GS1 and PEPPOL Adoption:

Supplier compliance timeline for medical devices and in-vitro diagnostic devices

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Revision details

This document is version 1.6 of the Supplier Compliance Timeline for Medical Devices and In-Vitro Diagnostic Devices and supersedes version 1.5, published in January 2017, and contains the following amendments:

- harmonisation of the changes to IVD classification with the IVDR (in the timeline table);
- acknowledgement of the different requirements for configured equipment (2.1, 2.5, 3.1, 3.2);
- an update on the requirement on price (2.6, 2.7);
- inclusion of the clarifications made via the NHS eProcurement Strategy Updates of July 2017 and January 2018 (3.1, 3.2, 4.1, 4.2, 4.3, 4.4, 5.3);
- removal of links in the body of the document and replaced by a References page (12);
- an updated Notes section to reflect the above amendments; some notes have been updated to improve their readability but don't have a material impact on the content.

Contents

Context

The NHS eProcurement Strategy[1] was published by the Department of Health (DH) 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 of contract for the Supply of Goods and the Provision of Services[2] were amended to include a requirement on suppliers to place master product data in a GS1 Global Data Synchronisation Network (GDSN) certified datapool. In January 2017, these conditions were further amended to require compliance with DH published supplier compliance timelines.

This supplier compliance timeline should be read in conjunction with the DH Self-Declaration guidance for suppliers[3]. Where the compliance dates have passed, suppliers should complete these actions at the earliest opportunity. Successful completion of outstanding actions will enable compliance to be declared when completing the Self-Declaration Questionnaire[4].

The DH established an online workspace, "GS1 and PEPPOL for Suppliers"[5], where all relevant documentation can be accessed. If you are not already a member of the workspace you can request access by emailing eProcurement@dh.gsi.gov.uk.

Timeline

For each of the numbered actions below, please see more detailed explanatory notes in the section following.

				Class III	Class IIb	Class IIa	Class I
1. Corporate	1.1	Join GS1					31-Mar-16
	1.2	Complete supplier readiness questionnaire					31-Mar-16
	1.3	Provide the Department of Health with a statement of commitment to the adoption of GS1 and PEPPOL standards					30-Sep-16
	1.4	Join PEPPOL access point					30-Sep-16
	1.5	Allocate GLNs					30-Sep-16
	1.6	Upload GLNs to the GLN Registry					30-Sep-17
	1.7	Update systems where needed to achieve compliance with GS1 and PEPPOL standards					to achieve dates below
		Medical Devices EU Classification		**Class III**	**Class IIb**	**Class IIa**	**Class I**
		In-Vitro Diagnostic Devices EU Classification		**Class D**	**Class C**	**Class B**	**Class A**
2. Data	2.1	Allocate GTINs at all packaging levels including unit of use		30-Sep-16	30-Sep-17	30-Sep-17	-
	2.2	Allocate GTINs at all packaging levels excluding unit of use		-	-	-	30-Sep-18
	2.3	Collate GTIN-level product attribute data		31-Mar-17	31-Mar-18	31-Mar-18	31-Mar-19
	2.4	Join GDSN certified datapool		31-Mar-17	31-Mar-18	31-Mar-18	31-Mar-19
	2.5	Publish product data using GDSN		30-Sep-17	30-Sep-18	30-Sep-18	30-Sep-19
	2.6	Collate GTIN-level price attribute data		Refer to note 2.6			
	2.7	Provide price attribute data		Refer to note 2.7			
3. Labelling	3.1	Packaging label to carry GS1 GTIN barcode		30-Sep-17	30-Sep-18	30-Sep-18	30-Sep-19
	3.2	Packaging label to carry GS1 GTIN and production identifier barcodes		30-Sep-18	30-Sep-19	30-Sep-19	30-Sep-20
4. Purchase-to-pay	4.1	Receive orders from NHS access points		31-Mar-17	31-Mar-17	31-Mar-17	31-Mar-17
	4.2	Send invoices to NHS access points		30-Sep-17	30-Sep-17	30-Sep-17	30-Sep-17
	4.3	Receive orders carrying GS1 GTIN and GLN data from NHS access points		31-Mar-18	31-Mar-18	31-Mar-18	30-Sep-18
	4.4	Send invoices carrying GS1 GTIN and GLN data to NHS access points		30-Sep-18	30-Sep-18	30-Sep-18	31-Mar-19

Notes

1.1   GS1 is the organisation through which you obtain Global Trade Item Numbers (GTINs). If you are using these you are already a member of GS1. You can be a member of any GS1 member organisation (MO) around the world.

1.2   This is an online questionnaire[6] to enable us to baseline where industry is up to with its adoption of GS1 and PEPPOL standards. This will provide us with a view as to how long adoption may take and where additional help is required. The Supplier Readiness Questionnaire should only be completed once.

1.3   In accordance with the Statement of Commitment Guidance[7]. Learning from other major standards adoption programmes suggests that it is important for all parties to demonstrate their commitment to the programme. This avoids concerns of isolation and provides reassurance to all parties that the whole sector is moving together on the journey to comply with the required standards.

1.4   Pan-European Public Procurement Online (PEPPOL) [8]. Trusts and suppliers must select a PEPPOL access point provider. The list of Access Point providers[9] can be found on the OpenPEPPOL website.

This technology facilitates the electronic exchange of purchase orders and invoices. The "four-corner model", on which PEPPOL is based, means that buyers and suppliers can choose their own access point and that a supplier's access point will transact with all their customers' access points (and vice versa for trusts) meaning there is no need for trusts and suppliers to use the same one. The supplier pays their access point for services and the trust pays their access point for services without any charges between access points.

1.5   On joining GS1 you will be provided with a company prefix and a range of numbers, from these you can allocate location numbers (Global Location Numbers, GLNs) to uniquely identify your locations for example, purchase order address.

1.6 GS1 UK has developed an online GLN Registry (Location Manager)[10]. The GLN Registry is a national online database to enable GLNs to be shared between buyers and suppliers. This removes the current inefficient process where each NHS organisation has a number to identify each of their suppliers, which is different to the number which each other NHS organisation uses to identify its suppliers. The same applies to the supplier side, in that each supplier identifies each buying organisation with a different number. You can use LocationManager to look up the GLNs for the NHS organisations that you trade with. You need to upload your GLNs to this registry to enable them to be exchanged with your NHS customers.

1.7 Audit your systems to understand where and when developments may be required to ensure your systems are able to hold the GS1 identifiers (GTIN and GLN) and will in the future be able to interface with a PEPPOL access point.

2.1 This action applies to manufacturers/brand owners only and does not apply to wholesalers/distributors, unless wholesalers/distributors are re-packaging or changing the unit of sale. As such a new GTIN would be required.

Unit of Use is defined as a single unit package (GTIN A, figure 1) that is used on a specific patient. If the product is priced, ordered or invoiced in a multi-unit package/case/pallet, it requires a different GTIN (GTIN B/C/D, figure 1).
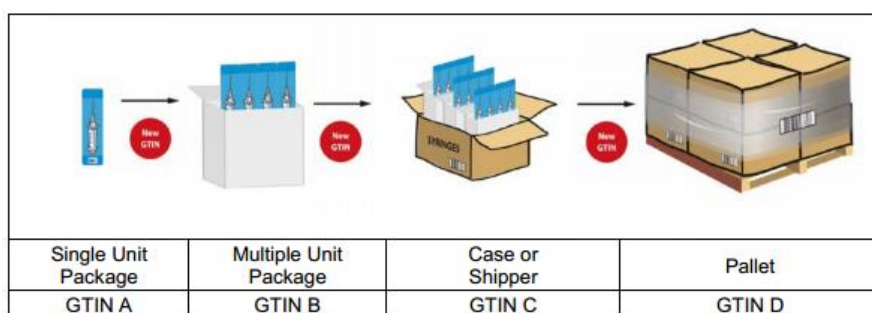

Single Unit Package	Multiple Unit Package	Case or Shipper	Pallet
GTIN A	GTIN B	GTIN C	GTIN D

Figure 1

See the GS1 Healthcare GTIN Allocation Rules[11] for further clarification.

It is acknowledged that there are complexities in the allocation of GTINs to configured equipment and further guidance for the requirements for configured

equipment is currently in development. The term "configured equipment" relates to products that vary according to customer specification.

2.2   This action applies to manufacturers/brand owners only and does not apply to wholesalers/distributors, unless wholesalers/distributors are re-packaging or changing the unit of sale. As such a new GTIN would be required.

2.3   This action applies to manufacturers/brand owners only and does not apply to wholesalers/distributors, unless wholesalers/distributors are re-packaging or changing the unit of sale. As such a new GTIN would be required.

In accordance with the Data Dictionary for Medical and In-Vitro Diagnostic Devices for Item Attributes[12].

2.4   There are a number of GS1 datapools[13] around the world and you choose which one to join.

Wholesalers/distributors can choose not to join a datapool and can instead receive data from the Master Data Service, when this becomes available. This is currently in pilot stage. For further information please see the DHSC Master Data Exchange[14] guidance document.

2.5   This action applies to manufacturers/brand owners only and does not apply to wholesalers/distributors, unless wholesalers/distributors are re-packaging or changing the unit of sale. For further information please see the DHSC Master Data Exchange guidance document.

Further guidance for the requirements for configured equipment is currently in development, as per Note 2.1.

2.6, 2.7 A formal Post Implementation Review of the Scan4Safety Demonstrator Site Project is under way. It is likely that this will result in some of the technical, supply chain focused activities moving from DHSC to reside elsewhere in the

health system. Whilst the details are clarified and, taking account of market feedback and NHS readiness,

- the milestones related to price are paused and
- the planned Demonstration of Technology for Price will not now take place

with the outcome that these milestones do not currently require compliance.

3.1   Required at unit of use level for Class III and IIb. This is aligned to action 2.1.

The MDR and IVDR state for single use Class I, Class IIa and Class A and B respectively, packaged and labelled individually the GTIN can be applied at the higher level of packaging, for example a carton containing several packages. DHSC requirements are harmonised with the EU requirement, as advised in the DHSC NHS eProcurement Strategy Update of July 2017[15].

Wholesalers/distributors are responsible for working with manufacturers to ensure that GS1 barcode labels are applied to product packaging, containing a device identifier (GTIN) on products they sell to the NHS.

Further guidance for the requirements for configured equipment is currently in development, as per Note 2.1.

3.2   Required at unit of use level for Class III and IIb, but aligned to the note in 3.1 above regarding the MDR and IVDR requirements.

Wholesalers/distributors are responsible for working with manufacturers to ensure that GS1 barcode labels are applied to product packaging, containing both a device identifier (GTIN) and the device's production information on products they sell to the NHS.

Further guidance for the requirements for configured equipment is currently in development, as per Note 2.1.

4.1   To have the ability to receive purchase orders electronically from your NHS customers, including NHS Supply Chain, via the PEPPOL network.

When you receive a purchase order from an NHS customer via the PEPPOL network, you are required to return an Order Response message via the PEPPOL network to those NHS customers. The compliance date for this was 31/03/18, as stipulated in the Update of July 2017. Where you are not receiving purchase orders via the PEPPOL network (because your NHS customers aren't sending them this way), you can still self-declare compliance with this requirement, provided you are capable of receiving a purchase order and returning an order response via the PEPPOL network.

4.2 Send invoices to NHS PEPPOL access points electronically from your PEPPOL access point to those customers who are capable of receiving them, including NHS Supply Chain.

4.3 To have the ability to receive purchase orders electronically via the PEPPOL network that contain the GS1 identifiers (GTIN and GLN).

When you receive a purchase order from an NHS customer via the PEPPOL network, you are required to return an Order Response message via the PEPPOL network to those NHS customers. The compliance date for this was 31/03/18, as stipulated in the Update in July 2017. Where you are not receiving purchase orders via the PEPPOL network (because your NHS customers aren't sending them this way), you can still self-declare compliance with this requirement, provided you are capable of receiving a purchase order and returning an order response via the PEPPOL network.

4.4 Send invoices to NHS PEPPOL access points electronically from your PEPPOL access point to NHS access points to include the GS1 identifiers (GTIN and GLN) to customers who are capable of receiving them, including NHS Supply Chain. Wholesaler/distributors are responsible for working with manufacturers to ensure that GS1 identifiers are included in the invoices sent to NHS customers.

Additional Notes

5.1 Suppliers that, as of September 2015, use the HIBCC product coding standard for labelling may exceed the above dates as follows:
By one year for actions 2.1 to 2.7 inclusive and 4.3 to 4.4 inclusive
By two years for actions 3.1 to 3.2 inclusive

5.2 Points 2.1 – 4.4 carry a provisional exemption for Research Use Only and Evaluation Use Only products until 31 March 2020, and further guidance will be provided by 31 March 2019.

5.3 As advised in the DHSC NHS eProcurement Strategy of January 2018[16], compliance requirements will be met if all applicable devices meet the requirements of the published sector-specific timelines from the date of manufacture. Any product that has a date of manufacture that exceeds DHSC compliance dates and is not in compliance with the requirements set out in the timeline will be non-compliant. Existing inventory manufactured prior to DHSC timelines can be consumed after the date required in the compliance timeline. This clarification is provided on the understanding that manufacturers, wholesalers and distributors should not stockpile product to deliberately delay compliance.

References

1. [NHS eProcurement Strategy](), located on the Gov.UK website
2. [NHS Terms and Conditions for the Supply of Goods and the Provision of Services](), located on the Gov.UK website
3. [Guidance for Medical and In-Vitro Diagnostic Device Suppliers on completing the Self-Declaration Questionnaire,]() located on the DHSC workspace
4. [Self-Declaration Questionnaire,]() located on the DHSC workspace
5. [GS1 and PEPPOL for Suppliers](), DHSC online workspace
6. [Supplier Readiness Questionnaire,]() located on Survey Monkey
7. [Statement of Commitment guidance](), located on the DHSC workspace
8. PEPPOL, Pan-European Public Procurement Online refers to a set of specifications and governance model that focuses on the critical eProcurement components to solve interoperability issues in Europe. In some cases it may also refer to the OpenPEPPOL association.
9. The list of [PEPPOL Access Points](), located on the PEPPOL website
10. The GS1 UK GLN Registry, [LocationManager]()
11. [GS1 Healthcare GTIN Allocation](), located on the GS1 website
12. [Data Dictionary for Medical and In-Vitro Diagnostic Devices Item Attributes](), located on the DHSC online workspace
13. [List of GS1 datapools](), located on the GS1 website
14. [Master Data Exchange Guidance](), located on the DHSC workspace
15. [NHS eProcurement Strategy Update, July 2017](), located on the DHSC online workspace
16. [NHS eProcurement Strategy Update, January 2018](), located on the DHSC online workspace