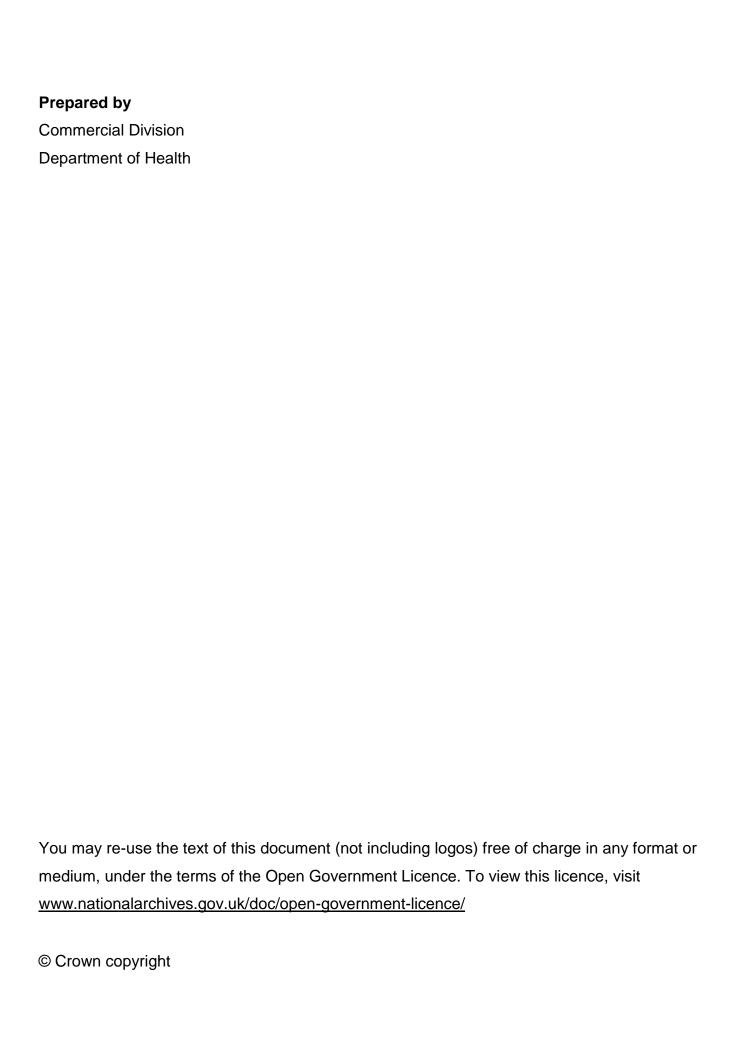




GS1 and PEPPOL Adoption:

Ten step guide for medical device and in vitro diagnostic device suppliers to the NHS

August 2016



Revision details

This document has been revised since the July 2016 edition to correct some links and provide some finer points of clarification.

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Introduction

The <u>NHS eProcurement Strategy</u> 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 data in a GS1 Global Data Synchronisation Network (GDSN) certified datapool.

One of the purposes of deploying GS1 data standards is to improve data accuracy and consistency across multiple 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.

All stakeholders will derive benefit 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.

The Department of Health has established an online workspace, "GS1 and PEPPOL for Suppliers". This guide is part of a suite of documents to support suppliers in their adoption of GS1 and Pan European Public Procurement Online (PEPPOL) standards that can be found on the workspace here. If you are not already a member of the workspace you can request access by contacting here. Where the procurement (PEPPOL) is the procurement (PEPPOL) and (PEPPOL) is the procurement (PEPPOL) is t

Ten step guide

1. Become a member of GS1

To join GS1 or find out if your company is already a member contact the GS1 UK healthcare team on Freephone 0808 172 8390 or healthcare@gs1uk.org or visit the GS1 UK web site at www.gs1uk.org.

2. Complete the Medical and In-Vitro Diagnostic Device Supplier Readiness survey

The survey can be found <u>here</u>; a PDF of the survey can be found on the Department of Health online workspace <u>here</u>.

3. Allocate a GS1 location identifier for your company

Global Location Numbers (GLNs) are used to identify your company, its significant locations and organisational teams. GLNs are required to identify your organisation when trading with the NHS. You will be able to share and maintain these GLNs with the NHS through a GLN registry in the future.

Your membership of GS1 provides you with a company prefix number. Using this prefix you allocate a unique GLN for each significant location of your company. In some instances your GS1 member organisation will have a numberbank service that generates the unique GLNs for you to simply add the location detail.

4. Add the NHS acute trusts GS1 GLN identifiers to your company systems

In the same way that as a supplier you identify your company locations and allocate GLNs, the NHS acute trusts will also be allocating location identifiers. You will need to add the trusts' GLNs within your transactional systems. These can then be used to identify the relevant locations in the information you exchange with your NHS customers. The NHS acute trusts will be able to share and maintain these with suppliers through a GLN registry in the future.

5. Allocate a GS1 product identifier to your products

Global Trade Item Numbers (GTINs) are used at each level of the product packaging hierarchy from unit of use through to shipper/case to identify products. GTINs are required to identify your products and services when trading with the NHS through the GDSN using a datapool.

Your membership of GS1 provides you with a company prefix number. Using this prefix you allocate a unique GTIN for each product and product packaging level. In some instances your GS1 member organisation will have a numberbank linked to a datapool service that generates the unique GTINs for you to simply add the product description and detail required.

6. Establish the capability and sustainable processes needed to extract and consolidate product and price information required by the NHS

NHS acute trusts will need to receive your product information including logistics, regulatory, marketing and safety data attributes to create accurate electronic records for their inventory management and product catalogue systems. The data attribute requirement is detailed in the Department of Health supplier data manuals that can be obtained from the Department of Health online workspace <a href="https://doi.org/10.1007/journal.org/10.1007

7. 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 that provides the capabilities you require to receive and send electronic messages with the NHS. A full list of accredited access point service providers is available at http://www.peppol.eu/adoption/access-point-providers.

8. Affix GS1 compliant barcode labels to your product packaging

These labels will include both a GS1 product identifier (GTIN) and the product's 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. Details of what to do to print a barcode on product packaging can be found in the supporting documentation below.

Enter standardised product data for your products into a GS1 Global Data Synchronisation Network compliant datapool

You will need to join a datapool service that provides the capabilities you require to enter and publish data to the NHS. This may involve online data entry, automatic or manual data upload of your data. A full list of GDSN compliant datapools is available at http://www.gs1.org/gdsn.

The Department of Health supplier data manuals explain how the GDSN is used order to support the supply chain scenarios. These manuals can be obtained from the Department of Health online workspace here.

10. Compliance Self-Declaration

For trusts and suppliers, self-declaration will be the method used for at least the first two years of implementation programmes and will monitor compliance to the Medical and In-Vitro Diagnostics Device Supplier Compliance Timeline. Supplier self-declaration is required twice per year from July 2016. For 2016 only self-declaration will be required in July and October, subsequently (from 2017 onwards) it will be required in April and October, aligned with the 10 compliance dates, 31st March 2016 through to 30th September 2020, in the timeline. Guidance on how to complete the self-declaration can be found on the Department of Health online workspace here.

Supporting documents

The following documents are available to support the ten step guide. 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.

Step	Document	Available from
1	NHS eProcurement Strategy	https://www.gov.uk/government/publicatio
-	Carling for Courses	ns/nhs-e-procurement-strategy
1	Coding for Success	https://www.gov.uk/government/publicatio
		ns/review-of-coding-for-success-
	Cuidonas for Cumplions of	implementation
1	Guidance for Suppliers of	https://dhexchange.kahootz.com/connect.
2	Medical Devices to the NHS	ti/SePWS/view?objectId=425001
	Readiness Survey PDF	https://dhexchange.kahootz.com/connect.ti/SePWS/view?objectId=423305
3, 4	GLN in Healthcare	
	Implementation Guide	http://www.gs1.org/healthcare/standards
5	GTIN Allocation Rules	http://www.gs1.org/healthcare/standards
F	GTIN Allocation Rules for	www.gs1uk.org/healthcare-gtin-rules
5	Healthcare	
6,9	User Needs	Upon request from the DH/GS1
6,9	Data Attribute Requirements	https://dhexchange.kahootz.com/connect.
		ti/SePWS/view?objectId=424969
6,9	Supplier Data Manual	https://dhexchange.kahootz.com/connect.
0,9		ti/SePWS/view?objectId=423017
7	Guidance for suppliers of medical	https://dhexchange.kahootz.com/connect.
,	devices to the NHS.	ti/SePWS/view?objectId=425001
	ISO/IEC standard 15415 and	
8	15416. AIDC techniques.	
	Barcode print quality test	
	specification.	http://www.bsigroup.com/en-GB/
_	ISO/IEC 15426. AIDC	
8	techniques. Barcode verifier	
	conformance specifications.	
8	Barcoding – Getting it Right	www.gs1uk.org/support/how-to-guides
8	GS1 barcode validation and verification	www.gs1uk.org/support/how-to-guides
	How to Choose Software for	
8	Digital Barcode Production	www.gs1uk.org/support/how-to-guides
	How to Print GS1 Barcodes on	
8	Demand	www.gs1uk.org/support/how-to-guides
8	GS1 Data Matrix – An	http://www.god.org/doog/boroodog/CC4_Dota
	Introduction and Technical	http://www.gs1.org/docs/barcodes/GS1_Data Matrix_Guideline.pdf
	Overview	wattix_Guidelitie.pui
10	Compliance Timeline for Medical	https://dhexchange.kahootz.com/connect.
	and In-Vitro Diagnostic Device	ti/SePWS/view?objectId=421833
	Suppliers	1/OCT VVO/VIEW: Objectiu-42 1000