GS1 Healthcare recommendations on
the use of GS1 standards to access digital content on medical products

Purpose

This document provides recommendations to health authorities to enable globally interoperable and harmonised access to digital content related to medical products. It can also be used by the healthcare industry to support the definition of a strategy on access to digital content.

The focus is on the technical components of the ecosystem needed to access digital content by scanning a barcode. In addition, assessment of regulatory compliance and specific legal provisions are needed to frame the governance and usage of these technical components. These are essential but not covered in this document as they are not part of GS1's scope of expertise.

Issue statement and discussions

There are many initiatives implemented/foreseen by regulators in order to enable access to digital content on medical products (e.g. electronic product information leaflets, electronic information for use). These initiatives are aiming at supporting sustainability, empowerment of patients, accessibility of a tailored-format and up-to-date information, opportunities for integration into electronic medical records or e-prescription, etc

For example:

- **in Japan**[1]**:** the PMDA requires the exclusive use of ePIL and eIFU since July 2023 by leveraging the DataBar used for traceability,

- **in Singapore**[2]**:** the GS1 DataMatrix has been used to implement the Health Sciences Authority guidance of 2021 on the labelling of therapeutic products,

- **in China:** since May 2023, NMPA allows the use of the GS1 DataMatrix to access ePIL via WeChat,

- **in the EU**[3]**:** the EU Medicines Agency is running pilots in a few EU countries and is also considering using the GTIN to link the product to the ePIL,

- **In Spain**[4]**:** The Spanish Agency of Medicines and Medical Devices (AEMPS) uses a mobile device app to scan barcodes as part of the voluntary harmonisation, procedure before the official submission of a multi-state clinical trials application,

- **In Brazil:** ANVISA is working on a regulation for access the ePIL using a specific platform centralising all ePILs,

- **In the GCC:** a recommendation to apply an additional QR code to access the ePIL for centrally registered pharmaceutical product has been released in July 2023,

- **development partners:** (i.e. TRVST: UNICEF, BMGF, USAID, The Global Fund, GAVI, the World Bank) are using the GS1 DataMatrix both to authenticate donated products and to access digital content on these products.

In order to ensure consistency between these requirements, it is critical to leverage the technologies and global standards available to ensure interoperability of the implementation across the world. It is also critical to enable a high level of data security and privacy while limiting the complexity and cost for implementation.

To support decision-making by the relevant health authorities and define harmonised implementation by the healthcare industry, GS1 HC developed the following recommendation on how to access digital content for medical products.

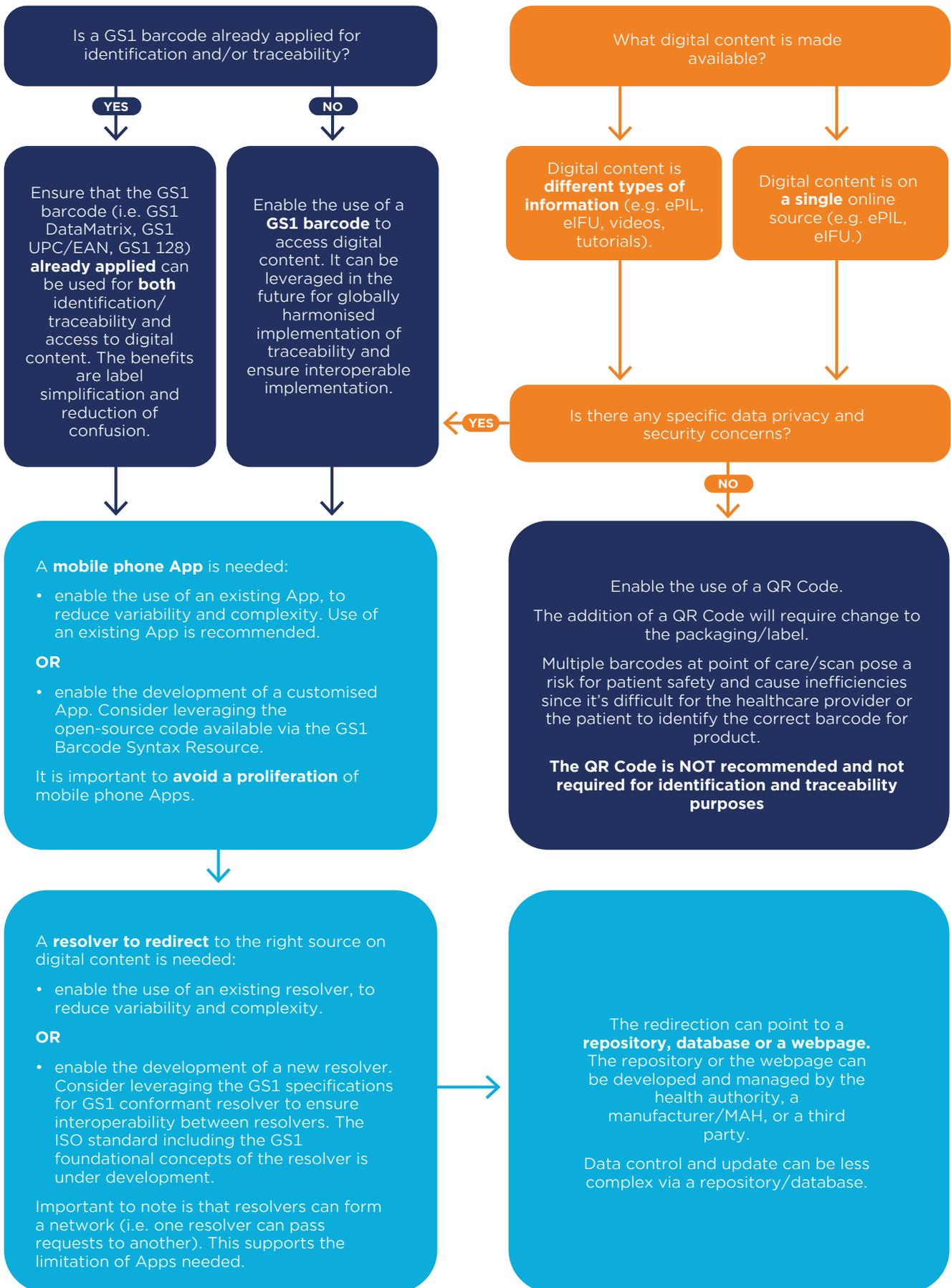[1] https://www.pmda.go.jp/english/safety/info-services/e-pack-ins/0001.html
[2] https://www.gs1.org/insights-events/case-studies/singapore-using-gs1-digital-link-based-app-give-patients-date-information-about
[3] https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/product-information/electronic-product-information-epi
[4] https://cima.aemps.es/cima/publico/home.html#

Recommendations

Is a GS1 barcode already applied for identification and/or traceability?

YES → Ensure that the GS1 barcode (i.e. GS1 DataMatrix, GS1 UPC/EAN, GS1 128) **already applied** can be used for **both** identification/ traceability and access to digital content. The benefits are label simplification and reduction of confusion.

NO → Enable the use of a **GS1 barcode** to access digital content. It can be leveraged in the future for globally harmonised implementation of traceability and ensure interoperable implementation.

What digital content is made available?

- Digital content is **different types of information** (e.g. ePIL, eIFU, videos, tutorials).
- Digital content is on **a single** online source (e.g. ePIL, eIFU.)

Is there any specific data privacy and security concerns?

YES → (leads to GS1 barcode/App path)

NO → Enable the use of a QR Code.

The addition of a QR Code will require change to the packaging/label.

Multiple barcodes at point of care/scan pose a risk for patient safety and cause inefficiencies since it's difficult for the healthcare provider or the patient to identify the correct barcode for product.

The QR Code is NOT recommended and not required for identification and traceability purposes

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A **mobile phone App** is needed:

- enable the use of an existing App, to reduce variability and complexity. Use of an existing App is recommended.

OR

- enable the development of a customised App. Consider leveraging the open-source code available via the GS1 Barcode Syntax Resource.

It is important to **avoid a proliferation** of mobile phone Apps.

A **resolver to redirect** to the right source on digital content is needed:

- enable the use of an existing resolver, to reduce variability and complexity.

OR

- enable the development of a new resolver. Consider leveraging the GS1 specifications for GS1 conformant resolver to ensure interoperability between resolvers. The ISO standard including the GS1 foundational concepts of the resolver is under development.

Important to note is that resolvers can form a network (i.e. one resolver can pass requests to another). This supports the limitation of Apps needed.

The redirection can point to a **repository, database or a webpage.** The repository or the webpage can be developed and managed by the health authority, a manufacturer/MAH, or a third party.

Data control and update can be less complex via a repository/database.

In addition to the considerations above, it is important for the health authorities to take the following points into account when developing requirements to access digital content online for medical products:

- **Clarify the type of products impacted:** most of prescribed medicines carry a GS1 DataMatrix and medical devices covered by UDI requirements carry a GS1 barcode which can be leveraged for access to digital content with no change to the packaging.

- **Communicate and raise awareness of healthcare providers and patients** on the possibility to access digital content on a medical product by downloading the relevant App and/or by scanning the relevant barcode on the pack/label.

- **Define the legal framework** for data privacy, data security, as well as the governance for development, management and update of the mobile device App, resolver and digital content.

- **Enable the mobile device App and the resolver** to be developed by the health authorities themselves, or by a third party and potentially - but not recommended - by a manufacturer/MAH.

- **Consider leveraging global standards**, in particular the GS1 barcodes already applied on the pack/label (if any), the GS1 Digital Link[5] and GS1-conformant resolver standards, and a standardised format of the digital content (e.g. HL7 FHIR ePI Profile, PDF).

- **If a QR Code is needed,** in addition to the GS1 barcode applied for identification and traceability purposes, it should be **strictly limited to accessing digital content**. In this case it should leverage the GS1 Digital Link URI Syntax standard and should contain the same identifier as the GS1 barcode.

- **Plan for a timeframe** for removal of the paper version of the information made available online.

Future considerations

Today when scanning a QR code that contains a URL, the mobile phone's camera App will recognise the structure and content of the barcode and propose to open the mobile phone's browser and then the webpage.

The same happens today with certain mobile phones when scanning a Data Matrix.
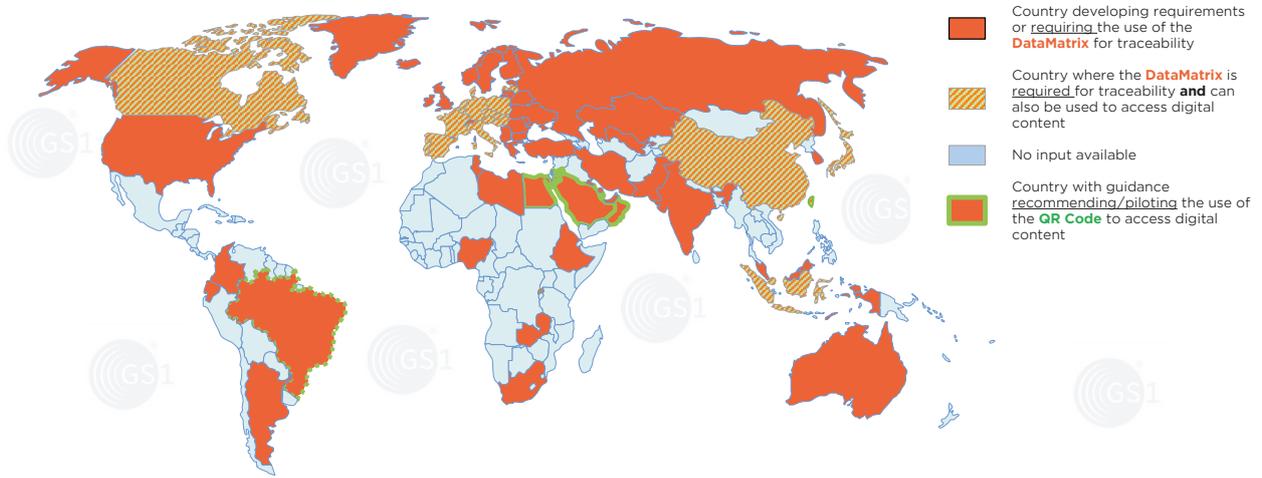
Further development of this automatic recognition of symbology and understanding of the content of the matrix by the mobile phone's App, will facilitate the development and deployment of relevant mobile phone Apps and increase the options the access to digital content by scanning a barcode.

The short-term goal is to increase the scope of the automatic recognition of the symbology of the DataMatrix.

The long-term goal is for mobile phone providers to enable the understanding of the content encoded in a GS1 DataMatrix, to improve usability by the end-user, the patients and the healthcare providers.

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[5] https://www.gs1.org/sites/gs1/files/2023-08/accessing-online-product-information-with-the-gs1-digital-link-standard_1.pdf

Pharmaceuticals: type of barcodes required/used for traceability and/or access digital content (Dec. 2023)

Legend:
- Country developing requirements or requiring the use of the **DataMatrix** for traceability
- Country where the **DataMatrix** is required for traceability **and** can also be used to access digital content
- No input available
- Country with guidance recommending/piloting the use of the **QR Code** to access digital content

No country is today requiring the use of **QR Code for identification** and traceability purposes.
A few countries are not specific on the type of 2D barcode to be used to access digital content.

Medical devices: type of barcodes required/used for traceability and/or access digital content (Dec. 2023)

Legend:
- Country requiring the use of **GS1 barcodes** (i.e. UPC/EAN, GS1-128, GS1 DataMatrix)
- No input available
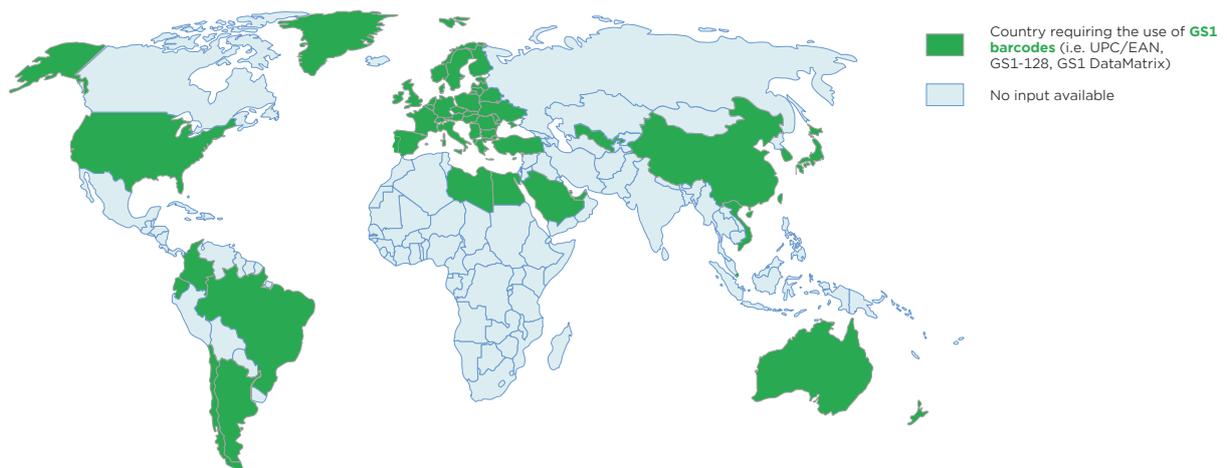
No country is today requiring the use of **QR Code for identification** purposes for medical devices

About GS1 Healthcare

GS1 Healthcare is a neutral and open community bringing together all related healthcare stakeholders to lead the successful development and implementation of global GS1 standards, enhancing patient safety, and operational and supply chain efficiencies.

The development and implementation of GS1 standards is led by the experts who use them: pharmaceutical and medical device manufacturers, wholesalers, distributors, group purchasing organisations, hospitals, pharmacies, logistics providers, solution providers, governmental and regulatory bodies, and trade associations. Evidence available from industry implementations shows that GS1 identification, data capture and data sharing standards in healthcare deliver tangible benefit to all stakeholders. Global members of GS1 Healthcare include more than 100 leading healthcare organisations worldwide.

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