

GS1 DIY Self-Learn Materials

Pharmaceutical Traceability using GS1 Standards

GS1 Malaysia Berhad





Preface

- This DIY Self Learn Material will provide insights into:
 - How GS1 Global Standards meets global regulatory requirements
 - The importance of **traceability** in the Healthcare supply chain
 - The importance of 2D Datamatrix for pharmaceutical traceability
 - Cross-border **regulations** on **medical product traceability**

GS1 Standards in Healthcare



Our Vision

GS1 Healthcare envisions a future in which the healthcare sector achieves harmonised implementation of global standards in business and clinical processes enabling interoperability, optimal quality and efficiency of healthcare delivery to benefit patient



Our Mission

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, operational and supply chain efficiencies.



One scan:
safer patients

Our Reach

- Recognised & Accepted Worldwide,
- Accredited Unique Device Identification (UDI) Issuing Agency for many countries, such as USA, EU, China, etc.
- GS1 2D Datamatrix barcode recognised use on Healthcare products,

GS1 Healthcare: an expanding, committed community of globally engaged stakeholders...



Leading hospitals implement GS1



Working with global organisations...



International
Organisation for
Standardisation



European
Committee for
Standardization



Health Level 7
International



International
Health Terminology
SDO



Clinical Data
Interchange Standards
Consortium



Integrating
the
Healthcare
Enterprise



Digital Imaging
and
Communications
in Medicine



Personal
Connected Health
Alliance



World Health
Organization



World Customs
Organization



International Hospital
Federation



International
Council for
Commonality
in Blood
Banking
Automation



International
Society for Quality
in Healthcare



European
Association of
Hospital
Pharmacists



European Federation of Pharmaceutical
Industries and Associations

European
Federation of
Pharmaceutical
Industries and
Associations



European Medical
Devices Industry
Association



Challenges in the Healthcare Supply Chain



A key driver in the Healthcare sector for:

- Patient Safety
- Anti-counterfeiting
- Correct patient records
- Effective product recalls
- Traceability down to the patient
- Regulatory compliance



Benefits of Visibility in a Healthcare Supply Chain



Simply Put, it will help ensure :

- Correct Patient
- Correct Medication
- Correct Doses
- Correct Time
- Correct Administration
- Correct Documentation



*Introduction of Patient Wristband
Containing Name, Case Number
and Barcode (GS1-Standard)*

WHO on Healthcare Industry Track & Trace



- Due to rapid growth and trade globalization, medical products are involved in **complex and extensive supply chains** that span the globe, **stretching** the monitoring capacity of regulatory agencies, raising the risk of **sub-standard** and **falsified** medical products entering the market, **increasing inefficiencies** and **reducing patient safety**.
- Stakeholders have turned to **traceability**, which is globally recognised as a **useful tool** to ensure **integrity** and **improve** supply chain **efficiency** to resolve product integrity issues.
- **The World Health Organisation (WHO)** has published several papers on the best practices, models, technologies & methodologies to provide guidance on **traceability**.
- WHO also recognises **GS1 Standards** as the **global family of standards** in wide use globally for **medical product traceability**.



Source:

<https://www.who.int/publications/i/item/policy-paper-on-traceability-of-medical-products>

WHO's 9 Features of Traceability Systems



- 1. Identification**
- 2. Use of Global Standards**
- 3. Lot/Batch-level Traceability**
- 4. Unit-level Serialization**
- 5. Aggregation Data**
- 6. Verification**
- 7. Full track & trace vs point of dispense verification**
- 8. Patient Verification**
- 9. Detection, Response and Reporting**

References:

1. <https://www.who.int/publications/i/item/policy-paper-on-traceability-of-medical-products>
2. <https://www.who.int/publications/i/item/9789240101197>

Regulations on Pharmaceuticals



- The **Drug Supply Chain Security Act (DSCSA)** under the Drug Quality and Security Act 2013, signed on November 27, 2013 by US President Barrack Obama, recognizes GS1 Standards for use on prescriptive drugs.
- EU's Delegated Regulation 2016/161 of the EU **Falsified Medicine Directive** **recognizes the** GS1 coding structure for traceability implementation:

➤ UI also ISO-compliant (ISO 15418; ISO 15434).

Product code	Serial number	Batch number	Expiry date
(01)09876543210982	(21)12345AZRQF1234567890	(10)A1C2E3G4I5	(17)180531

Illustrative example – not binding

- *Azerbaijan approved decree #348 for a Pharmaceutical Track & Trace System on January 1st 2024 (Dərman Vasitələrinin Təqib və İzləmə Sistemi (DVTIS)) that recognises GS1 Standards & 2D Datamatrix.*

European Federation of Pharmaceutical Industries and Associations (EFPIA):



Recommendation for Coding of Pharmaceutical Products in Europe Data Matrix

Manufacturer Product Code (GTIN or NTIN): 14 digits

Unique Serial Number (randomized): up to 20 alpha-numeric characters

Expiry Date: 6 digits (YYMMDD)

Batch Number: up to 20 alpha-numeric characters

Example:

GTIN: (01) 07046261398572

Batch: (10) TEST5632

Expiry: (17) 130331

S/N: (21) 19067811811



Specifications provided in EFPIA's:
"European Pack Coding Guidelines"



Track & Trace MOH Malaysia Perspective

Objective: Traceability & Visibility, Supply Chain Security & Efficiency, Combat Substandard & Falsified Medicine & Unregistered Products and Patient Safety

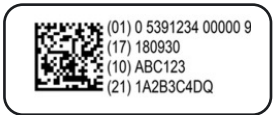
PRODUCT SCOPE



All registered product
(A,X,T,N)*

*Implementation in phases

DATA CARRIER & ELEMENTS



GS1 2D DataMatrix

- GTIN
- Expiry date
- Lot/ batch number
- Serial Number

PACKAGING LEVELS & AGGREGATIONS



Saleable Unit
Tertiary Packaging
Aggregations

DATA EXCHANGE & DATABASE



Central Authority's
Centralized Track & Trace
System
GS1 EPCIS Standard

FULL TRACEABILITY; END-TO-END MODEL



Centralized National Track & Trace Approach

Policy Consideration

Government issuing **mandates** (laws, regulations, directives etc.) that define, govern, and establish an appropriate incentive structure for the track and trace program. The mandates should address **identification, data capture (barcoding), aggregation, and data exchange** informed by the business need and/or challenge the country wishes to address through track and trace



PRODUCT SCOPE – *which products are subject to the regulation*

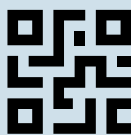
Category of Product:
A – Schedule Poison N – Health Supplement
X – OTC T - Traditional



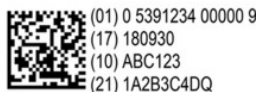
DATA CAPTURE – *how identification data should be encoded in data carriers on specific packaging levels*



GS1 2D DataMatrix



IDENTIFICATION – *how trade items and logistics units must be uniquely identified that enter the market/ supply chain*



(01) GTIN
(10) Lot/ Batch
(17) Expiry
(21) Serialization



DATA EXCHANGE – *what data must be exchanged*



EPCIS and CBV Implementation Guideline

The Process of Identifying, Encoding & Verifying



Encoding a Traceable Unit Barcode Symbol: GS1 Application Identifiers (AIs)

An **element string** that carries **dynamic** or “**production**” data that provides additional information about the item identified.

(01)19551234500005(17)250812(10)KULGS01

GS1 Application Identifier Code	Data Type	Data Length
01	Global Trade Item Number (GTIN-14)	Fixed, 14-digits
10	Batch or Lot Number	Variable, maximum 20
17	Expiry Date	Fixed, 6-digits
15	Manufacturing Date	Fixed, 6-digits
21	Serial Number	Variable, maximum 20
00	Serial Shipping Container Code (SSCC)	Fixed, 18-digits
02	GTIN of item within a Logistic Unit	Fixed, 14-digits
37	Count of Items within a Logistic Unit	Variable, maximum 8

Scan for full
AI List



How to adjust your GTIN-13 for Healthcare / UDI Product-Level Label Encoding



NOTE:

- This is a **simplified** step and only works for **product-level labelling** and **cannot be used** for **cartons** or **pallets**.
- Must acquire and understand the use of **GS1 Application Identifiers (AIs)**, i.e. the codes in brackets



A New Dimension in Barcodes

Supporting the Migration from 1D to 2D



GS1 2D
Datamatrix,
example

- Stores large amounts of data in **2 Dimensions**
- Created in **1987** by **International Data Matrix Inc.**
- Built-in **Error Correction**
- Recognized **Healthcare products** data carrier



GS1
QR Code,
example

- Stores large amounts of data in **2 Dimensions**
- Created in **1994** by **Denso Wave**
- More efficient at **encoding logograms**
- Can be **read natively** on **mobile devices**



1D / Linear
Barcodes



Transition Starts
with Awareness



Benefits of 2D
Implementation



GS1 Sunrise 2027
GS1 Ambition 2027

Goal:

By the **end of 2027**, all retail POS systems should be able to **read & process 2D barcodes** with GS1 standards, in **addition to existing linear barcodes**.

**What is
Expected in
2027?**

=



OR



OR



Barcode Certification Program

Providing Barcode Quality Control for GS1 Standards-based Barcode Symbols

(1) Validation



Confirms the **right barcode** is on the **right product** from the **right company**, with the **right details**.

(2) Verification



Guarantees your barcode will **scan successfully** on the **first & every try**, by **any POS**, **any store** or **any warehouse**.

(3) Decoding



Reviews your barcode's **structure** to see if the data is **accurate & correctly formatted** to **GS1 Standards**.

GS1 Barcode Certification Report



- **Globally Recognized**
- Ensures **readability first & every time, anywhere**, with **accurate data**
- RM100/label - **Member**
- RM200/label - **Non-member**

GS1 Malaysia 2D Repository Platform

Experience Track & Trace using 2D Datamatrix



Data Submitter

Scans a GS1 2D Barcode

GS1 Malaysia 2D
Capturing Portal

1. GTIN Number
2. GLN Number
3. Batch/Lot Number
4. Expiry Date
5. Manufacturing Date
6. Serial Number
7. Location Name

Submit Scanned
Data



GS1 Malaysia
2D Data Repository

Retrieve/Review
Data



Brand
Owners

Retailers

Marketplaces

Regulatory
Agencies

Validation & Authentication

- To confirm delivered/received goods matches manifest to root out **counterfeit and fraudulent products**
- To fight against **unauthorized barcode numbers**
- **Track & Trace** of products & trade items
- **First In First Out (FIFO)** Inventory Management to prevent spoilage or wastage

Curated to answer your enquiries!

GS1 DIY Self-Learning Materials!



Access the guide here:
<https://gs1my.org/?q=gs1-malaysia-diy-self-learning-materials>

OR

Scan to View



- Topic 1 - GS1 DIY Self-Learning - Overview of GS1 & Step By Step I...
Adobe Acrobat Document
- Topic 2 - GS1 DIY Self-Learning - How to Generate & Assign Barco...
Adobe Acrobat Document
- Topic 3 - GS1 DIY Self-Learning - How to Submit Product Listing
Adobe Acrobat Document
- Topic 4 - GS1 DIY Self-Learning - What is Global Location Number ...
Adobe Acrobat Document
- Topic 5 - GS1 DIY Self-Learning - GS1 Standards & Keys for Logistic...
Adobe Acrobat Document
- Topic 6 - GS1 DIY Self-Learning - Unique Device Identification (UDI)
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- Topic 7 - GS1 DIY Self-Learning - Platforms & Services offered by G...
Adobe Acrobat Document
- Topic 8 - GS1 DIY Self-Learning - GS1 Barcode Specifications
Adobe Acrobat Document
- Topic 9 - GS1 DIY Self-Learning - Unauthorised Barcode Numbers - ...
Adobe Acrobat Document

Official GS1 Communications Channels

Official GS1 Malaysia WhatsApp

+6014-3933 228

(Membership, Services & Support)

+6011-1616 8228

(Membership, Services & Support)

+6016-2455 228

(Strictly for Payment Only)

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(Strictly for Payment Only)

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