NHS eProcurement Strategy

Supplier Frequently Asked Questions

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Frequently Asked Questions

Data collection and maintenance

1. What material categories are covered by the strategy and as such will need to be maintained in the GDSN? eg are we expected to maintain all **materials** and **services** that we sell to the NHS in England?

    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.

2. We would like clarification on the status of:

    a. Pharmaceutical Special products (those materials manufactured under a specials licence).

        All types of product that result in an invoice line, and/or are the subject of traceability requirements, require a GTIN to be allocated.

    b. Third party materials that we procure and sell - who is responsible for the GDSN data elements for these materials?

        The brand owner is responsible for placing data in the datapool.

3. We are working with Medical Devices GDSN Attribute list V1.1. There is a major upgrade of GDSN next year with major release 3 which will affect the attributes available. Can you confirm that V1.1 for material & pricing is the final set of requirements we will be working to?

    The attributes we have set for medical and in vitro diagnostic devices take into account major release 3, so there will not be any conflict. At this stage we do not foresee changing the required attribute set to any significant degree,

although there may be minor changes over time following consultation with trade associations.

4. Can we deliver all classes, materials and services at the same time?

    Yes, you can deliver everything at the same time.

5. The draft timeline appears to focus only on materials with a European Device Classification. Will further timelines be issued for materials without a medical devices classification? Or should we proceed on the premise that all materials should be included in the **Data – P2P – Labelling** process?

    Yes, proceed on the basis that all materials should be included but note that we will issue different timelines for different sectors as follows:

    - *Medical and in vitro diagnostic devices*

    - *Medicines*

    - *Other products (ie all products other than medical and in vitro diagnostic devices and medicines)*

    - *Services (note that services may be sub-segmented)*

    The timeline for medical and in vitro diagnostic devices will be the first to be published. Timelines for the remaining sectors will be published in due course.

6. The timeline relies very heavily on medical device classification. So far there is no confirmation on how the EU will define UDI requirements. Is this process simply looking at the classification with a view to integrating with UDI requirements when available? As I understand it only one regulation is in place for managing UDI and this is in the USA.

    Our medical and in vitro diagnostic devices timeline anticipates the EU requirements and are later than the FDA requirements. Our intention is to be

consistent with the EU requirements and, in the event of differences, we will amend the relevant parts of our timelines to achieve consistency. Nevertheless, we would encourage suppliers to achieve compliance earlier than the EU requirements.

Purchase-to-Pay processes

7. For the P2P processes when will the technical implementation guidelines be issued that we will need to comply with?

    We are not planning to publish technical implementation guidelines to suppliers. In essence, we are asking suppliers to use a PEPPOL accredited access point to receive purchase orders and issue invoices. The access point provider will be conversant with any technical implementation guidance.

8. For the P2P process we would like further explanation of how OpenPEPPOL will work with the GDSN. As we understand it PEPPOL and GS1 work to different standards, e.g GLN is not a PEPPOL standard. Are the DH expecting us to work to CENBII standards for electronic documents?

    GDSN and OpenPEPPOL are unrelated elements of the programme. OpenPEPPOL is compliant with CENBIII standards so any PEPPOL accredited access point will be compliant with CENBII standards.

9. For the P2P process with PEPPOL, will we be issued a country specific implementation guide? For example as per the DIFI guide issued to Norwegian suppliers.

    DH is the PEPPOL Authority for the NHS. We are working with OpenPEPPOL to produce implementation guidance which will be available via the OpenPEPPOL website early 2016.

10. e-Tendering via PEPPOL in the EU will become a European Law around 2018-2020. The NHS eProcurement strategy only covers the post award process.

Are there plans for the UK to implement and comply with the proposed eTendering via PEPPOL regulations?

At present the focus of the NHS eProcurement strategy is on the post award process. There are no current plans to implement eTendering via PEPPOL.

Labelling of materials and packaging

11. The allocation of GTINs and the labelling of packaging levels. The requirement is 'all packaging levels', does this mean – 'all levels used by us for the sale and shipment of that material'?

   No, it means that a GTIN should be applied at each orderable level.

12. We propose to exclude the pallet level. Is this acceptable?

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

13. At which package level do the NHS expect to have a machine-readable barcode available (ie all orderable units or incl. the lowest package level)?

   For medical and in vitro diagnostic devices, we require a GS1 barcode for 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 (ie not the lowest packaging unit unless it is an orderable unit).

14. What about products/packs which are too small to carry a barcode, are there exception rules defined, eg are there special rules for reusable products (ie direct part marking)?
   For products/packs too small to carry a linear barcode and for reusable products, we would expect a GS1 2D DataMatrix barcode to be used. Note that

it is acceptable to use a GS1 2D DataMatrix barcode for any product or pack irrespective of size.