

GS1 and PEPOL Adoption

Supplier Compliance Timeline for Medical Devices and In-Vitro Diagnostic Devices

This Supplier Compliance Timeline should be read in conjunction with the Department of Health Self-Declaration scheme for suppliers. Where dates below 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. Published guidance can be found on the Department of Health eProcurement Supplier Workspace - to obtain access to the workspace email: eProcurement@dh.gsi.gov.uk

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 PEPOL standards (see note 2)	30-Sep-16
	1.4	Join PEPOL 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 PEPOL 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 (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

- Questionnaire available at: <https://www.surveymonkey.co.uk/r/MDIVDSupplierReadiness>
- In accordance with the Statement of Commitment Guidance (to be published on the Supplier Workspace)
- In accordance with the Data Dictionary for Medical and In-Vitro Diagnostic Devices for Item Attributes (available on the Supplier Workspace)
- For actions 2.4 to 2.5, this requirement is dependent upon:
 - Availability of Release 3 of the GS1 Global Data Synchronisations Network, and
 - Satisfactory completion of a Demonstration of Technology by the Department of Health in conjunction with GDSN and relevant technology providers
- In accordance with the Data Dictionary for Medical and In-Vitro Diagnostic Devices for Price Attributes (to be published on the Supplier Workspace)
- In accordance with the eProcurement Strategy update of March 2016 (available on the Supplier Workspace)
- For action 3.2, Class I date applies only if production identifiers are required by EU UDI legislation
- In the event that EU UDI legislation comes into force with differing timelines, the dates above will be amended to match the legislated timelines
- 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 4.4 to 4.5 inclusive (see also Note 5)
 - By two years for actions 3.1 to 3.2 inclusive