Department of Health

Date: July 2017

NHS eProcurement strategy

Update

This update clarifies a number of areas that have been subject to discussion over recent months relating to implementation of the NHS eProcurement strategy (also known as Scan4Safety). NHS acute trusts, suppliers to the NHS, and technology provider organisations should all be aware of, and act upon, the content of this update, which covers the following topics:

- Master data exchange;
- EU Medical Device and In-Vitro Diagnostic Device timelines;
- PEPPOL guidance documentation and purchase order messages;
- PEPPOL Access Point services - commercial model;
- Publication cycle for future updates on the eProcurement Strategy.

Master data exchange

1. Context

The update on master data exchange adds to the following previously published documentation on this topic that can be found in the DH eXchange Library:

- NHS eProcurement Strategy
- eProcurement Update March 2016
- MDE Demonstration of Technology Case Study
- MDE Demonstration of Technology Participant Feedback
- Master Data Exchange Industry Consultation

2. Background

The NHS eProcurement strategy identified that the use of master data throughout the supply chain, both within and outside hospitals, is essential to support supply chain efficiency and patient safety. The Department of Health (DH) requires NHS trusts and their suppliers to adopt GS1 standards for the coding of products and for the structuring of master data attributes that are associated to a specific product.

3. Data requirements

DH will publish Data Dictionaries and supporting Supplier Manuals for five expenditure categories, each setting out the specific requirements for that category:

- Medical and In Vitro Diagnostic Devices (already published);
- Medicines (in consultation phase);
- Office and IT products (in consultation phase);
- Estates and Facilities products;
- Services.

The Data Dictionaries contain the technical detail of each data attribute required from suppliers for each product and service they sell to the NHS and the Supplier Manuals will provide category specific guidance in support of each data attribute. All suppliers to the NHS must conform to the requirements set out in these Data Dictionaries and the Master Data Exchange Guidance document in line with published timelines.

The data attributes contained within the Data Dictionaries will be specified as either:

- Mandatory, or
- Conditional mandatory, or
- Optional.

Mandatory data attributes are those that must be provided; conditional mandatory data attributes must be provided if they are relevant to a given scenario for the specific product (for example a contract reference only needs to be provided if a contract exists); and optional data attributes can be provided if the supplier chooses to provide them.

4. Data sharing

Once a supplier has coded a product and identified the data attributes that relate to that product code, this forms the master data that then needs to be shared electronically with NHS trusts. To enable this electronic exchange, suppliers are required to place their master data in a GS1-certified datapool that is part of the GS1 Global Data Synchronisation Network (GDSN), a list of which is available on the GS1 website.

Only master **product** data is currently in scope for exchange via GDSN. **Price** data is not currently in scope for exchange via GDSN, but DH is currently considering options for the exchange of price data and will provide a further update in due course.

5. Pilot

In conjunction with the NHS Business Services Authority (BSA) and NHS Supply Chain (NHSSC), DH is piloting a master data validation and sharing service. This service will receive master product data from GS1 datapools via GDSN; validate and quality control the data against DH published Data Dictionaries; and exchange product data electronically with NHS trusts directly or via approved intermediary technology provider organisations.

The scope of the pilot will be limited to the six NHS Scan4Safety Demonstrator Sites; those suppliers that are currently compliant with the DH supplier compliance timeline for Medical and In Vitro Devices; those products that are currently supplied via NHSSC; and will utilise the existing electronic connections with the NHSSC catalogue.

This pilot is part of the development of the future steady-state solution and updates on progress will be provided over the coming months.

6. Commercial model

To ensure that the benefits of high quality master data are maximised, the current and future direction requires interoperability between the NHS and its supplier base through intermediary technology service providers, within a multi-vendor environment.

A key principle of this environment is that NHS trusts and suppliers should each pay for the technology services that they consume. Costs attributable to NHS trusts for product and price data exchange should not be passed on to suppliers, or vice versa.

Whilst we work toward the steady-state solution, NHS trusts and suppliers should continue to make their own commercial arrangements for catalogue services for the exchange of product and price data, within the key principle outlined above.

Impact of EU UDI legislation on the Medical and IVD Device supplier timeline

1. Context

The update on the supplier timeline adds to the following previously published documentation on this topic that can be found in the DH eXchange Library:

- *Medical and In-Vitro Diagnostic Device Supplier Timeline*

2. Background

EU UDI legislation, more properly the EU Medical Device Regulation (MDR) and In-Vitro Diagnostic Device Regulation (IVDR), was published in the Official Journal of the European Union in May 2017.

3. Labelling clarification

The EU UDI legislation indicates that all Class I and Class IIa medical devices shall carry a unique identifier label on the packaging at the level above unit of use, whereas the DH timeline indicates that Class IIa medical devices shall carry a unique identifier label at the unit of use level. DH will issue an amended timeline to harmonise with the EU labelling requirement for Class IIa medical devices.

4. Timeline clarification

The DH timeline states that, in the event that EU UDI legislation comes into force with dates that differ with those required by the timeline document in the previous section, the dates will be amended to match the legislated timelines.

However, after review of the dates required by the EU UDI legislation, DH has decided that dates specified in the DH timeline will remain unchanged, for the following reasons:

- *EU regulations have taken longer to come into force than previously anticipated*
  This has resulted in a timeline that lags several years behind the requirements of the NHS eProcurement strategy. For example, the EU regulation requires a UDI to be assigned to 'Implantable and Class III' medical devices three years and eight months after the DH timeline requirement for GTIN allocation.

- *DH does not want to disadvantage suppliers that are meeting the DH timeline*
  The latest round of supplier self-declarations shows that 66 suppliers (collectively representing 25% of in-category expenditure) are fully compliant with the March 2017 DH timeline requirements. This is a great achievement by those suppliers, showing the level of commitment that has already been delivered. Delaying adoption to harmonise with the MDR/IVDR timelines will devalue this commitment.

- *US Food and Drug Administration deadlines are in advance of the EU deadlines*
  To meet US FDA requirements, suppliers to the NHS that also trade in the US are already taking many of the necessary actions required by MDR and IVDR, well in advance of the EU timelines. DH requirements that are common to FDA requirements are set several years later than the FDA. For example, DH labelling and data requirements for Class III medical devices are set at four years after the FDA equivalent requirement.

- *Benefits*
  The DH timeline requirements, both UDI-related and more widely, are designed to improve patient safety and security in the NHS, whilst simultaneously realising supply chain efficiencies for both the NHS and its suppliers. It is not in the interest of patients, hospitals or suppliers to delay the realisation of these benefits.

5. Medicines and Healthcare products Regulatory Agency (MHRA)

The MHRA is a public health organisation with a focus on patient safety through its role as regulator of medicines, medical devices and blood components for transfusion in the UK and is the 'Competent Authority' responsible for implementation of the EU UDI legislation (MDR/IVDR) in the UK. MHRA has expressed its support for the approach outlined above.

PEPPOL guidance documentation and purchase order message

1. Context

The update on PEPPOL guidance adds to the following previously published documentation on this topic that can be found in the DH eXchange Library:

- *Guidance Registration of PEPPOL Capability*
- *PEPPOL Demonstration of Technology Case Study*

2. Background

To ensure consistent application of PEPPOL and the interoperability of Access Point providers within a four-corner model, DH has published a PEPPOL Guidance Manual and a set of PEPPOL Data Dictionaries. These documents are available in the DH eXchange Library. This new suite of documents was produced with input from industry and is intended to support a faster and more consistent take-up of PEPPOL in the NHS.

3. Order Response message

With publication of the PEPPOL Guidance Manual and Data Dictionaries, DH requires suppliers to acknowledge purchase orders across the PEPPOL network by sending Order Response messages. Suppliers are free to work with their chosen Access Point providers to establish a common and repeatable method to send order responses, using the PEPPOL BIS 28A Order and Order Response message type.

DH acknowledges that this is a new requirement, which has been added as a result of feedback on how best to increase the volume of healthcare business transactions across the PEPPOL network. With this step, we are adding an additional level of certainty and confidence to the PEPPOL network.

4. Timeline

The DH will amend the Supplier Compliance Timeline for Medical and In Vitro Devices to incorporate this requirement to be implemented by March 2018, although suppliers are encouraged to implement as soon as possible.

PEPPOL Access Point services - commercial model

1. Context

All NHS trusts and suppliers are required to utilise the services of a PEPPOL access point thereby establishing the PEPPOL 'four-corner' model for the electronic machine-to-machine exchange of purchase orders and invoices, together with related message types.

The information below responds to requests from suppliers for greater information and guidance on the commercial implication involved in procuring a PEPPOL access point. This document provides generalised indicative pricing from the framework agreement to aid suppliers in assessing costs submitted by PEPPOL access point service providers.

2. Background

The Crown Commercial Service (CCS) has set up a framework agreement for the provision of PEPPOL access point services. The agreement is available to all public sector bodies in the UK, including NHS trusts, who are able to make a direct award to their preferred service provider, using the terms and conditions of the framework agreement.

Suppliers are able to select any PEPPOL-certified access point service provider listed on the OpenPEPPOL website: http://peppol.eu/who-is-who/?rel=tab258 . Suppliers will make their own arrangements with the PEPPOL access point service provider of their choice.

3. Indicative fee structures

Fees for PEPPOL access point services typically comprise the following elements:

- *Annual subscription fee*
  Subscription fees are typically in the low £1,000s per year, although there can be significant variation between vendors. Suppliers are advised to compare options.

- *Charge per transaction*
  Transaction charges (either to send a message, receive a message, or both) are typically in the order of 'pence' per transaction, although there can be significant variation in charges. Suppliers are advised to compare options.

- *Additional services*
  Day rates may be charged to cover one-off implementation costs for project implementation; document mapping; technical expertise; and process testing.

3. Disclaimer

The above indicative fees are for information only and are based on the CCS framework. Detail differences between commercial models for NHS trusts and suppliers are likely.

Future publication cycle

1. Context

The update on the future publication cycle adds to the following previously published documentation on this topic that can be found in the DH eXchange Library:

- *eProcurement update, March 2016*

2. Background

The DH eXchange workspace continues to provide a rapid and effective mechanism for highlighting questions and answers to clarify DH requirements. However, we also need to ensure that significant clarifications are formally recorded, and made accessible for reference by all communities of interest.

3. Formal updates

This July 2017 update follows the first update that was issued in March 2016. From now on, DH will use this update format on a set cycle to provide stability and certainty to all parties involved in implementation of the NHS eProcurement strategy.

DH will publish updates twice yearly, in April and in October. By publishing in these months, we can harmonise with the rota for industry self-declarations (open in March and September) and include the results of the self-declaration exercises in each update.

If extraordinary circumstances arise and formal communications are required between these publication windows, DH will publish updates and clarifications as required.

4. Register

To join the DH eXchange workspace, please request access by email to: eprocurement@dh.gsi.gov.uk