GS1 India

The Global Language of Business

Implementation Guide For Pharmaceutical Brands

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1. Disclaimer

The document has been prepared to provide our subscribers a guidance for the implementation of the notification issued by MoHFW, Govt of India for barcoding by the Top 300 Pharmaceutical brands.

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GS1 India reserves the right to modify/amend the document as required from time to time.

2. Executive Summary

As per **G.S.R. 823(E) dated November 17, 2022,** Ministry of Health & Family Welfare has directed Top 300 Pharmaceutical brands in India to apply Barcode/ QR Code on the product packaging [Drugs / Medicines].

The notification specifies, "The manufacturers of drug formulations products as specified in Schedule H2 shall print or affix Bar Code or Quick Response Code [QR Code] on its primary packaging label or, in case of inadequate space in primary package label, on the secondary package label that store data or information legible with software application to facilitate authentication.

When consumers scan the Barcode / QR code, following information should be made available for verification:

- Unique product identification code
- Proper and generic name of drug
- Brand Name
- Name and address of manufacturer
- Batch number
- Date of Manufacturing
- Date of expiry
- Manufacturing license number

This guideline document has been prepared to support Manufactures / Brand Owners / Solution Providers or entities who is impacted with these notifications specified by MoHFW.

However, interpretation of the above stated notification is the responsibility of the customer and not of GS1 India. If any new notifications is / are issued later, the compliance of the same may not be covered under this project / proposal.

3. Global healthcare standards recommended for complying with this regulation

To ensure an appropriate level of interoperability, organizations will need to ensure that their systems are all built on a common set of standards. Interoperable codes enable products, locations and logistic units unique in the physical and the digital world. Transparency, traceability, visibility etc. in supplychain can be achieved only through standard interoperable codes. A system that is implemented with proprietary codes may struggle with limitation when it comes to share or exchange data or information with the systems of other parties in the supply chain or government in future

- **Global Trade Item Number (GTIN) :** Universal and unique Identification standard (ISO/IEC 15459-6) is recommended to use to identify products[Drugs/Medicines] for complying with this regulation. Unique product code identification can be achieved at the product level by giving GTIN to each product. Unique identification can be extended to the batch level by joining batch number to GTIN like GTIN + Batch Number. Unique identification can be further extended to unit level pack by adding a unique serial number to GTIN and Batch Number like GTIN + Batch Number + Serial Number
- **Global Location Number (GLN) :** Universal and unique Identification standard (ISO/IEC 6523) is recommended to use to identify any location [manufacturing plants, distribution locations, Pharmacies], if the manufacturer or brand owners intends to track the movement of products from the production to consumption.
- **Serial Shipping Container Code(SSCC) :** Universal and unique Identification standard (ISO/IEC 1549-1) is recommended to use to identify a logistic unit [Cartons, Pallets], if the manufacturer or brand owners intends to track the movement of products from the production to consumption.

4. Pharmaceutical Packaging Levels

Primary Pack

Packaging in direct contact with the product. E.g., Strips, Blisters, Bottles, Vials, IV Bottles

Secondary Pack

Packaging comprising one or more primary packs. E.g., Cartons

Tertiary Pack

It is considered as the outermost packaging/logistic unit, comprising one or more secondary packs. E.g., Cartons, Pallets

5. Barcode symbols recommended at each level of the packaging

Barcodes are broadly classified as linear or one-dimensional barcodes and two-dimensional barcodes.

Two-dimensional barcodes can hold more data and it occupies lesser space on the product packaging as compared with one-dimensional barcodes. Hence in the context of this regulation the barcode symbols that are recommended on the Primary Pack and the Secondary Pack are either of the below

DataMatrix

- Conforming to GS1 Standards, GS1 Datamatrix
- Omnidirectional
- Used in the global healthcare sector.
- ISO/IEC 16022
- Requires a specific mobile application interface connected with manufacturer database

QR Code

- Conforming to GS1 Digital Link URI Standard
- Omnidirectional
- Converts a barcode string to a web link
- Digital Link standard helps reinforce the one-barcode initiative
- Digital Link standard enables connections to all types of business-to-business and business-to-consumer information
- ISO/IEC 18004:2015
- Can be read through any Smartphone camera/scanning mobile application

The decision to choose the appropriate barcode symbol should be taken based on the feasibility of the current production process and the overall objective that is targeted to achieve. Since the regulation mentions Barcode or QR Code, the manufacturer can choose either of the barcode mentioned above that suits most appropriate to his production environment.

Optionally manufacturers or brand owners can choose GS1–128 as barcode symbol on Tertiary Packs if intended to extend this regulatory compliance to track the product movement from production to consumption.

6. Data to be written in the Barcode

While manufacturers and brand owners are getting ready to comply with this regulation, the short-term objective should be regulatory compliance but the long term objective should be deriving benefits beyond regulatory compliance such as track & trace, product recall, collaborating with supplychain stakeholders such as distributors, stockist, retail and online pharmacies for enabling supplychain visibility and empowering patients with information and ability to verify the genuineness of medicine.

From that perspective it is critical to ensure that data written in the barcode is optimised to address future use cases to derive larger benefit.

Hence it is recommended to write Unique Product Code, Batch Number and Expiry Date in the barcode and make provision to retrieve the rest of the data from the database of the manufacturer while the barcode is scanned using smart phone or handheld devices depending on the context in which it is scanned.

Data in Barcode

- Unique product identification code (GTIN)
- Batch Number
- Expiry Date

Data in the Manufacturer Database

- Proper and generic name of drug
- Brand Name
- Name and address of manufacturer
- Date of Manufacturing
- Manufacturing license number

Optional Information:

- Composition Details (Strength, Unit, Substance Name)
- Route of Administration
- Dose Form
- License Status
- Package Details (Size, Unit, and Form)
- Schedule of Drugs
- Classification of Drugs
- Therapeutic role
- Indication
- Contraindications
- Drug usage
- Interactions with Drugs

7. Data Encoding in the Barcode

Two-dimensional barcodes can hold more data and it occupies lesser space on the product packaging as compared with one-dimensional barcodes. Hence in the context of this regulation the barcode symbols that are recommended on the Primary Pack and the Secondary Pack are either of the below

GS1 DataMatrix :

01189010720000131725010110abcdef1234561

Attribute	Values
• 01	• Application identifier to indicate the data following is the unique product identification [GTIN]
• 18901072000013	• Unique product identification code [GTIN]
• 17	• Application identifier indicates the data following is the expiry date
• 250101	• Expiry date of the product
• 10	• Application identification indicating the data following is a batch number
• abcdef1234561	• Batch number of the product

QR Code with GS1 Digital Link URI

https://smartconsumer.org.in/01/18901072000013/10/abcdef1234561?17=250101

Attribute	Values
• Domain	• https://smartconsumer.org.in
• 01	• Application identifier to indicate the data following is the unique product identification [GTIN]
• 18901072000013	• Unique product identification code [GTIN]
• 10	• Application identification indicating the data following is a batch number
• abcdef1234561	• Batch number of the product
• 17	• Application identifier indicates the data following is the expiry date
• 250101	• Expiry date of the product

Application Identifiers :

These numeric prefixes that are used in barcode strings to define the meaning and format to the data elements that is encoded in the barcode string.

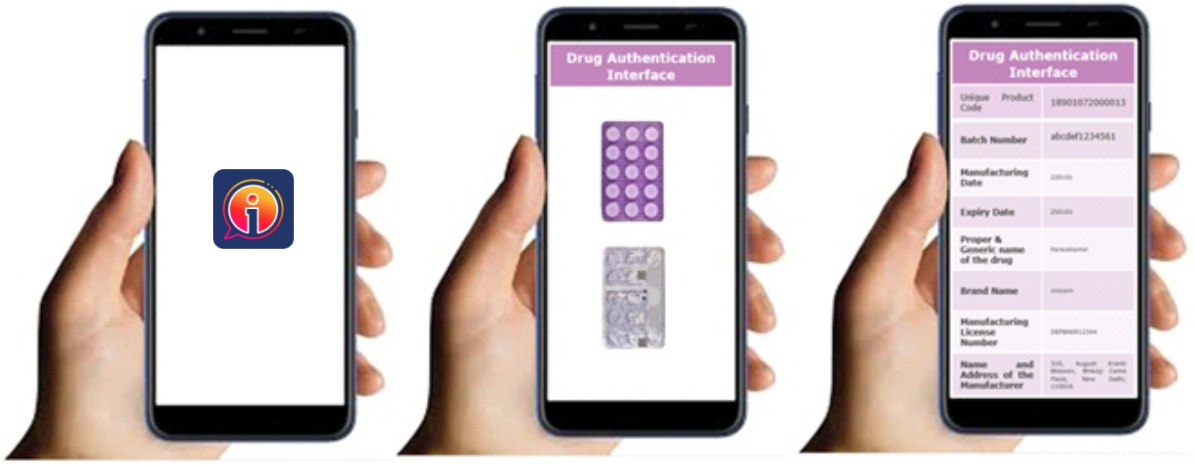
8. GS1 DataMatrix Vs. QR Code with GS1 Digital Link URI

Technically there is no significant difference between GS1 DataMatrix and QR code with GS1 Digital Link URI. Both are two-dimensional barcodes which can carry more data and occupies lesser space.

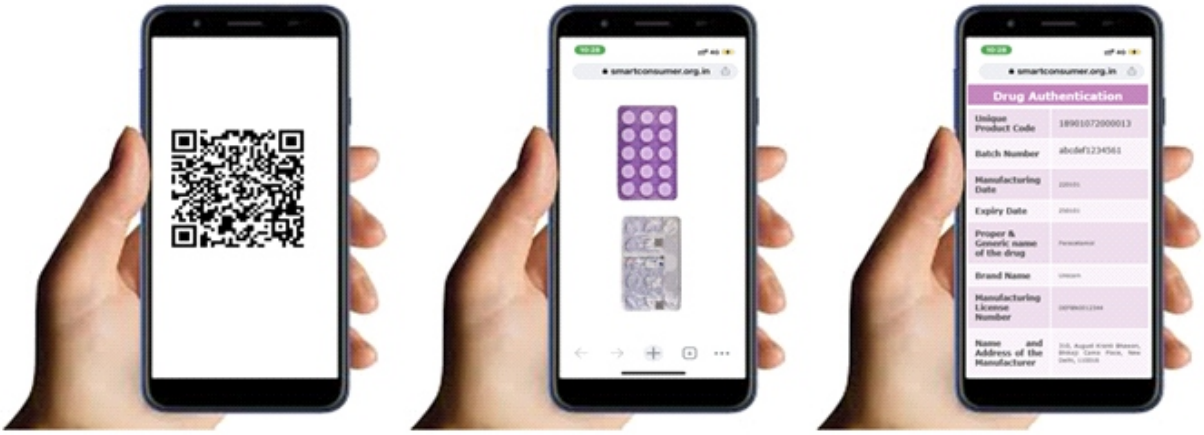
With GS1 DataMatrix, user should have access either to a mobile application or web interface to access product information beyond what is encoded in the barcode.

QR Code encoded with GS1 Digital Link URI can enable the user to access the product information seamlessly using an internet enabled smart phone since the barcode string itself can be encoded in a web URL form.

Product (Drug / Medicine) using GS1 DataMatrix



Product (Drug / Medicine) using QR Code with GS1 Digital Link URI



9. Serialisation (Optional)

In both the above options mentioned under point no:7 an optional serial number can be added to the barcode string to enable unit level unique identification as illustrated below:

GS1 DataMatrix

01189010720000131725010110abcdef123456121123456

Attribute	Values
• 01	• Application identifier to indicate the data following is the unique product identification [GTIN]
• 18901072000013	• Unique product identification code [GTIN]
• 17	• Application identifier indicates the data following is the expiry date
• 250101	• Expiry date of the product
• 10	• Application identification indicating the data following is a batch number
• abcdef1234561	• Batch number of the product
• 21	• Application identifier indicating the data following is a serial number
• 123456	• Serial Number
• FNC1	• This is an invisible character that is encoded between Application identifier 10 and Application Identifier 21 which helps the machines to differentiate between the end of batch number and start of the serial number. • These characters are encoded between data attributes that are variable in nature.

QR Code with GS1 Digital Link URI

https://smartconsumer.org.in/01/18901072000013/10/abcdef1234561/21/123456?17=250101

Attribute	Values
• Domain	• https://smartconsumer.org.in
• 01	• Application identifier to indicate the data following is the unique product identification [GTIN]
• 18901072000013	• Unique product identification code [GTIN]
• 10	• Application identification indicating the data following is a batch number
• abcdef1234561	• Batch number of the product
• 21	• Application identifier indicating the data following is a serial number
• 123456	• Serial Number
• 17	• Application identifier indicates the data following is the expiry date
• 250101	• Expiry date of the product

10. Benefits across stakeholders with this implementation

Manufacturer

- Inventory Management
- Traceability
- Visibility in supply chain
- Recall

Hospitals

- Inventory Management
- Automation in drug dispensing
- Point of sale at Pharmacy

Retail Pharmacies

- Point of sale
- Inventory Management

Patient

- Verfication of Drug
- Information about drugs
- Safe medicine

Online Pharmacies

- Product data
- Inventory Management
- Point of distribution

Goverment

- e-Health
- Tracebility data on demand
- Electronic procurement
- Inventory Management

11. Barcode Printing Methods

For printing barcodes on various packaging levels two common printing methods can be adopted:

- **Online or Inline Printing**
- **Offline Printing**

Online or Inline Printing refers to the printing method where the print and apply system is deployed on the production and packaging line itself and could be directly connected with an application/ERP that generates and print barcodes in the production process for Primary, Secondary, and Tertiary packaging.

Thermal ink jet (TIJ) printers are compact, cost-effective machines that are built to create high resolution codes on a variety of substrates. TIJ printers use a system of replaceable cartridges for ink delivery. Through a process called "drop ejection," TIJ models propel the ink from the desired substrate.

Thermal Transfer Overprinting (TTO) is a technology that creates messages in resolutions up to 300dpi by pushing a ribbon into contact with a substrate using a print head. Thermal Transfer Over printer is a method where heat is used to transfer ink from a Thermal Transfer Ribbon onto a flexible substrate, like food, beverage, and medication packaging. This technique is used for example for the printing of barcodes and variable information such as best-by dates and serial numbers

Laser Printer

Laser marking machines which are used majorly for a detailed, sharper and permanent marking on a variety of product substrates ranging from paper and plastic products to metallic parts.

Needing no inks or solvents, they minimise waste, and automatic temperature control cooling means the printer saves energy wherever possible, potentially providing a carbon footprint reduction (depending on your existing technology on site).

Such marking enables the customers to not only deal with counterfeits but also implement traceability for regulatory/supply chain tracking purposes.

Continuous Inkjet

Continuous Ink Jet systems (CIJ), or Industrial inkjet printers, work by expelling electrically charged ink droplets from a printhead nozzle and passing them through an electric field. CIJ is short for continuous inkjet. In a CIJ printer, ink is pumped from an ink reservoir and ejected through a nozzle that creates a jet of ink.

An industrial Continuous Inkjet (CIJ) printer is used for coding and marking products and packaging during production and packaging processes. Mainly variable data is printed; typical applications include expiry dates, batch and production information, serial numbers, and promotional codes or barcodes.

CIJ printing is a non-contact, versatile solution for these use cases, providing high-quality, reliable coding on fast-paced production lines

Offline Printing refers to the printing method where the printing and labelling process is done postproduction for all levels of packaging.

There are several barcode printing technologies that are available today. Some of the most common printing technologies used within the AIDC industry globally are:

- **Thermal Transfer Printer - Labels**

Thermal Transfer printed labels are easily identified by the crisp, often glossy, printed surface. The clarity is achieved by using a thin ribbon roll that when heated by the print head melts onto the label to form the image. The ink is absorbed so that the image becomes part of the media. When matched with suitable media, thermal transfer technology is not only impervious to heat and moisture, but the image cannot be rubbed off, making the printed labels the most durable available. An additional benefit of this technology is the continuity of the printed image. Because the color and density of the printed image is determined by the ribbon and the resolution of the printer, thermal transfer printing produces consistent, reliable printing on every label. This technique provides image quality and durability that is unmatched by other on-demand printing technologies.

For more information on the appropriate printing methods, please reach out to the solution providers at https://www.gs1india.org/find-a-solution-provider/

12. Support by GS1 India

GTIN, GLN Management & Product [Drug/Medicine] Catalogue Sharing

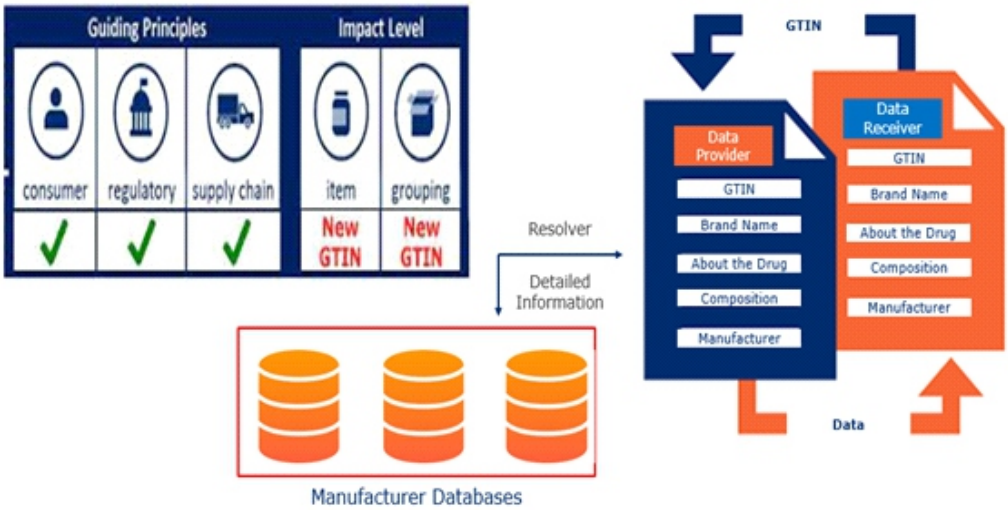
Manufacturers or brand owners can use GS1 India DataKart Service to allocate and manage unique product identification codes [GTIN] and unique location codes [GLN].

Regulatory requirements across the globe have enabled brand owners to implement multiple systems in the IT landscape of the company. All these IT applications are requiring GTIN, GLN or SSCC's. Managing unique identification codes through disparate systems can lead to the risk of duplicate allocation and thereby supply chain disruptions.

DataKart enables manufacturers or brand owners manage the GTINs, GLNs, SSCCs through uniform interface and capture detailed information related to the drugs or medicines to share seamlessly with any external stakeholders such as distributors, stockist, retail pharmacies, online pharmacies and patients.

DataKart also equipped with smart consumer mobile application and smart consumer web interface for enabling information sharing with consumers / patients

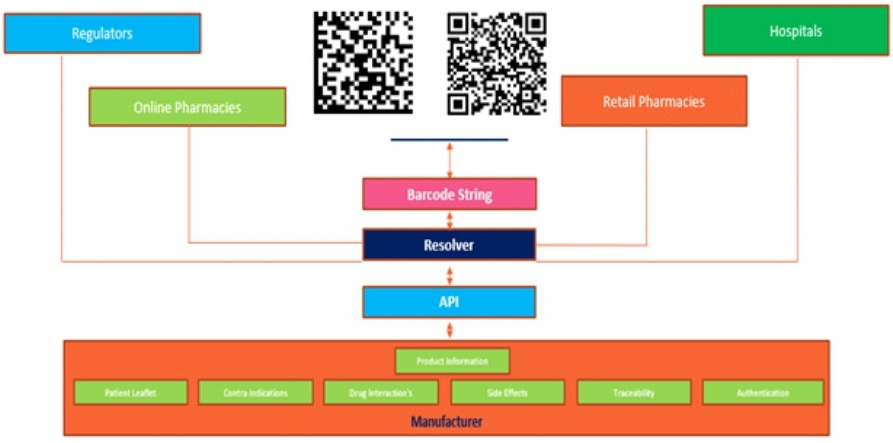
ClickIt mobile application which is a product image capturing mobile application extension of DataKart can help manufacturers or brand owners to capture and share the product images to build further authenticity of the product



Resolver Service

The resolver is the service based on the GS1 Digital Link standard. A system that 'resolves' GS1 identifiers to one or more sources of information about the identified item. For example, it can link a GTIN to traceability information about the product, patient leaflet and other details. At the same time, the resolver can link an identified item to information for business partners such as recall status, master data, storage instructions and more.

GS1 India can support the Manufacturer or brand owners with resolver service to facilitate information dissemination to the respective stakeholders as and when required based on the privileges.



Barcode Verification

The key to success of this implementation is to make sure that the barcode printed on the packs are scannable in all the scenarios. To ensure this barcode needs to be tested and verified before going for live production.

GS1 India can support the industry with barcode verification to ensure the scanability of barcodes across all scanning environments.

Training & Education

GS1 India training and education program can help industry with necessary knowledge on GTIN Management, GLN Management, Barcode Printing on various packaging levels, enabling application interfaces with barcode encode or decode capabilities.

Customised training programs can be delivered onsite /remotely as per the requirement of the company.

For more details, you can send in your request to enquiry@gs1india.org

13. About GS1 India

GS1 India is a standards organisation setup by the Ministry of Commerce & Industry, Government of India and apex trade bodies comprising CII, FICCI, ASSOCHAM, FIEO, IMC besides BIS, IIP, Spices Board and APEDA to spread awareness and provide guidance on adoption of global standards by Indian Industry, Government on barcodes and RFID.

GS1 is a neutral, not-for-profit global standards body with more than 2 million-member companies across 24 industry sectors including Government, Healthcare, Transport and Logistics, Retail and Food etc. Headquartered at Brussels, GS1 oversees a global network of over 116 GS1 member organisations serving over 150 countries for the past 40 years. GS1 India affiliated to GS1 Global Office.

GS1 is involved in development and promotion of global standards which provide end-to-end visibility of goods in Supply Chains. This in turn enables track & trace of parcels, consignments etc. from point of origin to its destination/delivery point with full visibility during transit across multiple trading partners which include Post Offices, Airports, Railways etc.

GS1 standards create a common foundation for business by uniquely identifying, accurately capturing and automatically sharing vital information about products, locations, assets and more.

The GS1 System of Standards is global, robust, multi-sector, user-generated, and scalable.

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