



GS1 and PEPPOL Adoption

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

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Revision details

This document has been revised since the July 2016 edition to update some of the language in the timeline table, update some links and to provide detailed explanatory notes. The dates in the timeline have not changed.

Contents

Context.....	4
Timeline.....	5
Notes.....	6
References.....	12

Context

This document should be used in conjunction with the wider NHS eProcurement strategy¹ and associated GS1 and PEPPOL guidance, which is available to suppliers by accessing the eProcurement Supplier Workspace within the Department of Health online portal for the adoption of GS1 and PEPPOL standards – to obtain access to the workspace email: eProcurement@dh.gsi.gov.uk.

This supplier compliance timeline should be read in conjunction with the Department of Health Self-Declaration guidance for suppliers². 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 questionnaire³.

Timeline

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

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	IVD List A	IVD List B	IVD self-test	IVD General
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	31-Mar-18	31-Mar-19	31-Mar-19	31-Mar-20
	2.7	Provide price attribute data	30-Sep-18	30-Sep-19	30-Sep-19	30-Sep-20
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 GTINs/EANs. If you are currently 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 electronic survey 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.
NOTE: the Supplier Readiness questionnaire only has to be completed ONCE. If your organisation has completed it once, you do not need to complete it again. The questionnaire can be found at <https://www.surveymonkey.co.uk/r/MDIVDSupplierReadiness>
- 1.3 In accordance with the Statement of Commitment Guidance found at <https://dhexchange.kahootz.com/connect.ti/SePWS/view?objectId=6982672#6982672>. 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). Trusts and suppliers must select a PEPPOL access point provider. The list of Access Point providers can be found at <http://www.peppol.eu/adoption/access-point-providers>.

This technology facilitates the electronic exchange of purchase orders and invoices. The “four-corner model”, on which PEPPOL is based, means that each buyer and supplier 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) and 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 and there are no 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 (eg purchase order address and invoice address). The GLN Registry is a national online database to enable GLNs to be shared between buyers and suppliers. This will remove 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 for the supplier side, in that each supplier identifies each buying organisation with a different number. You will be able to use the GLN Registry to look up the number of the NHS organisations that you trade with.

- 1.6 GS1 UK is building an online GLN Registry (Location Manager) and when this becomes available you will 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 (Global Trade Item Number (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 distributors/wholesalers, unless distributors/wholesalers 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).

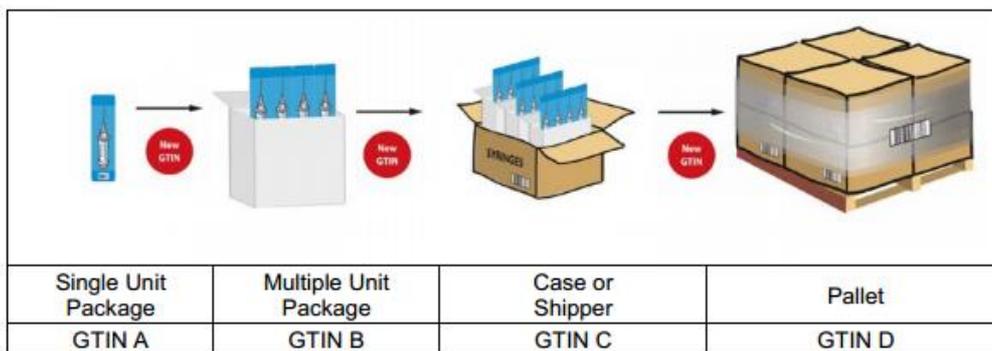


Figure 1

Please see the following link for the GS1 GTIN Allocation Rules for Healthcare http://www.gs1.org/docs/gsmpr/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf

- 2.2 This action applies to manufacturers/brand owners only and does not apply to distributors/wholesalers, unless distributors/wholesalers 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 distributors/wholesalers, unless distributors/wholesalers 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 found at

<https://dhexchange.kahootz.com/connect.ti/SePWS/view?objectId=6648464>

2.4 There are a number of GS1 datapools around the world and you choose which one to join. The list can be found at http://www.gs1.org/docs/gdsn/gs1_gdsn_certified_data_pools.pdf.

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

GTIN level product attribute data published to your GS1 datapool, to be made available to the Global Data Synchronisation Network (GDSN).

2.6 This action applies to all (manufacturers and distributors/wholesalers). In accordance with the Data Dictionary and Supplier Manual for Price Attributes found at <https://dhexchange.kahootz.com/connect.ti/SePWS/view?objectId=7934416&exp=e1>

2.7 In accordance with the eProcurement Strategy update of March 2016 found at <https://dhexchange.kahootz.com/connect.ti/SePWS/view?objectId=7262256&exp=e1>.

3.1 For a wholesaler/distributor packaging labels must carry a GS1 GTIN barcode where available; recognising that ultimately if distributors/wholesalers continue to work with non-compliant suppliers it may impact on their ability to trade with the NHS in England.

3.2 Class I date applies only if production identifiers are required by European Union Unique Device Identification (UDI) legislation.

For a wholesaler/distributor packaging labels must carry a GS1 GTIN in a barcode and production identifier in that same barcode where available; recognising that ultimately if distributors/wholesalers continue to work with non-compliant suppliers it may impact on their ability to trade with the NHS in England.

- 4.1 To have the ability to receive purchase orders electronically from your NHS customers via the PEPPOL network. This means you will have signed up to a PEPPOL access point and updated your local systems to support this. (See 1.4 for additional detail regarding PEPPOL).
- 4.2 Send invoices to NHS PEPPOL access points electronically from your PPEPOL access point. This means you will have signed up to a PEPPOL access point and updated your local systems to support this. (See 1.4 for additional detail regarding PEPPOL).
- 4.3 To have the ability to receive purchase orders electronically via the PEPPOL network which contain the GS1 identifiers (GTIN and GLN). For a wholesaler/distributor purchase orders must carry GS1 GTIN and GLN data where available; recognising that ultimately if distributors/wholesalers continue to work with non-compliant suppliers it may impact on their ability to trade with the NHS in England. See 1.3 for additional detail regarding PEPPOL.
- 4.4 Send invoices to NHS PEPPOL access points electronically from your PPEPOL access point to NHS access points to include the GS1 identifiers (GTIN and GLN). For a wholesaler/distributor invoices must carry GS1 GTIN and GLN data where available; recognising that ultimately if distributors/wholesalers continue to work with non-compliant suppliers it may impact on their ability to trade with the NHS in England. See 1.3 for additional detail regarding PEPPOL.

Additional Notes

- 5.1 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.

- 5.2 In the event that amended IVD 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.

- 5.3 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

- 5.4 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.

References

1. NHS eProcurement strategy:
<https://www.gov.uk/government/publications/nhs-e-procurement-strategy>
2. Please go to the Department of Health eProcurement Supplier Workspace to access all published documents related to this initiative, including *Guidance for Medical & In-Vitro Diagnostic Device Suppliers on completing the NHS eProcurement Self-Declaration*

<https://dhexchange.kahootz.com/connect.ti/SePWS/view?objectId=6648464>

To obtain access to the workspace email: eProcurement@dh.gsi.gov.uk.

3. The Compliance Self-Declaration questionnaire for Medical and In-Vitro Diagnostic Device Suppliers can be accessed here:
<https://dhexchange.kahootz.com/connect.ti/SePWS/view?objectId=4127491&exp=e1>

Suppliers are required to complete this self-declaration every 6 months in April and October, aligned with the 10 compliance dates, 31-Mar-2016 through to 30-Sep-2020, in the timeline. The questionnaire will be open for ONE CALENDAR MONTH at these times. If you don't already have access to the workspace, please email eProcurement@dh.gsi.gov.uk to request access.