Department of Health

NHS

GS1 and PEPPOL Adoption

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

June 2016

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Context

This document should be used in conjunction with the wider NHS eProcurement strategy[1] 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[2].

In addition, this supplier compliance timeline should be read in conjunction with the Department of Health Self-Declaration scheme for suppliers. 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 under the Self-Declaration scheme.

The latest version of the Compliance Timeline will always be available on the Supplier Workspace, so please check to ensure that you have the latest version.

Timeline

1. Corporate	1.1	Join GS1				31-Mar-16
	1.2	Complete supplier readiness questionnaire (see note 1)				31-Mar-16
	1.3	Provide the Department of Health with a statement of commitment to the adoption of GS1 and PEPPOL standards (see note 2)				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 **In-Vitro Diagnostic Devices EU Classification**	**Class III** **IVD List A**	**Class IIb** **IVD List B**	**Class IIa** **IVD self-test**	**Class I** **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 (subject to Note 3)	31-Mar-17	31-Mar-18	31-Mar-18	31-Mar-19
	2.4	Join GDSN certified datapool (subject to Note 4)	31-Mar-17	31-Mar-18	31-Mar-18	31-Mar-19
	2.5	Synchronise product data using GDSN (subject to Note 4)	30-Sep-17	30-Sep-18	30-Sep-18	30-Sep-19
	2.6	Collate GTIN-level price attribute data (subject to Note 5)	31-Mar-18	31-Mar-19	31-Mar-19	31-Mar-20
	2.7	Provide price attribute data (subject to Note 6)	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 (refer to Note 7)	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. Questionnaire available at https://www.surveymonkey.co.uk/r/MDIVDSupplierReadiness
2. In accordance with the Statement of Commitment Guidance (available on the Supplier Workspace)
3. In accordance with the Data Dictionary for Medical and In-Vitro Diagnostic Devices for Item Attributes (available on the Supplier Workspace)
4. For actions 2.4 to 2.5, this requirement is dependent upon:
    - 4a availability of Release 3 of the GS1 Global Data Synchronisation Network, and
    - 4b satisfactory completion of a Demonstration of Technology by the Department of Health in conjunction with GDSN and relevant technology providers
5. In accordance with the Data Dictionary for Price Attributes (to be published on the Supplier Workspace)
6. In accordance with the eProcurement Strategy update of March 2016 (available on the Supplier Workspace)
7. For action 3.2, Class I date applies only if production identifiers are required by EU UDI legislation
8. In the event that EU UDI legislation comes into force with differing timelines, the dates above will be amended to match the legislated timelines
9. Suppliers that, as of September 2015, use the HIBCC product coding standard for labelling may exceed the above dates as follows:
    - 9a by one year for actions 2.1 to 2.7 inclusive and 4.4 to 4.5 inclusive (see also Note 5)
    - 9b by two years for actions 3.1 to 3.2 inclusive

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 the Compliance Self-Declaration Checklist for Medical and In-Vitro Diagnostic Device Suppliers. If you don't already have access to the Workspace, please email eProcurement@dh.gsi.gov.uk to request access.