Department of Health

NHS

Adoption of GS1 and PEPPOL Standards:

Guidance for suppliers of medical devices to the NHS

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Contents

Introduction

The *NHS eProcurement Strategy*[1] was published by the Department of Health in May 2014 and compliance with the strategy by NHS trusts was mandated as a requirement of the NHS Standard Contract. Additionally, the NHS Terms and Conditions for the Supply of Goods and the Provision of Services have been amended to include a requirement on suppliers to place master product and price data in a *GS1 GDSN certified datapool*[2].

The primary purpose and advantage of deploying a GS1 Master Data Management strategy is to improve data accuracy and consistency across multiple IT systems. The use of GS1 standards will also act as an enabler for Automatic Identification and Data Capture (AIDC) technology, which is used to correctly identify a product at the point of use.

There will be many benefits to all stakeholders from the NHS eProcurement Strategy, those of significant value to suppliers to the NHS include:

- **A single data source** for product information available to all NHS customers. The supplier will benefit from having one method of delivering an agreed list of attributes using a globally recognised standard and a set of processes that are consist for all NHS acute trusts;
- **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;
- **Greater efficiency** and visibility of product throughout the supply chain reducing wastage, lowering the costs of product recall and enabling compliance with forthcoming European anti-counterfeiting and traceability legislation.

In line with the *NHS eProcurement Strategy*[1] acute trusts are required to put in place a board-approved strategic outline case for the adoption of GS1 and PEPPOL

standards by the end of June 2015. This supplier guidance document provides a resource package to support suppliers in their adoption of GS1 and PEPPOL standards.

Background

In 2007, the Department of Health published *Coding for Success*[3], which recommended the adoption of GS1 standards for patient identification and for manufactured products. With the subsequent publication of the *ISB1077*[4] standard, adoption of GS1 for patient identification became a requirement for NHS Trusts.

The benefits noted by *Coding for Success*[3] by the introduction of patient identification included: fewer medication errors; reduced risk of wrong-site surgery; and more accurate track and trace of surgical instruments, equipment and devices. In addition to patient safety benefits, benefits from the coding of manufactured goods were also identified, including improved efficiency.

About GS1 and PEPPOL

GS1

GS1 is a global not-for-profit organisation dedicated to the design and implementation of standards that improve the efficiency of demand and supply chains. GS1 is a global organisation, with 110 member organisations serving over one million companies across 150 countries. GS1 has been working with members for over forty years to define and deploy global standards across a range of sectors.

GS1 has defined standards and corresponding barcodes to enable clear identification of such things as patients, caregivers, locations, products, asset and records. Scanning of barcodes enables accurate management, tracking and tracing of medicines, medical devices and instruments throughout the supply chain through to the patient record. It also enables accurate location of equipment, assets and medical records within hospitals and other care settings.

PEPPOL

PEPPOL (Pan European Public Procurement On Line) is the culmination of a multi-year project co-funded by the European Commission and 11 member states. It provides a set of messaging standards that enable procurement documents (such as purchase orders, advance shipping notes and invoices) to be electronically exchanged without manual intervention between buying and selling organisations through commercial PEPPOL 'Access Points'.

OpenPEPPOL is a not-for-profit association established to take responsibility for the development and maintenance of the PEPPOL standards and specifications. Its purpose is to enable European businesses to easily trade electronically with European public sector buyers, increasing competition for government contracts and providing improved value for taxpayers' money.

Benefits to suppliers, distributors and the NHS

The application of the GS1 System in the healthcare sector is globally recognised as the biggest potential area of benefit from adoption of standards. In 2011 McKinsey & Company estimated that the adoption of a single standard for the identification, capture and share of information in the global healthcare sector could save 22-43,000 lives and avert 0.7-1.4 million patient disabilities while reducing cost across the sector by $40-100bn. In NHS terms this equates to savings of between £5,000-8,000 per bed with these savings realised by all parts of the supply chain from manufacturer or service provider through to wholesale, retail, distribution and into the hospital or primary care provider.

Suppliers to the NHS will be able to gain the following benefits:

- 40-45% average reduction in data management costs associated with rekeying, poor transcription, maintenance, cleansing and synchronising with supply partners for product catalogues and location identification;
- 15% average reduction in inventory levels through more accurate and timely information leading to improved demand forecasting and inventory planning;

- 10% average reduction in wastage due to improved expiry date management;
- Saving in time and increased efficiency and reliability in production, storage, picking, shipping and reporting through the use of barcode scanning;
- Increased protection against counterfeit products and the associated loss of sales and damage to brand integrity;
- Reduction in the costs associated with delivering product information to NHS customers as product data will be entered once into a datapool and is then available to all NHS customers;
- Fewer price based invoice queries because of automated price updates to trust systems;
- Reduced cost and time associated with supply chain partner disputes by provision of accurate and timely information about orders, deliveries and invoices;
- Improved product traceability delivering faster, and lower cost, product recall processes through more accurate and timely information about product locations within the supply chain;
- More effective monitoring of customer contractual requirements through accurate and comprehensive information relating to orders, deliveries and invoices;
- Provides the basis for compliance with the upcoming European anti counterfeit and traceability regulations for medicines and medical devices.

National infrastructure

Implementation of the infrastructure included in the *NHS eProcurement Strategy*[1] will reduce the costs of the whole healthcare supply chain from manufacturers and distributors to trusts and other healthcare providers.

There are two parts to the proposed infrastructure the Department of Health would like to establish, the first being an NHS Product Information Management (PIM) system. The PIM is used to interface with the GS1 Global Data Synchronisation

Network (GDSN); and is needed to draw down the product and price information we are asking suppliers to publish into a *GS1 GDSN certified datapool*[2].

A single point of connection and commercial agreement with one of 32 available GDSN certified datapools[2] will link the supplier to the infrastructure needed to synchronise product and price information with the NHS in a consistent way.

The supplier will benefit from having a single point of connection and one method of delivering an agreed list of attributes using a GS1 data formatting standard and a set of processes that are consistent for all NHS acute trusts.

The second part of the proposed infrastructure the Department of Health will establish is a PEPPOL Network. The PEPPOL Network will facilitate the electronic exchange of business documents such as purchase orders and invoices.

The supplier will again benefit from having a single point of connection with one technology provider, leveraging the PEPPOL interoperability and data standard to communicate with all NHS acute trusts using a single connection and common set of processes.

Actions required

The *NHS eProcurement Strategy*[1] requires suppliers to take the following actions in accordance with the prioritised scope that is illustrated in the Medical Device Brand Owner Timeline document. The timeline has been amended following initial consultation with key stakeholders, so that the timeline can be agile and reflect changes that result from third party critical path dependencies.

Getting ready

1. Become a member of GS1.
2. Allocate a GS1 place identifier, GLN, to your company and its significant locations and organisational teams. The GLN will be used to identify your organisation when trading with the NHS.
3. Add the NHS acute trust GLNs to the locations that exist within your transactional systems, so that the GLN can be used to identify the place in the information you exchange with your NHS customers. As an interim measure prior to the GLN Registry being established, trusts and suppliers can share GLNs via the GLN Information Exchange form.

Datapool

Suppliers to the NHS must manage product information as a single source of truth so that the information can be synchronized electronically with NHS trusts' local systems without being re-entered manually into a different system, using a single point of connection to the GDSN.

1. Allocate a GS1 product identifier, GTIN, to your products at each level of the packaging hierarchy from unit of use through to shipper/case.
2. Establish the capability and processes needed to extract and consolidate product and price information that is defined within the Supplier Manual from the transactional systems used to produce the transactional business documents exchanged with the NHS.

3. Enter standardised product and price data for your products into a GS1 GDSN compliant datapool. There are 32 GS1 GDSN compliant datapools[2]; a full list is available at http://www.gs1.org/gdsn

Purchase to pay

Suppliers must use the PEPPOL network to facilitate the electronic exchange of business documents such as the purchase order and invoice.

1. Implement electronic orders and invoices using the PEPPOL standard with GS1 identifiers. You will need to sign up to and then integrate with a PEPPOL access point. A full list is available at http://www.peppol.eu/adoption/access-point-providers.

Barcode labelling

1. Print a GS1 compliant barcode that includes both a GS1 product identifier (GTIN) and the products production information. The production information need only be included to comply with a regulatory requirement or if the supplier can foresee the need to make provision for a batch recall.

Implementation guide

The remainder of this document provides a more detailed guide to implementing the action points listed above.

Getting ready

1. Become a GS1 member

GS1 members create GS1 identifiers by adding numbers or characters to a globally-unique GS1 Company Prefix (GCP) number which is assigned by GS1. Since the GCP is unique, all the identifiers created from it will also be unique and can be used anywhere in the world. GCPs have between four and 12 digits, depending on the GS1 member's requirements.

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,. and it is not necessary to be a member of GS1 UK. Additionally anyone who sells anything through the major supermarkets will already be a member. To join GS1 or find out if your company is already a member contact the GS1 UK healthcare team on freefone 0808 172 8390 or healthcare@gs1uk.org or visit the GS1 UK web site at www.gs1uk.org.

2. Allocate a GS1 identifier to your company and its significant locations

The *NHS eProcurement Strategy*[1] requires that a GS1 Global Location Number (GLN) be used to identify your company and its significant locations and departments.

What is a GLN?

The Global Location Number (GLN) is the GS1 identifier used to identify any legal, operational or physical location associated with a business or organisation.

The format of a GLN is a 13-digit, fixed-length numeric field, starting with the GS1 company prefix (GCP) allocated by GS1, followed by a location reference allocated by the owner of the location and finally a check digit.

Note that the same number can refer to either a GTIN or a GLN depending on the context.

GS1 Company Prefix	Location reference	Check digit	Complete GLN
5012345	98765	1	5012345987651
50456789	1234	2	5045678912342

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 GS1 UK members can create, manage and store their GLNs online using the GS1 UK Numberbank. More details are available from the GS1 UK helpdesk: healthcare@gs1uk.org or freephone 0808 172 8390 (int. +44 207 092 3501).

GLNs can be used to identify any physical location or organisational entity against which data needs to be captured in electronic application systems and databases. Some examples of business or organisational entities include:

Legal entities

- A company
- A subsidiary of a company

Operational entities

- The invoice department
- The sales order department at a supplier

Physical locations

- A warehouse, a drop off point or a specific shelf within a store

Typically, data associated with a GLN – e.g. name and address, location type, contact persons, communications numbers, banking information, delivery requirements or restrictions, etc. – is stored in database files for retrieval. The GLN is strictly an identifier (reference key) and does not carry any information about the location it identifies.

GLNs are used in electronic messaging to identify the sender and recipient of an electronic transmission and any party relevant to the transaction, e.g. buyer, seller, carrier etc. Additionally, within electronic messages GLNs also identify relevant physical locations such as the “ship-to” location. GLNs are also used in barcode symbol format, typically the GS1-128 barcode, to enable scanning and identification of physical locations.

Allocating GLNs

Each supplier should allocate a GLN to identify the company as a legal entity. In addition the following GLNs should be allocated to uniquely define where:

- customers can send orders;
- customers will receive products from;
- customers will be invoiced from;
- customers should pay;
- customers should send returned products.

For smaller companies the same GLN may be used for each of the above.

Communicating GLNs via a GLN registry

The Department of Health will create an NHS GLN Registry and supplier GLN master data will be made available to trusts through this registry which will also specify the detail of what GLN master data is required. In advance of the GLN registry, the master data can be shared with customers using the GLN Information Exchange Form.

3. Allocate a GS1 identifier to your company and it's significant locations

The *NHS eProcurement Strategy*[1] requires that a GS1 Global Location Number (GLN) be used to identify your company and its significant locations and departments.

Customer GLNs

Through the NHS GLN registry, or initially excel spreadsheets, your NHS customers will provide you with GLNs and associated master data including some or all of the following:

- The identity of the trust and/or hospital;
- The entity to which invoices should be sent;
- The entity to which Advice Shipping Notices should be sent;
- The initial physical location to which products should be delivered;
- The "forward to" physical locations within the trust.

Note that the existing NHS Supply Chain requisition points currently identify both trust cost centres and their physical locations. This can be an issue where locations are shared or when departments change their physical location. Trusts may provide a GLN for the trust cost centre and a different GLN for physical delivery location. This may require changes to your customer database.

More information is available in the *GLN in Healthcare Implementation Guide*[5].

Internal Customer IDs and GLNs

GLNs should be used in all external communication with NHS customers including invoices, orders, and advance shipping notices. However internal customer IDs can be mapped or 'anchored' to GLNs thus enabling internal systems and staff to continue to use internal customer codes if this is more convenient. Note however that suppliers should be able to use GLNs when discussing issues with NHS customers.

Datapool

1. Allocate a GS1 product identifier.

The *NHS eProcurement Strategy*[1] requires that any product or service sold to the NHS must be identified by a GS1 Global Trade Item Number (GTIN) and certain standardised information about the product or service entered into a GS1-compliant datapool. Following consultation with trade associations, compliance dates for these requirements have been amended as detailed in the Medical Device Brand Owner Timeline. Dates for other market sectors will be advised in the future.

What is a GTIN?

The Global Trade Item Number (GTIN) is the GS1 identifier used to uniquely identify any product or service.

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 the GS1 UK: healthcare@gs1uk.org or freephone 0808 172 8390 (int. +44 207 092 3501.

The most commonly 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 table below:

GS1 Company prefix	Item reference	Check digit	Complete GTIN
5012345	98765	1	5012345987651
50456789	1234	2	5045678912342

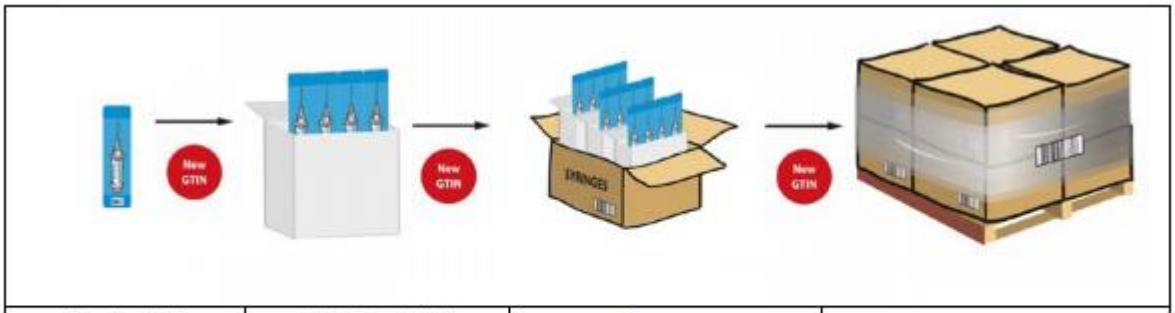
GTIN-14s may be used to identify specific packaging configurations, such as multipacks or outer cases and other packaging groupings. They are derived from the GTIN-13 used to identify the lowest product configuration contained in the outer case by adding an extension digit (zero) as a prefix to the GTIN-13 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.

GTINs and the packaging hierarchy

It is important that different levels within the packaging hierarchy (e.g. single unit, multipack, shipper or case, pallet, etc.) 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.



Single Unit Package	Multiple Unit Package	Case or Shipper	Pallet
GTIN A	GTIN B	GTIN C	GTIN D

Managing GTINs

Brand owners 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*[6] provides general guidance applicable to all industries. The GS1 *GTIN Allocation Rules for Healthcare*[7] provides more specialised guidance for healthcare products and services.

Note that GTINs may be reused in most industries subject to the *GTIN Allocation Rules*[6]. However GTINs allocated to regulated healthcare products (those regulated by the Medicines and Healthcare Products Regulatory Agency (MHRA) must never be reused.

Internal SKUs and GTINs

GTINs should be referenced in all external communication with 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. Note however that suppliers should be able to use GTINs when discussing issues with NHS customers.

2. Establish the capability and processes needed to extract and consolidate product and price information.

All required data attributes are provided in the Data Attributes Requirements document and Supplier Manual.

3. Enter product and price data into a GS1 Datapool

Suppliers of product and services to the NHS are required to enter standardised data into any *GS1 GDSN certified datapool*[2] of their choice. There is a list of GS1 compliant datapools at http://www.gs1.org/gdsn.

Data held in the datapool is strictly private between buyer and seller and as such pricing is completely confidential.

GS1-compliant datapools will offer a variety of services and functions to support their customers. A variety of data entry methods may be offered such as online key entry, excel or CSV upload or XML.

The data required by the NHS also satisfies the requirements of the US FDA UDI datapool. The GS1 UK datapool has a direct link to the US FDA Global UDI datapool (GUDID) and so can upload data on behalf of suppliers. The same approach will be taken for the EU and other regional and national UDI datapools.

More information about GS1 datapools and their operation is available at http://www.gs1.org/gdsn.

Purchase to pay

Implement electronic orders and invoices using PEPPOL

The *NHS eProcurement Strategy*[1] requires suppliers to use EDI to exchange orders/invoices and ASNs (also known as a despatch advice), using a PEPPOL access point, which is designed specifically for EDI with governments.

What is PEPPOL

In order to become PEPPOL compliant buyers and suppliers need to be capable of sending and receiving the following electronic documents based on the PEPPOL specifications to automate related procurement processes:

- Purchase Orders (PEPPOL BIS 3A);
- Invoices (PEPPOL BIS 5A);
- Advanced Shipping Notes (PEPPOL BIS 30 - Despatch Advice).

The electronic documents in scope will have to be exchanged between two PEPPOL access points, respectively one for the NHS provider and one for their supplier, implementing a 'Four-Corner' model. Further information on this can be found at www.peppol.eu

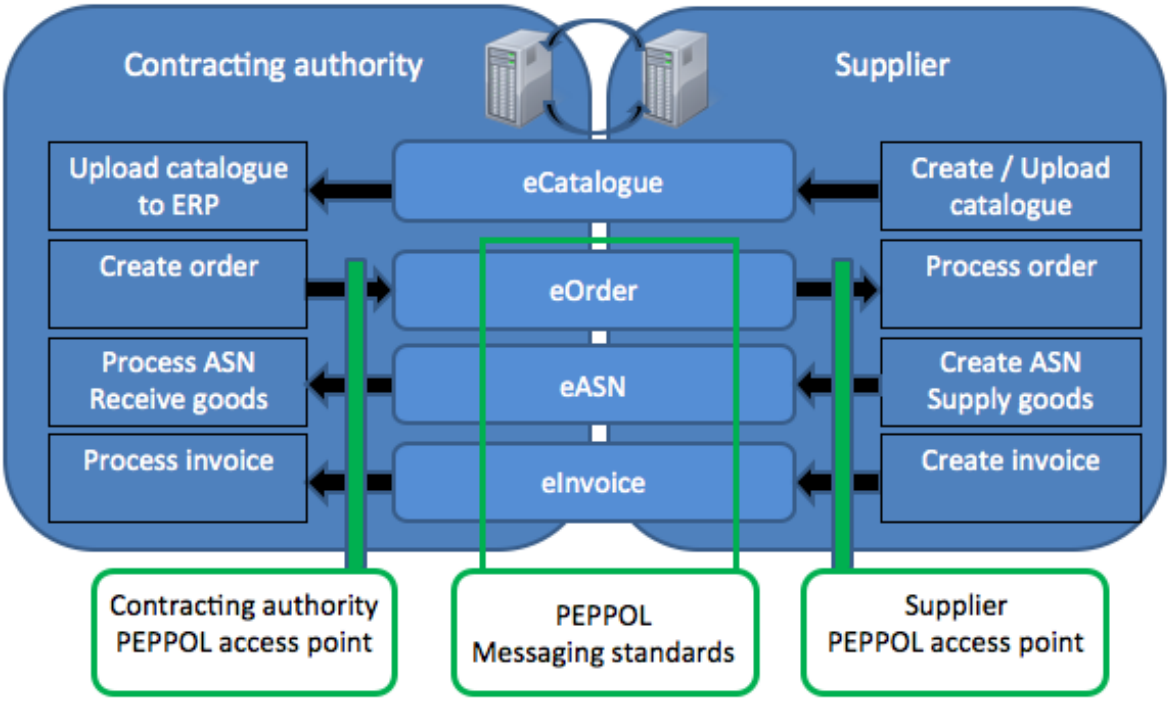


Figure - PEPPOL messages flow within NHS

Buyers and suppliers will each need to select a single approved access point provider. A list of NHS approved access points will be made available during 2015. Alternatively, buyers and suppliers who have the technical expertise may decide to implement an access point for their organisation or may be engaged with a particular service provider who wishes to become a PEPPOL access point provider.

The adoption of PEPPOL specifications and use of access points for document exchange will enable interoperability between existing NHS providers and suppliers.

What does this mean for suppliers?

Electronic invoices and orders sent to or received from a trust must be sent over the PEPPOL infrastructure in a PEPPOL message format via a PEPPOL-accredited access point service provider.

Within the PEPPOL messages products should be identified by GTINs; and companies and their locations should be identified by GLNs (note this is a requirement of *the NHS eProcurement Strategy*[1] rather than the PEPPOL standard itself).

Suppliers who are already electronically exchanging messages with trusts will need to find out if their existing EDI service provider will become a PEPPOL access point. If not they will need to select another service provider who is a PEPPOL access point.

Suppliers who do not currently use EDI will need to select an accredited PEPPOL access point provider who can help them implement electronic orders and invoices.

For more information about PEPPOL see www.peppol.eu.

Tasks and resources required to become PEPPOL compliant

To ensure interoperability, buyers and suppliers must exchange PEPPOL compliant documents such as eOrders, eASNs and eInvoices, within the PEPPOL network through their respective access points (gateways). These documents are formatted using the PEPPOL 'BIS' (Business Interoperability Specifications).

PEPPOL access point providers typically offer a range of additional services including the conversion of document formats, transaction monitoring and in some cases, document archiving. Buyers and Suppliers each choose their own respective access point provider and are free to choose whether they wish to develop the ability to accept or extract PEPPOL BIS-compliant documents internally or use the document formats of their choice (typically the format used by their ERP system) and leave the format conversion process to their respective access point provider.

It is important to note that a key benefit of the PEPPOL 4-Corner model is that suppliers are free to choose their own access point provider and must not be compelled to use the access point provider of their buyer(s).

Scenario A. Supplier currently exchanges electronic documents with the NHS

An organisation supplying goods or services to the NHS is currently exchanging eOrders, eASNs and eInvoices with their NHS buyer(s) through an eBusiness

Service Provider, using the file formats of the supplier's choice and an established exchange mechanism (common examples are: AS2, FTP, SFTP, eMail, Portal) for the transportation of the documents.

a) In this scenario, the supplier needs to ensure that their current eBusiness Service Provider (or provider of choice) plans to become a PEPPOL access point provider.
b) Develop the translation process necessary to convert eInvoices and eAdvance Shipping Notices from the supplier's chosen format to the appropriate PEPPOL BIS format.
c) Develop the translation process necessary to convert PEPPOL BIS eOrders received from the NHS buyer into the supplier's chosen document format.
d) Develop the necessary routings to validate, control and monitor the files sent and received.
e) Ensure tracking processes are in place to provide periodic statistical reporting to the NHS on the numbers and types of transactions processed.

Alternatively, the supplier can choose an existing PEPPOL access point provider and arrange for an agreement to provide any additional services mentioned above.
In either case, the supplier and access point provider need to reach an agreement outlining each party's responsibilities, and any development, subscription and/or transaction fees for services rendered.

Scenario B. Supplier currently exchanges manual documents with the NHS

An organisation supplying goods or services to the NHS is currently sending and receiving invoices and orders manually, typically either paper documents sent/received by post or PDF documents by eMail.
In this scenario the supplier needs to first investigate the ability of their internal systems and technical resources to:

a) Extract an invoice file from their ERP system in a common or structured format.

b) Accept and handle (preferably import) an incoming electronic order

c) Develop a process to send and receive electronic documents

d) Develop a procedure to monitor and control the above-mentioned processes to avoid duplication or missed files.

e) Decide whether to develop the necessary programs to process electronic files in their ERP systems without manual intervention or accept files electronically but process them manually.

f) Create an environment to carry out the necessary end-to-end testing of the file extract, import and transfer processes and ensure internal business experts are involved and engaged to ensure change management procedures are developed accordingly.

External resources may be required to carry out some or all of the above-mentioned development.

Next the supplier needs to choose an eBusiness Service Provider who plans to:

a) Become a PEPPOL access point provider
b) Develop the translation process necessary to convert outbound eASNs and eInvoices from the supplier's chosen format to the appropriate PEPPOL BIS format.
c) Develop the translation process necessary to convert inbound PEPPOL BIS eOrders received from the NHS buyer into the supplier's chosen document format.
d) Develop processes to validate, control and monitor the files sent and received.

2. Alternatively, the supplier can choose an existing PEPPOL access point provider (http://www.peppol.eu/adoption/access-point-providers)

and arrange an agreement to provide any additional services mentioned above.

In either case, the supplier and access point provider need to reach an agreement outlining each party's responsibilities, and any development, subscription and/or transaction fees for services rendered.

Barcode labelling

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 barcodes are most commonly used. Capturing information from a barcode is faster and more accurate than recording the information with paper and pen or keying into a terminal.

Information to be barcoded

The minimum information to be carried on a traded item barcode is the GTIN. In this case the barcodes can be pre-printed as part of the normal product packaging. This should have no impact on production processes and is merely a matter of redesigning the product packaging to include the barcode. Most printing and design companies will be able to assist in doing this.

If additional production data such as batch number or expiry date is to be included in the barcode then this will require printing the barcode during the production process. There are an increasing number of companies able to provide equipment to do this with minimal impact on existing production processes.

Medical devices and pharmaceuticals sold in the UK will have to conform to the various European directives currently under development that will specify the minimum information to be barcoded. For more information see http://ec.europa.eu/health/human-use/falsified_medicines/index_en.htm

For other products the information to be barcoded will be determined by the supplier in light of their customers' requirements.

Choice of barcode

Suppliers should use an EAN/UPC barcode, normally an EAN-13, a GS1-128, a GS1 DataMatrix or an ITF-14 on their products. The use of other GS1 barcodes is not recommended for the NHS. 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, the NHS will require all suppliers to exclusively use the GS1 Datamatrix barcode for all products.

Clarification Note:
GTIN-13 is the number that identifies a product. EAN-13 is just one type of barcode symbol that can contain a GTIN-13 number.

Products that are sold through a retail point of sale must carry one of the EAN/UPC barcodes which can encode only the product's GTIN. The EAN-13, shown below, is the most common EAN/UPC barcode symbology.

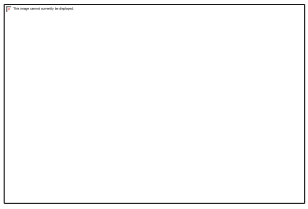
Outer cases or shippers should be marked with their GTIN in an ITF-14 bar code or preferably in a GS1-128 bar code label which can contain additional information such as batch number and expiry date.

An ITF-14 barcode can only contain a GTIN as shown in the example below.

GS1-128 or GS1 DataMatrix barcodes should be used on the product itself and can contain the product's GTIN and additional supplementary data such as batch number, serial number and expiry date as shown below.

GS1-128 barcode showing the GTIN, and expiration date

GS1 DataMatrix barcode showing the GTIN, expiration date and batch 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.

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

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

If required, a product can carry both an EAN/UPC barcode and a GS1-128 or GS1 DataMatrix barcode providing that the GTIN number in both barcodes is the same.

Printing barcodes

The individual product barcodes may be pre-printed as part of the product packaging. However some barcode printing on site is likely to be required for case labels, and this will require barcode generation software and a suitable printer. There is a wide selection of barcode software varying in price from free to over £1,000 depending on the levels of sophistication required.

Barcode quality

A barcode's primary function is to carry data from the point at which it originated to the points at which data has to be 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 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 in order 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.

ISO/IEC standard 15415 and ISO/IEC standard 15416[8] specify requirements for barcode quality and *ISO/IEC 15426 parts 1 and 2*[9] cover requirements for verification for linear and two dimensional barcodes.

For more information, refer to Barcoding - Getting it Right[10] or one of the following more specialist documents.

- *GS1 Barcode Validation and Verification*[11]
- *How to Choose Software for Digital Barcode Production*[12]
- *How to Print GS1 Barcodes on Demand*[13]
- *GS1 Data Matrix an Introduction and Technical Overview*[14]

Certification

Suppliers to the NHS will be required to participate in a Certification Scheme which will provide initially self-certification and then subsequently independent assurance, that trusts, suppliers and solution providers are delivering GS1 standards, mapped against the nine Use Cases attached at Appendix A. PEPPOL eProcurement specifications will also be fully integrated into the certification programme, complementing GS1 standards. Details of the scheme and the timelines trusts and suppliers will be required to meet are currently being developed and more information will be made available regarding this in due course.

Classification systems

The Department of Health is currently consulting with Trade Associations and key suppliers on the current use of NHS eClass and the potential transition to global classification standards on a category specific basis.

Following on from this consultation, additional guidance will be added to this document.

Additional related documents

The following documents will be circulated in conjunction with this guidance.

1. Trade Association Consolidated Response
2. User Needs
3. Data Attribute Requirements
4. Supplier Manual
5. Medical Device Timeline
6. GLN Information Exchange Form

Reference documents

Note that some of the references on the GS1 UK website are only available to GS1 UK members. Please contact the GS1 service team on 0808 178 8799 if you need access.

Name	Link
NHS eProcurement Strategy[1]	https://www.gov.uk/government/publications/nhs-e-procurement-strategy
GS1 GDSN Certified Datapools[2]	http://www.gs1.org/gdsn
Connecting for Health[3]	https://www.gov.uk/government/publications/review-of-coding-for-success-implementation
ISB1077 AIDC for Patient Identification[4]	www.isb.nhs.uk/documents/isb-1077
GLN in Healthcare Implementation Guide[5]	http://www.gs1.org/healthcare/standards
GTIN Allocation Rules[6]	http://www.gs1.org/healthcare/standards
GTIN Allocation Rules for Healthcare[7]	www.gs1uk.org/healthcare-gtin-rules
ISO/IEC standard 15415 and 15416 information technology. Automatic identification and data capture techniques. Barcode print quality test specification.[8]	http://www.bsigroup.com/en-GB/
ISO/IEC 15426- information technology. Automatic identification and data	

capture techniques. Barcode verifier conformance specifications.[9]	
Barcoding – Getting it Right[10]	www.gs1uk.org/support/how-to-guides
GS1 barcode validation and verification[11]	www.gs1uk.org/support/how-to-guides
How to Choose Software for Digital Barcode Production[12]	www.gs1uk.org/support/how-to-guides
How to Print GS1 Barcodes on Demand[13]	www.gs1uk.org/support/how-to-guides
GS1 Data Matrix – An Introduction and Technical Overview[14]	http://www.gs1.org/docs/barcodes/GS1_DataMatrix_Guideline.pdf

Glossary

Term	Description
AIDC	Automatic Identification and Data Capture – the ability to use unique numbers, and other sets of standardised data, shown in barcodes or other data carriers to identify different items automatically
ASN	Advanced Shipping Notification, also known as a despatch advice.
EAN	European Article Number – a defunct term; this has been replaced by the term GTIN
EAN-13	The most commonly used barcode symbol for a 13-digit GTIN
eCom	The GS1 term for GS1 EANCOM and GS1 XML EDI standards. Note that TRADACOMS, an obsolete GS1 UK standard, is no longer supported
EDI	Electronic Data Interchange – the computer-to-computer exchange of standard business documents in electronic format between two companies
FDA	US Food and Drug Administration
FMD	Falsified Medicines Directive
GCP	GS1 Company Prefix, variable length string of numeric digits licensed by GS1 which GS1 members can use to create unique GS1 identifiers
GDS	Global Data Synchronisation – enables product information from a supplier to be made available to a retailer, using a standardised process. The information is defined using agreed standards which all parties can understand and can include, for example, product description, price, size, pack, name, address and the quantity of items in a purchase order
GDSN	Global Data Synchronisation Network – the network which allows information on products held in datapools to be accessed by trading partners – a datapool must be GDSN-certified to be part of GDSN

Term	Description
GLN	Global Location Number – the GS1 identification key used to identify companies and locations
GS1 DataMatrix	A two-dimensional (2D) barcode that can hold large amounts of data in a relatively small space. These barcodes are used primarily in identifying pharmaceutical and medical device products.
GS1-128	A special version of Code 128 that is used only to represent GS1-defined identifiers and attribute information
GTIN	Global Trade Item Number – the GS1 identification key used to identify any product line or service that may be ordered, priced or invoiced at any point in the supply chain. GTINs may be 8, 12, 13 or 14-digit numbers
ITF-14	The barcode symbol often used on outer cases to represent GTINs
MHRA	Medicines and Healthcare Products Regulatory Agency
PEPPOL	Pan-European Public Procurement On-Line – designed to facilitate electronic procurement (including e-invoicing) in Europe. PEPPOL provides a solid infrastructure for exchanging e-business information based on standards for electronic messaging
PIM	Product Information Management – enables Trusts to pull the master product data they require from the NHS datapool into their local systems
RFID	Radio Frequency Identification – Like a barcode, an RFID tag is a data carrier. A barcode carries data in a visible symbol and is read by a barcode scanner using optical or infrared wavelengths. An RFID tag carries data programmed into a small computer chip and operates at a wide range of radio frequencies
SKU	Stock Keeping Unit
SME	Small to Medium size Enterprise
UDI	Unique Device Identifier

Appendix A - Use cases

Introduction

The GS1 coding and PEPPOL messaging standards support a number of use cases across the healthcare setting which impact on both buyers and suppliers to the NHS. This section briefly summarises three core enablers and nine separate use cases for the application of the standards. The following table shows the core enablers that support each of the use cases:

Use case	Core enabler		
1 Product recall	Patient Identification	Location Numbering	Catalogue Management
2 Inventory management		Location Numbering	Catalogue Management
3 Purchase-to-pay processing		Location Numbering	Catalogue Management
4 eMedicines	Patient Identification	Location Numbering	Catalogue Management
5 Surgical instrument management	Patient Identification	Location Numbering	
6 Medical equipment management	Patient Identification	Location Numbering	
7 Community equipment management	Patient Identification	Location Numbering	
8 Medical records management	Patient Identification	Location Numbering	
9 Pathology sample management	Patient Identification	Location Numbering	

Trusts will need to undertake an assessment of the costs and benefits of each of the use cases. Within GS1 adoption guidance documents for trusts there is a model provided that enables trusts to undertake this assessment and then determine which cases they wish to adopt, together with the sequence of adoption. After implementation of the core enablers, we are recommending that trusts should plan for early adoption of product safety recalls, purchase-to-pay processing and inventory management. The procurement related use cases apply to all departments

engaged in procurement activity, and not just the activity managed by the supplies/procurement department.

Core enabler 1 - Patient identification

The *ISB1077*[3] standard requires trusts to adopt GS1 barcoding standards for use on patient identity wristbands, enabling accurate identification of the patient, with barcode scanning facilitating the upload of clinical data into the electronic patient record. The GS1 standards enable electronic records to be created that capture details of the patient, caregiver, care location, and equipment and consumables utilised during an episode of care, facilitating clinical audit and product recall.

Core enabler 2 – Location numbering

GS1 provides the Global Location Number (GLN) standard for the identification of unique locations, such as a *legal entity* (e.g. a trust or a supplier); a *functional entity* (eg a cost centre or an accounting office); and a *physical entity* (e.g. a hospital or a warehouse). GLNs support each of use case by enabling an event to be matched to a location, whether this relates to a person; an asset; a product or a service.

Core enabler 3 - Catalogue management

Suppliers are required to place standardised master product data into a GS1 certified datapool. The GS1 Global Data Synchronisation Network links these datapools and an NHS Product Information Management system will be established to enable Trusts to draw supplier master data from the datapools into their local catalogue solution. This process will ensure that accurate and consistent product information is used consistently across the NHS and its supporting supply chains.

Use case 1 - Product safety recall

Forthcoming European legislation will require hospitals to be able to electronically track and trace medical devices to individual patients. Scanning barcodes on the patient wristband and on the device, into the patient record enables product safety recalls to be managed, facilitating prompt recall of affected patients upon receipt of a product recall notice, together with identification and isolation of faulty products.

Use case 2 - Purchase-to-pay processing

The use of PEPPOL messaging standards supports the electronic transfer of information between trust and supplier, without manual intervention. Together with

the GS1 coded product information this enables automated matching of order, invoice and delivery notification speeding up subsequent payment. The accuracy and automation of barcodes reduces costs in requisitioning, ordering and payment.

Use case 3 - Inventory management

Many products provided by suppliers to the NHS already carry GS1 barcodes and, over time, all products will have to comply with this requirement. These barcodes can be used to manage inventory in all locations around a trust, from central stores to local stock rooms in wards and departments. Scanning the barcode enables key data to be captured electronically and exchanged without manual intervention into patient administration and purchase order processing systems.

Use case 4 - eMedicines

The use of solutions such as robotic dispensing can utilise barcodes for input into the storage area and retrieval for dispensing. The use of GS1 standards can provide access to product information and enable process controls to ensure the efficient management of pharmaceuticals. Hospital pharmacy manufacturing units can assign GS1 barcodes in the same way as commercial manufacturers to enable automated data capture processes within the hospital.

Use case 5 - Surgical instrument management

GS1 barcodes can be etched onto individual surgical instruments and trays so that when used on patients or passing through sterilisation processes they can be scanned and recorded, enabling events around individual instruments to be accurately monitored and any restrictions on usage strictly complied with. Complete trays can be tracked and traced using GS1 barcode labels.

Use case 6 - Medical equipment management

GS1 barcodes can be applied to individual items of medical equipment, enabling equipment to be identified and tracked in and out of equipment libraries and point-of-use locations. This leads to improved equipment utilisation, greater scheduled maintenance compliance and better equipment availability. At the point of care, use of the equipment can be associated with the barcode patient wristband.

Use case 7 - Community equipment management

Identifying all loan stock assets with a unique GS1 barcode or RFID tag enables community equipment to be tracked throughout their full life cycle. This leads to more cost effective processes, better asset utilisation and an improved service for patients. The barcode can be scanned, along with location and patient identifiers, to record the asset when issued, returned, decontaminated and taken back into stock.

Use case 8 - Medical records management

Medical records can be identified with a unique GS1 bar code or RFID tag. Coupling the GS1 bar code with GS1 location number information and uploading that to the Medical Records Management system enables the accurate tracking of medical records throughout the estate. This leads to improved patient care by having records to hand and improves efficiency by reducing time taken to locate specific records.

Use case 9 - Pathology sample management

GS1 standards can be used to accurately track samples from patient to laboratory, reducing the incidence of lost samples and helping to make results available as quickly as possible. Through scanning each barcoded sample along with the GS1 location identifier, progress can be recorded through to use in patient diagnosis.