Department of Health

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GS1 and PEPPOL adoption – Scan4Safety

Frequently Asked Questions - Suppliers of Medical and In-Vitro Diagnostic Devices

What is this about?

Improving patient safety, clinical productivity and supply chain efficiency by using GS1 coding standards and PEPPOL messaging standards.

What is GS1?

GS1 is a global not-for-profit standards organisation that provides standards for barcoding to uniquely identify places, products and people (patients and staff). Their standards are used by all supermarkets and many other sectors in the UK, and around the world.

What is PEPPOL?

PEPPOL is a European not-for-profit standards organisation that provides standards for the exchange of purchase orders and invoices between buying and selling organisations. Their standards are widely used by several European governments.

Why are we doing this?

The combined use of GS1 and PEPPOL standards in clinical and functional departments within a trust will automate many processes currently done manually, simply by the scanning of barcodes.

Is this yet another big IT project?

No - it is based on the adoption of standards not systems, and relies on making better use of existing systems already implemented across trusts.

Will it work?

Each element in the strategy is already in use somewhere, either in the NHS, in other countries or in other sectors. What is new is combining all the elements into a single programme. DH has funded six NHS trust Demonstrator Sites to validate our assumptions and generate learning.

What are the benefits to suppliers?

- A single data repository for product information for the NHS
- Reduced transaction costs
- Greater efficiency and visibility of product throughout the supply chain
- Reduced data management costs
- Saving in time and increased efficiency and reliability in production, storage, picking, shipping and reporting through the use of barcode scanning

What are the benefits to trusts?

Current estimates suggest approximately £450m per year across the acute sector, equivalent to £3m per year for an average acute trust. In the main, these financial benefits are derived from:

- reductions in adverse drug events (where wrong products/quantities are administered);
- reductions from inventory management;
- more accurate costing data to inform productivity and efficiency improvements.

Quality benefits accrue from:

- freeing up clinical time – more time for patient care and less time to fill in paper work;
- traceability – faster to locate recalled products and affected patients;
- patient safety – using barcodes to positively identify each patient prior to product usage.

What is Scan4Safety?

A single title given to the adoption of GS1 and PEPPOL standards by six DH funded demonstrator sites. Further information will be available in due course at www.scan4safety.nhs.uk

Who are the demonstrators?

Royal Cornwall, Plymouth, Salisbury, Derby, Leeds and North Tees.

How long will adoption by the whole acute NHS take?

Current indication for an average trust is it's a 2-year programme. Given varied starting times, we expect it to take around 5 years for all acute trusts to implement the changes.

What are other trusts doing?

Including the demonstrator sites, 120 have a nominated a senior sponsor for GS1 and PEPPOL adoption, of which 52 trust have produced strategic adoption plans.

What about everyone else?

All acute trusts should have a senior manager nominated as the trust lead for GS1 and PEPPOL adoption. All trusts should be producing plans to adopt and looking at ways to start. Guidance is already available on how to put the plans together.

What about non-acute trusts?

We started with acute trusts because the use cases and benefits cases were clearer early on. In the meantime, we encourage non-acute to nominate a lead and baseline their current position.

What categories does this programme cover?

Ultimately, every transaction that results in an invoice will be subject to this methodology. However, our initial focus is on products and not services and this will be reflected in our published timelines.

At which package level is a barcode required? (i.e. all orderable units or including the lowest package level)?

For medical and in vitro diagnostic devices, we require a GS1 barcode on the outer packaging of all orderable units AND the lowest packaging level for Class III, IIa and IIb products. For in vitro diagnostic devices, this equates to IVD List A, IVD List B and IVD self-test. For Class I medical devices and IVD General, we only require a GS1 barcode for all orderable units (i.e. not the lowest packaging unit unless it is an orderable unit). For detailed guidance, please refer to the GS1 guidance found here.

Do we have to allocate a GTIN at pallet level?

The only time you would need to include a GTIN on a pallet is if it is an orderable unit, i.e. if it has a set configuration and a price.

What about products/packs which are too small to carry a barcode, are there exception rules defined?

For products/packs too small to carry a linear barcode, we would expect a GS1 DataMatrix barcode to be used. A GS1 DataMatrix containing the GTIN/Expiry date/Lot number can be less than 4mmx4mm. It is also acceptable to use a GS1 DataMatrix barcode for any product or pack irrespective of size.

Are there special rules for reusable products such as surgical instruments etc. (i.e. direct part marking)?

This is not currently in scope and guidance will be developed with the support of the demonstrator sites as a further use case. We expect to follow any EU directives that apply.

Is there a preferred barcode type, i.e. 1D or2D?

No, this is down to supplier preference and what makes sense dependent on the size of packaging, you may opt for linear or 2D

I've been told that I have to use GTIN-14s. Is this correct?

When encoding the GTIN into a GS1-128 or GS1 DataMatrix barcode type the GTIN field is 14 digits long. If you are using a GTIN-13, simply add a leading zero as a filler character.

Do I need to include production information in the barcode? e.g. batch number/expiry date?

If there is a regulatory requirement to carry production information on the label for the product, it should also be included in the barcode. This can include expiry date/production date/batch number/serial number. This can be carried in a GS1-128 linear barcode or a GS1 DataMatrix 2D barcode using the GS1 Application Identifier standards.

Where do I get more information about GDSN and GS1 datapools?

Contact healthcare@gs1uk.org for more information.

What product data is required to be entered into the GS1 datapool?

A set of data attributes was published in June 2015; an update to this list will be published in October 2016. Please access the Department of Health GS1 and PEPPOL for Suppliers online workspace for more information. If you do not already have access, please email eProcurement@dh.gsi.gov.uk.

As a supplier I am being asked to populate multiple catalogue systems for different trusts, is this right?

Yes, at the moment. The DH is working with various partners on a Demonstration of Technology exercise for the GS1 Global Data Synchronisation Network (GDSN), which, if successful, will mean that suppliers will only need to populate their data in one place (a GS1 datapool) and then trusts can pull data into their catalogue systems via the GDSN. This process is happening through the summer and we expect to feedback later this year on the outcomes.

I'm a distributor. Do I still need to do this?

The product brand owner is responsible for product labelling and entering product data attributes to a GS1 datapool. Your business will need to be capable of receiving orders and sending invoices via a PEPPOL access point.

The Supplier Compliance Timeline has different dates for different classes of products; can we deliver all classes at the same time?

Yes, you can deliver everything at the same time and you can achieve compliance before the required dates set out in the timeline.

Will there be Compliance Timelines published for other category areas?

Yes, we will issue different timelines for different sectors as follows:

- Medicines
- Other products (i.e. all products other than medical and in vitro diagnostic devices and medicines)
- Services (note that services may be segmented into more than one category)

Suppliers are being asked to meet compliance deadlines but the NHS isn't being compelled to do this.

The six demonstrator trusts are under-going a self-declaration process in the same way that suppliers have been asked to undertake self-declaration. All provider trusts are mandated through the NHS Standard Contract to comply with the NHS eProcurement Strategy.

How is progress being monitored?

A programme of self-declaration is being established for both trusts and suppliers, and guidance is being provided to technology providers so that they understand the needs of both trusts and suppliers.

The demonstrator trusts are quoting different timelines to the DH; please can you provide clarity on the timeline?

DH policy is reflected in the published supplier compliance timeline that quotes end dates that have been agreed through a process of industry consultation. However, some trusts want to move faster as early adopters and it is a commercial decision for you as to whether you can support earlier dates set by individual trusts.

Does this programme extend to private healthcare?

It extends to private healthcare that is funded by the NHS, but only in respect of requirements around product recall.

What impact does Brexit have on the programme?

We don't expect Brexit to make any material difference to GS1 and PEPPOL adoption. It's too early to say if there will be any differences. The expectation is that the UK will continue to cooperate with the EU and look for consistency in how EU-wide issues are handled, such as medical devices and medicines.

Where can I get more information?

For suppliers, manufacturers and distributors there is a dedicated supplier workspace, "GS1 and PEPPOL for Suppliers". If you do not already have access, please email eProcurement@dh.gsi.gov.uk to request access.
