

Accessing online information for healthcare products

Purpose of document

This document explains how the existing GS1 barcode (e.g., GS1 DataMatrix, EAN/UPC and GS1-128) used for identification and traceability already on the product or pack can be used to access online information about healthcare products.

The document includes recommendations solution providers can use when developing solutions that translate the existing data from GS1 barcodes (e.g., GS1 DataMatrix, EAN/UPC and GS1-128) into online connections that enable an endless number of use cases. This document does not provide design specifications for a particular technical solution. Supporting technical information is listed at the end of this document

Note: This document was updated in April 2024 reflect the industry's preference about accessing online information for healthcare products without increasing the number of barcodes on the product pack. It also includes an extended set of Frequently Asked Questions.

Audience

The main audiences for this paper are the manufacturers and distributors of medical products, ministries of health, regulators, industry associations, solution providers, healthcare providers, GS1 Member Organisations and industry associations.

What is meant by online healthcare product information

Online healthcare product information refers to content such as electronic Product Information Leaflet (ePIL), Summary Product Characteristic (SmPC), electronic Instruction for Use (eIFU), instructional and informational videos, storage and handling information, interactions and any other content that can be accessed over the web.

Standards based solutions

The GS1 barcode already found on millions of healthcare products all over the world, a mobile device app and a <u>GS1 Conformant Resolver</u>, and in some cases the GS1 Digital Link URI Syntax (to link from the app to the resolver) provide the foundation to develop secure solutions to access online information for healthcare products.

A barcode

GS1 Healthcare's recommendation is that the GS1 barcode used for identification and traceability purposes is also leveraged via a mobile device app to access online information.

However, GS1 Healthcare acknowledges that the use of a GS1 barcode to access online product information may be challenging and perhaps not possible in some cases. Additionally, labelling changes are required in cases where an additional 2D barcode (i.e., QR Code) is added to the pack to access online information. More information about GS1 DataMatrix and QR Codes can be found in the paper titled <u>The key role of GS1 DataMatrix barcodes for product identification</u> in healthcare on the GS1 Healthcare website.

To avoid unnecessary changes to packaging and risk of confusion, regulations and tender requirements should not mandate the use of a specific type of 2D barcode and should allow the use of the most appropriate one based on global standards.

A Mobile Device app and the GS1 Digital Link URI Syntax

The GS1 barcode used for identification purposes encodes only GS1 Application Identifiers (AIs). However, it's easy to convert the GTIN, and other data in the barcode, into a Web address following the GS1 Digital Link URI syntax. The GS1 Digital Link URI syntax is the standardised



method for encoding identifiers like GS1 GTINs in 2D barcodes. For more information refer to the <u>GS1 Digital Link Standard: URI Syntax</u>.

The conversion must be performed by a mobile device application that introduces an internet domain name which is not included in the GS1 barcode. This means that apps carrying out this conversion will likely point to a single reference location online as the start of the journey towards the desired content. For additional supporting information refer to the <u>GS1 Barcode</u> <u>Syntax Resource</u>. This is a free open-source reference software that makes the conversion easier.

In response to the mobile app, the internet domain owner can respond in a variety of ways. Such as providing information about the product, a digital leaflet, videos or simply redirect to another authoritative source of information such as a national eLeaflet repository.

A resolver

A GS1-Conformant Resolver is very useful when it is necessary to point to multiple sources of information. A <u>GS1-Conformant Resolver</u> connects a GS1 identifier structured in GS1 Digital Link format to one or more sources of information about the identified entity. For example, it can connect a product's GTIN to a Web page about the product, electronic Product Information electronic Instructions for Use, sustainability information and more. See the example in option 1 below for more information.

Options for accessing online information for healthcare products

There are two basic ways to use the existing GS1 barcode to create solutions to access online information for healthcare products.

Scenario	How to access the online information
There are multiple sources of	 A mobile device app takes the information from the
information in multiple destinations	GS1 barcode and connects the user to a GS1-
available online. For example,	Conformant Resolver that contains various web
leaflets in various languages,	addresses (i.e., URLs) - one for each piece of online
videos, audio files, clinical	information. The resolver responds to the request from the app
information, instructions for use	and provides the available web link(s) for the
and more.	specific product information. The user chooses the desired information.

Option 1: (GS1 Healthcare preferred option)

In this scenario the mobile device app scans the GS1 barcode containing a GTIN, and other data elements as available (e.g., Batch/Lot, Expiry Date and Serial Number) which are transferred to the resolver. The resolver responds to the request from the mobile device app and provides web links registered for that product.

The links can serve a variety of purposes and there is no limit to the number of web links that can be associated with a single GTIN.



The mobile device app scans the GS1 barcode and connects to a GS1-Conformant Resolver



For more information refer to <u>GS1 Conformant Resolver</u>.

Solution providers can develop an endless number of applications that can help patients and care providers become more informed by connecting them to all types of information about products – all made possible by using the internet and trusted GS1 standards. The combination of mobile a device app and a resolver provide a foundation for solution providers to developed secure and specialised solutions and services that help improve supply chain operations, patient safety and medical outcomes.

Solutions might include features as described below among many others.

- Use of the variable data such as batch/lot and/or a serial number to enable a product verification solution within a regulatory framework.
- Solutions that help identify counterfeit products as part of an initiative to fight falsification of medicines and medical devices.
- Instructional videos aimed at healthcare professionals and patients.
- Product information and other trusted digital content that provides important information to patients and healthcare providers.

Option 2:

Scenario	How to access the online information
There is one piece of online product information in a single location.	An app takes the information from the GS1 barcode and based on the GS1 Digital Link URI Syntax standard, turns it into a web address and the online product information is displayed on the mobile phone.

In this scenario the mobile device app scans the GS1 barcode containing a GTIN and other data elements as available (e.g., Batch/Lot, Expiry Date and Serial Number) and constructs a web link following the GS1 Digital Link URI Syntax standard. This will provide access via the device's web browser to the online information. This is a simple option for scenarios where there is a single destination for the information. For example, a web link to the location of a leaflet on a national repository, or the manufacturer's website. See illustration below.





A mobile device app scans the GS1 barcode and constructs a web link

For more information refer to GS1 Digital Link Standard: URI Syntax.

Additional information

If a QR Code is required, in addition to the GS1 barcode applied for identification and traceability purposes, it should be strictly limited to accessing online information. In this case it should leverage the GS1 Digital Link URI Syntax standard and should contain the same identifier as the GS1 barcode. For more information refer to the GS1 General Specifications, section on the GS1 Digital Link URI syntax standard for extended packaging applications for trade items.

GS1 has submitted a call for action to mobile phone operating system providers to improve native scanning of a GS1 DataMatrix. For more information refer to Enabling native GS1 DataMatrix scanning.

Frequently Asked Questions

1. What is the difference between the GS1 Digital Link Syntax standard and the GS1-conformant resolver and a URL?

The GS1 Digital Link Syntax standard provides a means for expressing GS1 identifier keys, key gualifiers and data attributes in a format that can be used on the Web in an intuitive manner (via a straightforward HTTP request) to enable users to access information and Services about products, assets, locations, etc. A GS1 Digital Link URI can be encoded natively in any data carrier that can support the encoding of a Web address (URL).

A Uniform Resource Locator (URL) is a specific type of URI colloquially known as Web address. A URL is a URI starting with http or https. For example, the Web URL address for GS1 is <u>https://qs1.orq</u>.

The term 'resolver' is not unique to GS1. It is the name for any service that accepts an identifier as input and sends the request about the identified item to information about it. In the GS1 context, a resolver connects GS1 identifiers, expressed as a GS1 Digital Link URI, to one or more online resources that are directly related to the identified item. The item may be identified at any level of granularity, and the resources may be either human or machine readable. Examples include product information pages, instruction manuals, patient leaflets and clinical data, product data, service APIs, marketing experiences and more.

For additional information refer to: Linking GS1 identifiers to multiple sources of data, the GS1-Conformant resolver implementation guide, the GS1 Digital Link URI Syntax standard and the GS1-conformant resolver standard.



2. Why is GS1 DataMatrix recommended for healthcare product identification?

The GS1 Healthcare community recommends the GS1 DataMatrix barcode due to its ability to capture a significant amount of identification data in a small space, direct printing on products, and robust error detection and correction algorithms allowing it to be scanned even if damaged, torn or printed poorly. It is globally endorsed and widely implemented for medicines traceability and Unique Device Identification (UDI) in more than 75 countries. For more information refer to <u>The key role of GS1 DataMatrix</u> <u>barcodes for product identification in healthcare</u>.</u>

For additional information about correct creation and encoding of GS1 barcodes please refer to the <u>GS1 Barcode Syntax Resource</u>.

3. Why is GS1 DataMatrix considered the only globally endorsed 2D data carrier for healthcare product identification?

In the early 2000s several manufacturers of healthcare products conducted testing with 2D barcodes and approached GS1 to help harmonise the global use of GS1 DataMatrix as the single 2D Barcode for identification of healthcare products.

Today, GS1 DataMatrix is the single 2D barcode used to fulfil medicines traceability regulations in over 70 countries. GS1 DataMatrix is also used for compliance with Unique Device Identification (UDI) requirements. It captures substantial identification data in a compact space, it can be printed directly on products, and has advanced error correction capability allowing it to be scanned even if damaged, torn or printed poorly.

Apps that scan a GS1 DataMatrix can readily convert the data into GS1 Digital Link syntax and may carry out basic integrity and security checks before accessing online information. The combination of an app and a resolver provide a foundation to solution providers to develop secure and specialised solutions and services that help improve supply chain operations, patient safety and medical outcomes.

4. What is the GS1 Healthcare community's guidance on the use of QR codes in healthcare?

The GS1 Healthcare community recommends GS1 DataMatrix or linear GS1 barcodes for product identification and traceability and accessing online information. QR codes shall not be used for product identification in healthcare. They are acceptable for providing electronic product information when the GS1 DataMatrix or linear GS1 barcode can't be used, but should be used only as secondary barcodes, preferably in addition to GS1 DataMatrix or linear GS1 barcodes to avoid confusion, especially in healthcare settings.

Refer to the answer to question 5, below, for information on how to use GS1 DataMatrix or linear GS1 barcodes to access online information for healthcare products.

5. Can the GS1 Digital Link URI standard be used with GS1 DataMatrix in healthcare applications?

A GS1 DataMatrix encodes the GS1 Element String syntax (i.e. AI(01), AI(10), AI(17) and AI(21) and does not currently support the encoding of the GS1 Digital Link URI syntax.

This preferred way to access online information for healthcare products using a GS1 DataMatrix, or any other linear GS1 barcode, is explained in this document "<u>Access</u> <u>online information for healthcare products with the existing GS1 Barcode"</u>. This includes examples of using the existing GS1 barcode on the product, an app and a GS1-



conformant resolver. This approach helps minimise the number of barcodes on a pack and prevents the need to add a QR Code solely to access online information.

Additional sources of information on the GS1 Healthcare website.

- GS1 Digital Link URI Syntax
- <u>GS1-Conformant Resolver</u>
- <u>GS1 Healthcare recommendations on the use of GS1 standards to access digital</u> <u>content on medical products</u>

6. Is there a specific tool or app required to access ePIL through GS1 DataMatrix?

Accessing an electronic product information leaflet (ePIL), or any other online information with a GS1 DataMatrix, requires the use of an app that can recognise a GS1 barcode and construct a GS1 Digital Link URI which points directly to the online source, or connects to a GS1-Conformant Resolver that contains web links for the GTIN and other data elements encoded in the GS1 DataMatrix.

Both options are explained in this document <u>Accessing online product information with</u> <u>the GS1 Digital Link Standard.</u>

Additionally, the ScanMatrix 🖨 app supports the GS1 Digital Link standard and resolver functionality and is available at the Apple App Store or Google Play for public use.

7. Does GS1 provide an app to be used to access digital content online?

As a neutral not-for-profit standards development organisation, GS1 does not provide solutions, including apps. Apps are best developed by solution providers built for specific purposes and/or health authorities who manage online information such as electronic Product Information (ePI), electronic Instructions for Use (eIFU), Summary of Product Characteristics (SmPC) and other regulated information about medical products.

8. What is GS1 Digital Link URI Syntax, and can it work without an app?

GS1 Digital Link URI syntax is a way to encode GS1 identifiers as a URL, serving as both a product identifier and a link to online information. When the GS1 Digital Link URI Syntax is encoded in a QR Code, and a Data Matrix (e.g. ECC200) on some Android devices, the built-in camera can scan these barcodes and provide access to online information.

An app is required to scan the GS1 barcode and access eLeaflets and other information online. GS1 has initiated efforts with mobile phone operating system providers to improve native scanning capabilities of GS1 DataMatrix.

GS1 Healthcare has prepared a call to action to Apple and Google to enable native GS1 DataMatrix scanning, via the camera on their devices. More information is available here <u>#ScanMyGS1DM</u>. Help spread the word by posting this call to action on your preferred social media platform.

9. Can the GS1 Digital Link URI Syntax standard work without a QR Code?

Yes, the GS1 Digital Link URI Syntax standard can work without a QR Code. It was designed to function with all GS1 barcodes without needing an additional QR Code to encode a URL. This aligns with the GS1 Healthcare ambition of reducing and ultimately eliminating multiple barcodes on product packs scanned at the point of care.



10. What is GS1's guidance if national requirements mandate the use of a QR Code for online product information?

GS1 recommends that national requirements align with the principle of a single barcode and the use of GS1 Digital Link URI Syntax standard. If a QR code is required, it should leverage the GS1 Digital Link URI Syntax standard and contain the same identifier as the GS1 barcode, minimising confusion and packaging changes.

11. What are the recommendations to health authorities to enable globally interoperable and harmonised access to digital content related to medical products?

To ensure harmonisation in approaches to access digital content related to medical products online, GS1 Healthcare recommends using the existing GS1 DataMatrix or linear GS1 barcodes already on the product or package for product identification and traceability. This can be accomplished using an app enabled to support the GS1 Digital Link syntax URI or an app and a GS1-conformant resolver. Refer to the answer in question 5 for information on how to use GS1 DataMatrix or linear GS1 barcodes to access online information for healthcare products.

Reference Documents

- GS1 Healthcare recommendations on the use of GS1 standards to access digital content on medical products (2023) - <u>https://www.gs1.org/sites/gs1/files/2023-</u> <u>12/gs1seg231205-01-for hclt gs1 stds to access digital-content in hc a4 08.pdf</u>
- GS1 Healthcare Public Policy brief: Using GS1 barcodes to access digital content about healthcare products.

https://www.gs1.org/docs/healthcare/position-papers/gs1-healthcare-paper-onusing-gs1-barcodes-to-access-digital-content.pdf

- GS1 Conformant Resolver Standard <u>https://www.gs1.org/standards/gs1-</u> <u>conformant-resolver</u>
- GS1 Digital Link <u>https://www.gs1.org/standards/gs1-digital-link</u>
- The latest version of the GS1, "GS1 General Specifications" is always available at https://www.gs1.org/standards/barcodes-epcrfid-id-keys/gs1-general-specifications
- The key role of GS1 DataMatrix barcodes for product identification in healthcare (2021) -<u>https://www.gs1.org/docs/healthcare/position-papers/GS1-DataMatrix-Position-Paper-FINAL.pdf</u>