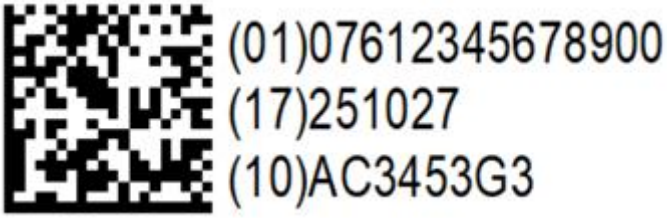
Choice of barcode

Suppliers should use, wherever possible, a GS1 DataMatrix barcode to streamline the scanning process for clinicians or failing that a GS1-128 linear barcode on their products. The use of other GS1 barcodes is not recommended for use in healthcare.

Selection of the appropriate GS1 barcode to be placed on the product, or more commonly on the product packaging, is based upon the class of product and the types of location where the barcode will be scanned. It is likely that, over time, healthcare organisations will require all suppliers to use the GS1 DataMatrix barcode for all products.

The barcodes should be used on the product itself and on all higher packaging levels where additional supplementary data such as batch/lot number, serial number and expiry date is required as shown below.

GS1 DataMatrix barcode showing the GTIN, expiration date (YYMMDD) and batch/lot number.



Note that the brackets shown in the GS1 DataMatrix and GS1-128 examples are to assist human readable interpretation and are not included in the barcode itself.

GS1-128 barcode showing the GTIN, and expiration date (YYMMDD).

Clarification Note For GS1-128 and GS1 DataMatrix barcodes the GTIN must be extended to 14 digits by prepending zeroes as required.

GS1 DataMatrix barcodes require a camera-based scanner but can be much smaller and are less affected by damage. GS1-128 barcodes can be read by any barcode scanner but are relatively large.

Printing barcode
To capture production information in addition to device information, on-demand barcode printing on site is likely to be required, and this will require barcode generation software and a suitable printer. There is a wide selection of barcode software programmes available.

Barcode quality
A barcode's primary function is to carry data from the point at which it originated to the points at which data is captured, making it a vital link in the data communication chain of any application. If it fails, the chain breaks. A barcode that does not scan often causes more problems to trading partners than no symbol at all.

Any printing method chosen must be able to produce barcodes that can be scanned anywhere in the supply chain. If the barcode printing is being outsourced to another company, the brand owner should agree with the printer who is to be responsible for ensuring and checking the barcode quality. Wherever barcodes are created, it is recommended that the size and quality of the symbols is checked and verified before distribution to avoid problems and the potential rejection of goods.

A barcode verifier is a useful tool to add to quality control procedures to ensure that the barcodes will scan correctly throughout the supply chain.

The GS1 UK website, www.gs1uk.org**,** has a list of accredited solution providers who either offer verification services or can provide appropriate equipment to enable you to check barcode quality yourself. The GS1 UK Healthcare Team can perform initial checks. Labels can be submitted for review at https://www.gs1uk.org/industries/healthcare/supplier-barcode-verification

ISO/IEC standard 15415 specifies requirements for barcode quality and ISO/IEC 15426 parts 1 and 2 cover requirements for verification for linear and 2D barcodes.

For more information, refer to Barcoding - Getting it Right or one of the following more specialist documents:

- GS1 Barcode Validation and Verification
- GS1 Data Matrix an Introduction and Technical Overview

These videos recorded by GS1 UK also provide more information on barcoding and UDI, GS1 UK | Barcoding success bitesize.

4. For Clinical Consumables include product identifier (GTIN) compliant barcodes on all levels of packaging

Whilst clinical consumable products do not fall within any regulatory obligations there are other benefits to including these products in this policy, such as patient level costing per procedure and the efficiencies in scanning all products involved in a particular episode of care, and not just some of them (makes the process simpler for clinical staff); it also maximises visibility of inventory to support demand management in a hospital and enables product recall.

Print a GS1 compliant barcode label that includes the product identifier, the GS1 GTIN. The product identifier label should be applied to all levels of packaging including the unit of use, in accordance with the Supplier Adoption Timeline.

Supplier Adoption Timeline

		Medical Devices UK Classification				Clinical Consumables
	Requirements	**Class III**	**Class IIb**	**Class IIa**	**Class I**	
Data	Allocate GTINs/UDI-DIs at all packaging levels and at unit of use level where the item is not packaged separately[1]	30 September 2024				31 March 2025
	Include GTINs/UDI-DIs in all relevant data submissions to NHS Supply Chain[2]	30 September 2024				31 March 2025
Labelling	Include a Unique Device Identifier compliant barcode at all packaging levels including unit of use[3] [4]	30 September 2024			26 May 2025	N/A
	Include a product identifier barcode at all packaging levels including unit of use	N/A				31 March 2025
	[1] Unit of use level where the item is not packaged separately is not required for clinical consumables					
	[2] For example, catalogue templates and tender submissions					
	[3] In the event of there being significant space constraints on the unit of use packaging, the UDI carrier may be placed on the next higher packaging level					
	[4] For single-use devices of Class I and IIa packaged and labelled individually, the UDI carrier shall not be required to appear on the packaging, but it shall appear on a higher level of packaging e.g., a carton containing several individually packaged devices.					