



醫院管理局  
HOSPITAL  
AUTHORITY

**Briefing to Pharmaceutical Suppliers & Manufacturers**

# **Incorporating Unique Identifier Requirement into Drug Procurement Tender**

Hospital Authority  
27 March 2023

# Welcome

# Background

---

- ▶ Pharmaceutical products are manufactured and distributed in complex supply chain nowadays.
- ▶ We have identified a need to create a safe and efficient Pharmacy service through the supply chain.
- ▶ Our goal is to enhance medication safety by implementing track and trace capabilities on pharmaceutical items supplied to HA.

# Our Vision on Drug Journey

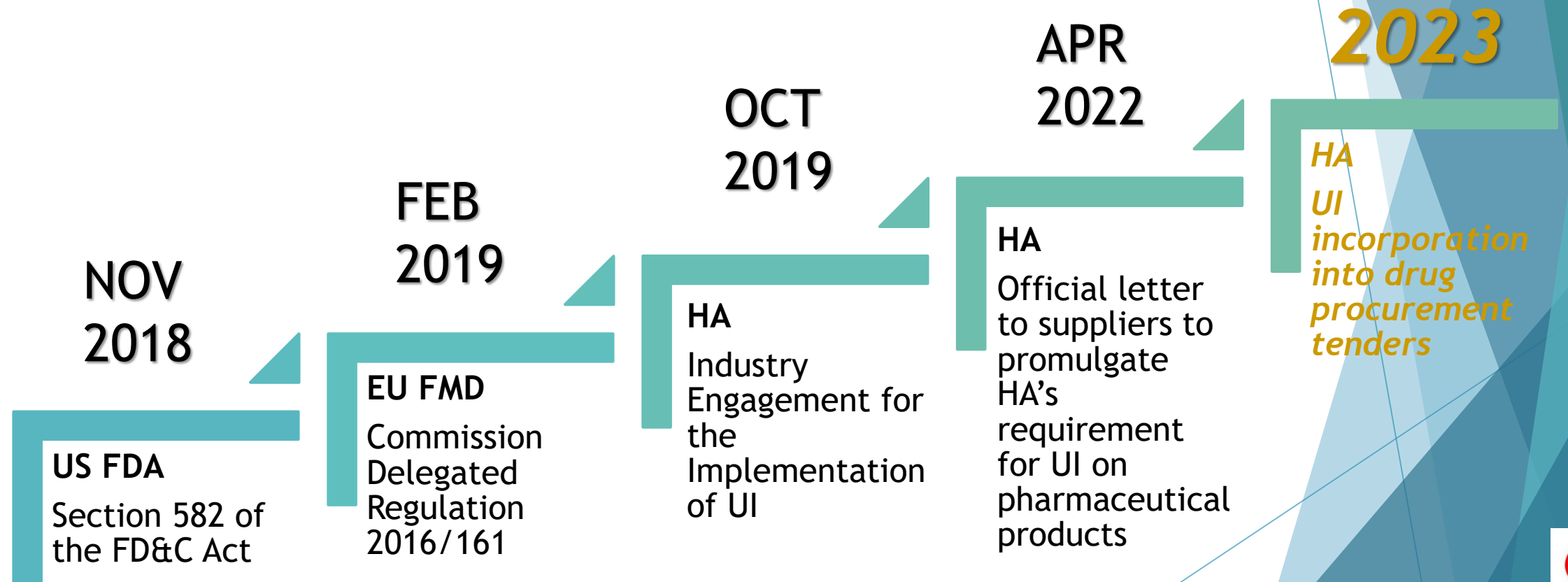
---

## ▶ Pharmaceutical Product

- ▶ To enable the tracking and tracing of medicines, all products shall incorporate the 2D DataMatrix to facilitate these initiatives.
- ▶ The barcode will aid the transfer of information along the supply chain and aid shelf life management up to and including the point of dispense.
- ▶ To facilitate electronic identification and verification.

Development of Smart Pharmacy and  
Modernization of the Pharmaceutical Supply Chain

# Unique Identifier (UI) Milestones

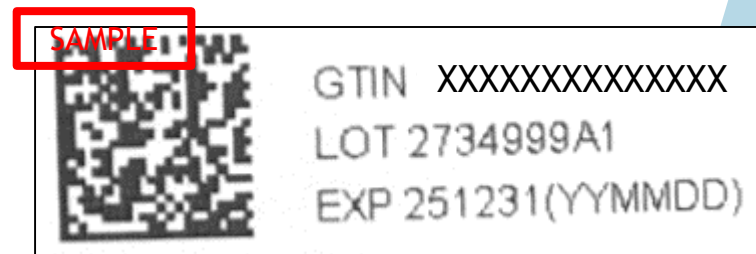


# Unique Identifier (UI) 2D DataMatrix

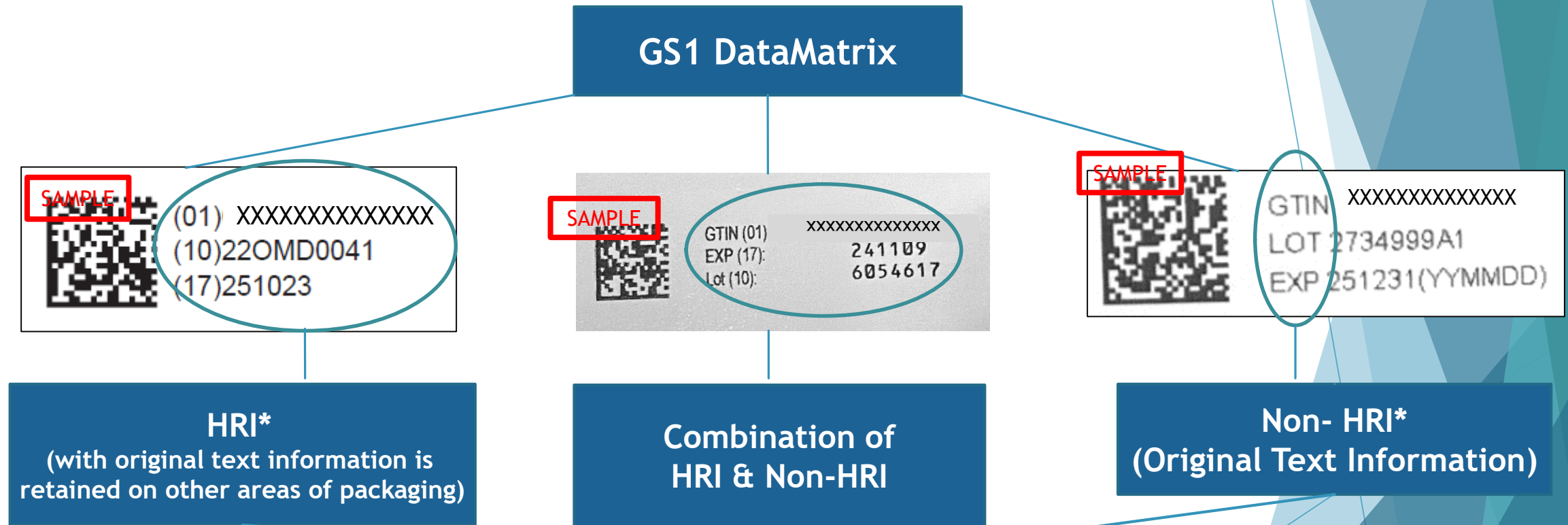
# UI 2D DataMatrix Requirements



- ▶ HA requires pharmaceutical products to be labelled in such a way as to facilitate the transfer of product identification information, the expiration date/ the best before date, and the batch number from the product to the tracking system at Sales Pack Level.
  - ▶ Please refer to “Guideline Implementing GS1 DataMatrix on Pharmaceutical Products for Hong Kong Hospital Authority V7”.
- ▶ The package of sales pack of all pharmaceutical products supplied to HA should carry a GS1 DataMatrix with at least the following elements:
  - ▶ Global Trade Item Number (GTIN)
  - ▶ Batch or Lot number
  - ▶ Expiration Date/ Best Before Date



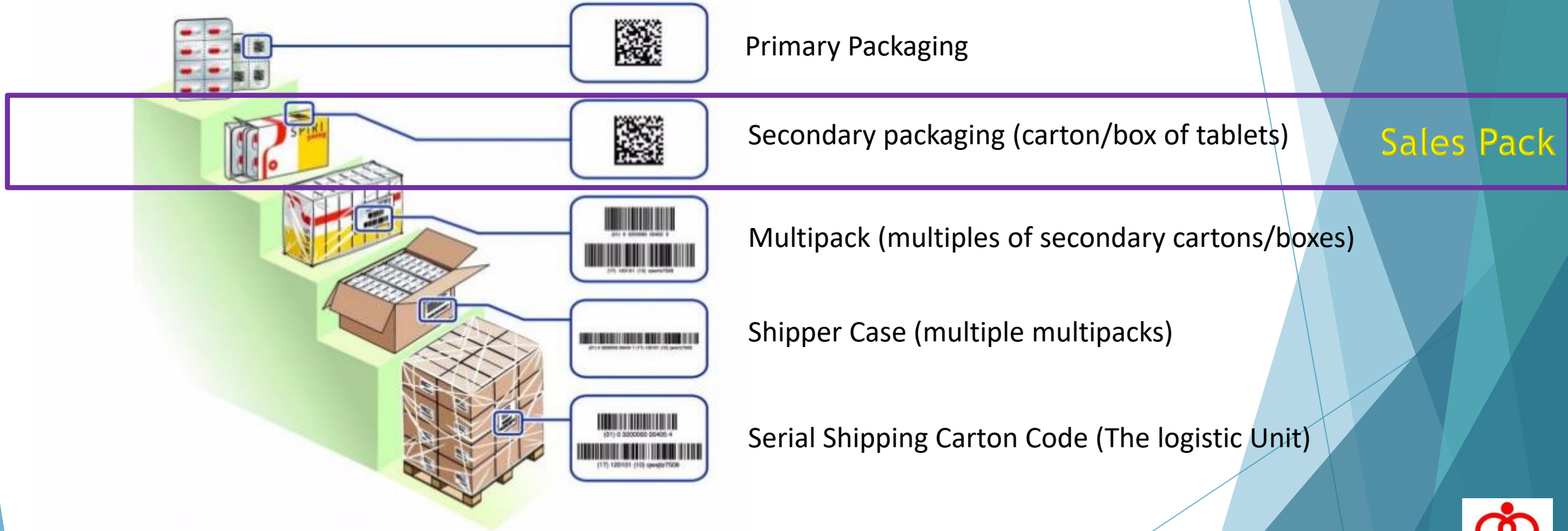
# UI 2D DataMatrix Requirements



- To facilitate key entry in the event that a barcode symbol cannot be scanned
- Actual data content which is encoded in the barcode
- Shall be printed adjacent to (obviously associated with) the bar code


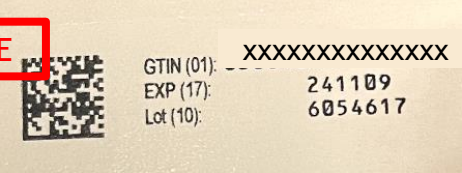
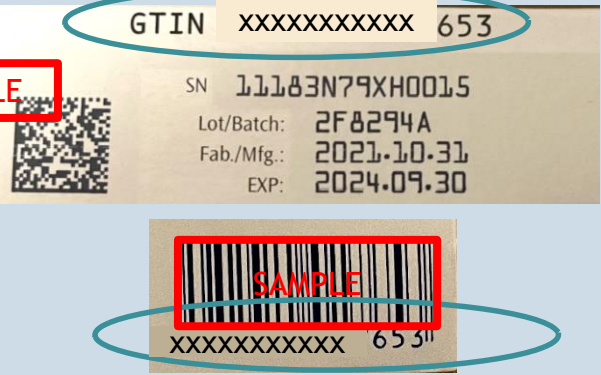


# GS1 Barcoding Levels

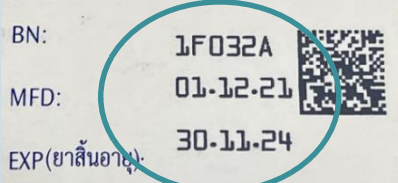


# Examples of UI 2D DataMatrix

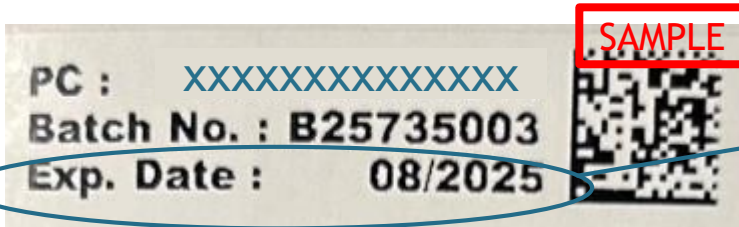
# Examples of UI 2D DataMatrix

Product UI with printed presentation	Data Encode in 2D DataMatrix	Remarks
<p>SAMPLE</p> 	<p>(01)XXXXXXXXXXXXXX (10)2502999A1 (17)241031</p>	<p>✓ Non-HRI is added near 2D DataMatrix</p>
<p>SAMPLE</p> 	<p>(01)XXXXXXXXXXXXXX (10)6054617 (17)241109</p>	<p>✓ Combination of HRI and non-HRI is added near 2D DataMatrix</p>
<p>SAMPLE</p> 	<p>(01)XXXXXXXXXXXX653 (10)2F8294A (17)240930</p>	<p>✓ Same GTIN for 1D barcode and 2D DataMatrix</p>

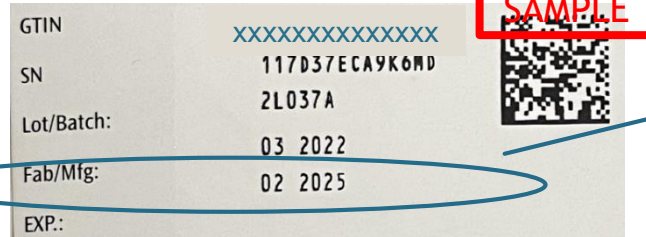
# Examples of UI 2D DataMatrix

Product UI with printed presentation	Data Encode in 2D DataMatrix	Remarks
<p data-bbox="104 422 277 482">SAMPLE</p>  <p data-bbox="333 429 624 465">BN: 1F032A</p> <p data-bbox="333 482 624 518">MFD: 01-12-21</p> <p data-bbox="333 535 624 571">EXP(ยาสิ้นอายุ): 30-11-24</p>	<p data-bbox="963 439 1205 489">(10)1F032A</p> <p data-bbox="963 496 1205 546">(17)241130</p>	<p data-bbox="1689 446 1773 558">X</p> <p data-bbox="1854 415 2384 575">No GTIN number in 2D DataMatrix &amp; printed presentation</p>

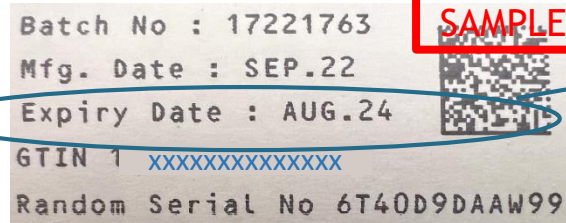
# More Examples...



01/08/2025? 15/08/2025?



01/02/2025? 28/02/2025?



01/08/2024? 20/08/2024?

- To facilitate key entry in the event that a barcode symbol cannot be scanned
- Actual data content which is encoded in the barcode

# Aim of Incorporating UI Requirements into Tender of Pharmaceutical Products

- ▶ Encourage the market to explore and provide UI-ready products to HA
- ▶ Continue to monitor the market readiness of UI through tenders, and at a suitable juncture in due course to incorporate UI provision as a mandatory procurement requirement on pharmaceutical products

# Current Tender Evaluation Steps are Essentially Maintained

- ▶ Please refer to The Authority's Supply Requirements in Appendix 1 to Part III of drug tender document for current steps in tender evaluation
- ▶ Current steps would essentially remained unchanged

Demo: How to search drug tender document in HA internet

**Tender Notice**

The following tenders are invited:

Tender No.	Tender Subject
HAHO(S)/T/22-D183	<a href="#">Tender for the Supply of Ampicillin and Sulbactam for Injection</a>
HAHO(S)/T/22-IT007(S)	<a href="#">Tender for the Provision of Mobile Data Services and Related Hardware Accessories</a>
KWC/K/012-22	<a href="#">Tender for the Supply and Installation of Heated Food Trolley for Kwai Chung Hospital, Kowloon West Cluster, Hospital Authority</a>
KWC/C/014-22	<a href="#">Tender for the Supply and Installation of Public Address System for Kwai Chung Hospital, Kowloon West Cluster, Hospital Authority</a>
NWT01822	<a href="#">Tender for the Provision of Security Services for New Territories West Cluster, Hospital Authority</a>
KCC/TH1/040/22/BTS	<a href="#">Tender for the Supply of Pre-storage Dock-on Leukocyte Filtration System for Red Cells for Hong Kong Red Cross Blood Transfusion Service, Kowloon Central Cluster, Hospital Authority</a>
HAHO(S)/T/22-D204	<a href="#">Tender for the Supply of Multivitamin Tablet</a>
HAHO(S)/T/22-D205	<a href="#">Tender for the Supply of Plasma-lyte A (or equiv) Infusion 1000ml</a>
HAHO(S)/T/22-D196	<a href="#">Tender for the Supply of Sodium Chloride 0.9% and Water for Irrigation Solution</a>
HAHO(S)/T/22-D197	<a href="#">Tender for the Supply of Micafungin Sodium for Injection 50mg</a>
KCC/TH3/074/22/KWH	<a href="#">Tender for the Supply and Installation of Defibrillator/Pacemakers, External for Kowloon Central Cluster, Hospital Authority</a>



# Propose Contract Durations to be Awarded Based on UI-Readiness of Offered Product

- Routine tendered contract duration is 36 months
- To engage market to supply UI-ready products, the final contract durations of individual pharmaceutical products to be awarded will be based on:

Supplier's indication on UI-readiness at tender	Duration of contract to be awarded
Committed to deliver UI-ready product at contract commencement	36 months (full tendered contract duration)
Committed to deliver UI-ready product at not later than first 9 months after contract commencement	24 months + conditional 12 months (subject to successful UI implementation as follows) : <ul style="list-style-type: none"> <li>- submission of contract change in particulars (CIP) with proposed sample/artwork and proof of submission to DH for stand-alone Change of Registered Particulars (CORP)* on UI at not later than 3 months after contract commencement</li> <li>- Delivery of UI-ready product at not later than 9 months after contract commencement</li> </ul>
No commitment to offer UI-ready product	24 months

\* DH CORP application Category 9 Acknowledgment



# HA Tender Document

- ▶ UI requirements will be incorporated in next update
- ▶ The next briefing to industry partners will be upon completion of tender document revision to advise on the finalised details and implementation date

# Tentative Timeline of Implementation

2019 to 2022	1Q 2023	3Q 2023 (tentative)	2Q 2024 (tentative)
		Implement requirement to tender	Award first contract with new UI requirement
<ul style="list-style-type: none"> <li>Promulgation to industry</li> <li>Letter to suppliers</li> </ul>	1 <sup>st</sup> vendor briefing	2 <sup>nd</sup> vendor briefing	

HA internal processes  
Communication to market

# Meanwhile, suppliers and manufacturers are recommended to continue :

- ▶ Submitting to CPO on adding / updating of product UI
- ▶ Exploring and planning the presence of UI for all pharmaceutical products supplying to HA
- ▶ Approaching CPO on any enquiries regarding UI through
  - ▶ Email: [2d\\_cip@ha.org.hk](mailto:2d_cip@ha.org.hk)

# Q & A Session



## Guideline:

# Implementing GS1 DataMatrix on Pharmaceutical Products for Hong Kong Hospital Authority

<b>Document Purpose</b>	This document is to provide technical details on how trading partners of Hong Kong Hospital Authority will implement GS1 DataMatrix on pharmaceutical products. In particular this document will describe <ol style="list-style-type: none"> <li>1 the data requirement; and</li> <li>2 the bar code technical characteristics</li> </ol>
<b>Document created by</b>	Julian Sin, Mignone Cheng & KC Leung, GS1 Hong Kong Ltd (GS1 HK)
<b>Document Date</b>	16 Mar 2022
<b>Document Version</b>	7
<b>Reference Documents</b>	<ol style="list-style-type: none"> <li>1. GS1 DataMatrix Guideline (Release 2.5.1, Ratified, Jan 2018), GS1 AISBL</li> <li>2. GS1 General Specifications (Release 22.0, Ratified, Jan 22),</li> <li>3. AIDC Healthcare Implementation Guideline (Release 3.0.1, Ratified, July 2015), GS1 AISBL</li> </ol>
<b>Disclaimer</b>	GS1 HK makes all reasonable efforts to ensure that the information contained in this document is accurate at the time of their creation, but GS1 HK does not, expressly or impliedly, assure or guarantee the accuracy, correctness or completeness of any information, content or materials in this document. In no event shall GS1 HK be liable for losses and/or damages of any kind arising out of or in connection with this document.

## Document Control

### Change Record

Issue	Date	Created By	Change Description
1.0	4 Dec 2019	KC Leung, GS1 HK	First Release
2.0	22 Jun 2020	KC Leung, GS1 HK	2 <sup>nd</sup> Release: <ol style="list-style-type: none"> <li>1. p. 6: Added AI 90</li> <li>2. Minor wording change on p. 4, 5, 11 &amp; 15</li> </ol>
3.0	15 Jul 2020	KC Leung, GS1HK	3 <sup>rd</sup> Release: <ol style="list-style-type: none"> <li>1. P.1: updated the version of GS1 General Specification</li> <li>2. P. 4, 6, 8, 9, 15: added the requirement of "Best Before Day" as per update of HA</li> </ol>
4.0	5 Oct 2020	KC Leung, GS1 HK	4 <sup>th</sup> Release <ol style="list-style-type: none"> <li>1. Added disclaimer on p.1</li> <li>2. Updated multiple wording for clearer interpretation</li> <li>3. Added footnotes for referencing</li> <li>4. P.5: added explanatory note to the diagram.</li> <li>5. P.10: added reserves colour</li> <li>6. P.11: added supplementary information for red colour</li> <li>7. P.13: updated the business rule of HRI</li> <li>8. P.18: added bibliography</li> </ol>
5.0	12 Nov 2020	KC Leung, GS1 HK	5 <sup>th</sup> Release <ul style="list-style-type: none"> <li>• Corrected typos and grammatical mistakes.</li> <li>• P. 5 &amp; 6: updated diagram</li> </ul>

			<ul style="list-style-type: none"> <li>• P.7: added the reference to GS1 General Spec. in respect of the 3 AIs.</li> <li>• P.8: added a note in relation to the use of AI 90.</li> <li>• P.9-10: re-structured section 4 and in particular updated the requirement of data sequence and corrected an error in relation to encoded/decoded data.</li> <li>• P.11: updated the wording in relation to the light background and dark bar code; corrected an error in relation to red colour; added a reference to the scanning test.</li> <li>• P.12-13: replaced the recommendation of x-dimension and symbol size by referencing to 2 tables with more size options.</li> <li>• P.14: added another consideration in relation to bar code location.</li> <li>• P.15: regarding HRI, added reference to GS1 general specification.</li> <li>• P.19: updated the remarks to expiration date without day value by referencing HA feedback.</li> <li>• P.20: updated the terms of Brand owner and GS1 DataMatrix.</li> <li>• P.22: added the scanning test result.</li> </ul>
6.0	July 2021	Julian Sin, GS1 HK	<p>6<sup>th</sup> Release</p> <ul style="list-style-type: none"> <li>• P.19-26: major change of HRI in response of latest development of HA and DoH requirement</li> <li>• P.26: supplemented a table to illustrated the accepted scenario by HA in relation</li> </ul>

			<p>to the absence of printed expiry day in HRI</p> <ul style="list-style-type: none"> <li>• P.24: re-arranged the order of the tested samples.</li> </ul>
7.0	Feb 2022	Julian Sin, GS1 HK; Mignone Cheng, GS1 HK	<p>7<sup>th</sup> Release</p> <ul style="list-style-type: none"> <li>• Revised the scenarios in the table of Section 6.4.</li> <li>• Added "Format 3" as acceptable format by HA</li> </ul>







## Contents

1.	Background .....	6
2.	Type of Product in Scope .....	7
3.	Bar Code Data Requirement.....	8
4.	Basic Bar Code Requirement and Common Practice.....	10
4.1	Symbolology Requirement .....	10
4.2	Data Requirement.....	10
4.3	Common Practice of Data Sequence .....	10
4.4	Encoded and decoded data .....	11
5.	Recommendation for Bar Code Technical Characteristics .....	12
6.	Human Readable Interpretation (HRI) .....	16
6.1	Purpose .....	16
6.2	Definition .....	16
6.3	Requirement of HRI Format.....	17
6.3.1	Primacy of Requirement.....	17
6.3.2	HA's Requirements of Data Presentation.....	17
6.3.3	GS1's Requirements and Recommendations for HRI.....	20
6.3.4	Consistency across encoded data, HRI and non-HRI .....	22
6.4	Expiration Date or Best Before Date, with month and year only, in GS1 preferred format of HRI or its deviation: .....	22
7.	Glossary of terms .....	25
8.	Bibliography .....	26
9.	Appendix I .....	27

## 1. Background

In 2010, the Hospital Authority (HA) began its Supply Chain Modernisation project with the aim to achieve two main goals: firstly, to enable the track and trace capability in its handling of the large volume of pharmaceutical products through the adoption of industry standards including Global Trade Item Number (GTIN) and Serial Shipping Container Code (SSCC) as well as electronic data messaging protocols, Electronic Data Interchange (EDI); secondly to achieve operational efficiency in the supply chain management process. The project required the identification and bar code mainly at the level of logistic units only. The goal, with the full collaborative support from the major pharmaceutical distributors, has been successfully achieved since 2013.

Packaging Hierarchy	Example	HA Terms	HA requires an Identifier?	HA requires a bar code?	Required type of bar code	Remarks
Primary Packaging	A pill in blister cell 	Base Unit	No	No	NA	Not in scope
Secondary Packaging	2 blisters in 1 box 	Sales Pack	Yes, HA requires GTIN to identify a Sales Pack. Example of GTIN: 4891668000018	Yes	GS1 Data Matrix	1) HA refers the identifier to "Unique Identifier" (UI) 2) Enforced by 2022
Case	20 boxes in 1 case 	Carton	No	Yes	GS1-128	Done since 2012 by local supplier or logistic providers
Logistic Unit	Pallet of 8 cases 	Pallet	Yes, HA requires sSSC to identify a logistic unit. Example of SSCC 148916680000000000	Yes	GS1-128	Done since 2012 by local supplier or logistic providers





Now HA intends to require pharmaceutical products to be labelled in such a way as to facilitate the transfer of product identification information, the expiration date/ the best before date and the batch number from the product to the tracking system at Sales Pack Level.

It is intended that the package of sales pack of all pharmaceutical products supplied to HA should carry a GS1 DataMatrix with at least the following elements:

- Global Trade Item Number (GTIN)
- Batch or Lot Number
- Expiration Date or Best Before Date

## 2. Type of Product in Scope

The barcoding requirement will apply to all pharmaceutical product at Sales Pack level as defined by HA:

Packaging Hierarchy	Example	HA Terms	HA requires an Identifier?	HA requires a bar code?	Required type of bar code	Remarks
Primary Packaging	A pill in blister cell 	Base Unit	No	No	NA	Not in scope
Secondary Packaging	2 blisters in 1 box 	Sales Pack	Yes, HA requires GTIN to identify a Sales Pack. Example of GTIN: 4891668000018	Yes	GS1 Data Matrix	1) HA refers the identifier to "Unique Identifier" (UI) 2) Enforced by 2022
Case	20 boxes in 1 case 	Carton	No	Yes	GS1-128	Done since 2012 by local supplier or logistic providers
Logistic Unit	Pallet of 8 cases 	Pallet	Yes, HA requires sSSC to identify a logistic unit. Example of sSSC 148916680000000000	Yes	GS1-128	Done since 2012 by local supplier or logistic providers

Please note that the diagram above describes a generic physical package of 4 levels, which may not be necessarily applicable to all suppliers. For example, for some products the lowest level is Sales Pack in form of a box, with no blisters inside.

When HA defines sales pack with the suppliers, it may be "Each", "Pack" or "Case" in physical appearance. For example, there are 2 suppliers of Drug ABC, if HA defines the sales pack as Each with Supplier 1, then the GTIN and GS1 DataMatrix are required on the Each. If HA defines the sales pack as Case with Supplier 2, where Case = 50 x Each, then the GTIN and GS1 DataMatrix are required on the Case.

### 3. Bar Code Data Requirement

It is recommended to reference section 3.3.2, 3.4.1, 3.4.5 and 3.4.7 of the GS1 General Specifications<sup>1</sup> for full details in respect of the GS1 Application Identifiers mentioned below.

Required Encoded Data	Encoded Data Format	AI
GTIN	<ol style="list-style-type: none"> <li>It must be 14 numeric value in bar code.</li> <li>If your GTIN only has 13 digits, put a leading zero before the GTIN <b><u>for the sake of bar code creation only.</u></b> There is no need to update the <u>GTIN in HA's systems.</u></li> </ol>	(01)
*Expiration Date or Best Before Date	<ol style="list-style-type: none"> <li>YYMMDD, must be numeric value</li> <li>E.g. 30 Oct 2019 should be converted into 191030 for encoding</li> </ol>	(17) or (15)
Batch/ Lot Number	At most 20 alphanumeric characters only under the set of ISO/IEC 646 <sup>2</sup>	(10)

**\*Important Note: Either Expiration Date or Best Before Date is required, not both.**

There are two options:

- GTIN + Expiration Date + Batch/Lot Number + Other non-required data (if any)
- GTIN + Best Before Date + Batch/Lot Number + Other non-required data (if any)

Please see section 6.3 for further discussion of expiration date with month and year only.

<sup>1</sup> GS1 AISBL, *GS1 General Specifications* (Release 22.0, Ratified, Jan 2022) 156, 158, 160, 161-162

<sup>2</sup> Ibidem 501, s 7.11

Required Data	Data Length	Example
GTIN	(01) + 14 numeric digits	(01)03453120000011
Expiration Date or Best Before Date	(17) or (15) + 6 numeric digits (YYMMDD)	(17)191125 or (15)200713
Batch/ Lot Number	(10) + at most 20 alphanumeric characters	(10)ABCD1234

There may be additional data in the same bar code. If your organisation and HA have agreed to contain a reference number in the bar code, you may use AI 90 (Information mutually agreed between trading partners) for the purpose. You may append the AI 90 after the 3 required data fields.

Agreed Additional Data	Data Length	Example
Reference Number	(90) + at most 30 alphanumeric characters	(90)987654321EFG

Please note that the data carrier (the GS1 DataMatrix) containing this element string (i.e. AI 90) should be removed from any item that leaves the jurisdiction of the trading partners. Failure to remove the symbol may cause problems if another trading partner using the same AI for a separate internal application scans the item.<sup>3</sup> This means that the GS1 DataMatrix encoded with AI 90 should only be used between your organization and HA. It should not be used with other trading partners, because the AI 90 may not be defined with the same meaning by other trading partners, and it may cause problems to the trading partners interpreting the data contained within the GS1 DataMatrix.

<sup>3</sup> GS1 AISBL, *GS1 General Specifications* (Release 22.0, Ratified, Jan 2022) 132, s 2.6.10.1

## 4. Basic Bar Code Requirement and Common Practice

### 4.1 Symboloy Requirement

#### **GS1 DataMatrix is required, which is not a QR code or generic DataMatrix:**

Function 1 Symbol Character (FNC1, codeword 232<sup>4</sup>) must be in the first position of the data encoded for GS1 DataMatrix. If made correctly, upon reading by a bar code reader/imager, the ISO / IEC Symbology Identifier Jd2<sup>5</sup> will be transmitted.

Example:



(01)03453120000011  
(17)191125  
(10)ABCD1234

### 4.2 Data Requirement

The minimal requirement is defined in section 3 and you may have additional data in the same bar code.

### 4.3 Common Practice of Data Sequence

AI (01) encoding the GTIN should appear first<sup>6</sup>. In most cases predefined length element strings (e.g. expiration date) should be followed by non-predefined element strings (e.g. batch number). The sequence of predefined and non-predefined element strings should be at the discretion of the creator of the element strings.<sup>7</sup>

In this regard, the most common practice is: 1<sup>st</sup> order: AI 01; 2<sup>nd</sup> order: AI 17 or 15; 3<sup>rd</sup>

---

<sup>4</sup> GS1 AISBL, *GS1 DataMatrix Guideline* (Release 2.5.1, Ratified, Jan 2018) 15, s 2.2.1

<sup>5</sup> Ibidem

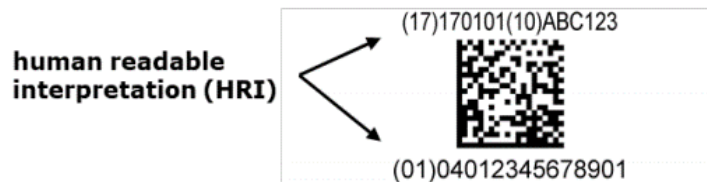
<sup>6</sup> GS1 AISBL, *GS1 General Specifications* (Release 22.0, Ratified, Jan 2022) 149, s 3.1

<sup>7</sup> Ibidem

order: AI 10. For example: (01)03453120000011(17)191125(10)ABCD1234.

#### 4.4 Encoded and decoded data

Parentheses “(“ and “)” should be used in Human Readable Interpretation (HRI) only and shall NOT be encoded in bar code<sup>B</sup>. HRI is the characters, such as letters and numbers, which can be read by persons and are encoded in GS1 AIDC data carriers confined to a GS1 standard structure and format (please see section 7 or Glossary of terms for full definition).





Below are examples of decoded data transmitted from bar code readers/imagers. You may see that no parentheses are decoded.

	Example
<b>HRI</b>	(01)03453120000011(17)191125(10)ABCD1234
<b>Decoded Data</b>	]d201034531200000111719112510ABCD1234

Element in Decoded Data	Meaning
]d2	the ISO/IEC symbology identifier of GS1 DataMatrix
01	AI for GTIN
03453120000011	GTIN
17	AI for Expiration Date
191125	Expiration Date
10	AI for Batch Number
ABCD1234	Batch Number

## 5. Recommendation for Bar Code Technical Characteristics

	Recommendation	Remarks
Shape	Square 	Rectangle is acceptable <sup>8</sup> 
Colour	Black bar code and white space <sup>9</sup>	<ol style="list-style-type: none"> <li>1. Common application: light background and dark bar code</li> <li>2. Colours can be reversed for GS1 DataMatrix<sup>10</sup>: light modules on a dark background or dark modules on a light background. When using this reverse/inverse image feature scanner/imager capability to read reverse/inverse images must be checked. A scanning test was conducted with HA in November 2020, please reference p. 22 Appendix I for the result.</li> <li>3. Avoid red bar code<sup>11</sup>, especially if your packaging will have 2 bar codes: one GS1 DataMatrix and one EAN/UPC bar code. Although red colour may work for GS1 DataMatrix, it may NOT work for EAN/UPC bar code.</li> </ol>

<sup>8</sup> GS1 AISBL, *GS1 DataMatrix Guideline* (Release 2.5.1, Ratified, Jan 2018) 8, s 1

<sup>9</sup> Ibidem, 30 s 4.5

<sup>10</sup> Ibidem

<sup>11</sup> Ibidem



<b>X-dimension</b>	Please refer to the Table 5-1 below, which is for Regulated healthcare non-retail consumer trade items not scanned in general distribution only.	<p>1 For example, you may consider the target value 0.380mm for your GS1 DataMatrix, if the space of your packaging/product allows.</p> <p>2 If your product fits the following criteria, please contact GS1 for advice about x-dimensions</p> <p>A. Barcode to be direct part marked;</p> <p>B. Trade items scanned in retail pharmacy and general distribution or non-retail pharmacy and general distribution</p>
<b>Symbol size</b>	Please refer to the Table 5-2 on the next page.	For example, if you only encode the GTIN, Expiration Date and Batch Number, you may consider 26 x 26 GS1 DataMatrix which can contain at most 64 alphanumeric characters.
<b>Height</b>	Height is determined by X-Dimension and the number of encoded data	-

**Table 5-1** : Symbol specification table - Regulated healthcare non-retail consumer trade items<sup>12</sup>

Symbol(s) specified	X-dimension mm (inches)			Minimum symbol height for given X mm (inches)			Quiet Zone		Minimum quality specification
	Minimum	Target	Maximum	For minimum X-dimension	For target X-dimension	For maximum X-dimension	Left	Right	
GS1 DataMatrix (ECC 200) (*)	0.254 (0.0100")	0.380 (0.0150")	0.495 (0.0195")	Height is determined by X-dimension and data that is encoded			1X on all four sides		1.5/08/660
(*) 2D X-dimension - Optical effects in the image capture process require that the GS1 DataMatrix symbol be printed at 1.5 times the equivalent printing X-dimension allowed for linear or Composite symbols.									


<sup>12</sup> GS1 AISBL, *GS1 DataMatrix Guideline* (Release 2.5.1, Ratified, Jan 2018) 42, Annex A.1.1

**Table 5-2 : GS1 DataMatrix symbol attributes (square form)<sup>13</sup>**

Symbol size*		Data region		Mapping matrix size	Total codewords		Maximum data capacity		% of Codewords used for error correction no.	Max. correctable codewords error/erasure
							Num	Alpha - num.		
Row	Col	Size	No		Data	Error	Cap.	Cap.		
10	10	8x8	1	8x8	3	5	6	3	62.5	2/0
12	12	10x10	1	10x10	5	7	10	6	58.3	3/0
14	14	12x12	1	12x12	8	10	16	10	55.6	5/7
16	16	14x14	1	14x14	12	12	24	16	50	6/9
18	18	16x16	1	16x16	18	14	36	25	43.8	7/11
20	20	18x18	1	18x18	22	18	44	31	45	9/15
22	22	20x20	1	20x20	30	20	60	43	40	10/17
24	24	22x22	1	22x22	36	24	72	52	40	12/21
26	26	24x24	1	24x24	44	28	88	64	38.9	14/25
32	32	14x14	4	28x28	62	36	124	91	36.7	18/33
36	36	16x16	4	32x32	86	42	172	127	32.8	21/39
40	40	18x18	4	36x36	114	48	228	169	29.6	24/45
44	44	20x20	4	40x40	144	56	288	214	28	28/53
48	48	22x22	4	44x44	174	68	348	259	28.1	34/65
48	48	22x22	4	44x44	174	68	348	259	28.1	34/65
52	52	24x24	4	48x48	204	84	408	304	29.2	42/78
64	64	14x14	16	56x56	280	112	560	418	28.6	56/106
72	72	16x16	16	64x64	368	144	736	550	28.1	72/132
80	80	18x18	16	72x72	456	192	912	682	29.6	96/180
88	88	20x20	16	80x80	576	224	1152	862	28	112/212
96	96	22x22	16	88x88	696	272	1392	1042	28.1	136/260
104	104	24x24	16	96x96	816	336	1632	1222	29.2	168/318
120	120	18x18	36	108x108	1050	408	2100	1573	28	204/390
132	132	20x20	36	120x120	1304	496	2608	1954	27.6	248/472
144	144	22x22	36	132x132	1558	620	3116	2335	28.5	310/590

\* **Note:** Symbol size does not include Quiet Zones.

<sup>13</sup> GS1 AISBL, *GS1 DataMatrix Guideline* (Release 2.5.1, Ratified, Jan 2018) 10, Table 1-1

<p><b>Quiet Zones</b></p>		<p>1 x-dimension width on all four sides<sup>14</sup>, as represented in the left image by the yellow area around the DataMatrix</p>
<p>Top</p>	<p>If the x-dimension is 0.380 mm, the quiet zone is 0.380mm</p>	<p>If you use 0.254 mm, the Quiet Zone will be 0.254 mm.</p>
<p>Down</p>	<p>Same as above</p>	<p>Same as above</p>
<p>Left</p>	<p>Same as above</p>	<p>Same as above</p>
<p>Right</p>	<p>Same as above</p>	<p>Same as above</p>
<p><b>Bar Code Location</b></p>	<ol style="list-style-type: none"> <li>1. Determined by the manufacturer who will need to consider (a) The available space on the product package, (b) The type of product and printing substrate<sup>15</sup> and (c) any other regulatory requirements relating to label contents and layout.</li> <li>2. Generally, avoid folds or seams in the packaging, or curvature (e.g. bottle or vial), etc. which can all impact scanning.<sup>16</sup></li> </ol>	
<p><b>Orientation</b></p>	<p>Thanks to its intrinsic properties<sup>17</sup>, the orientation of the symbol has no impact on scanning performance.</p>	

<sup>14</sup> GS1 AISBL, *GS1 DataMatrix Guideline* (Release 2.5.1, Ratified, Jan 2018), 42 Annex A.1.1

<sup>15</sup> Ibidem, 20, s 2.4

<sup>16</sup> Ibidem

<sup>17</sup> Ibidem

## 6. Human Readable Interpretation (HRI)

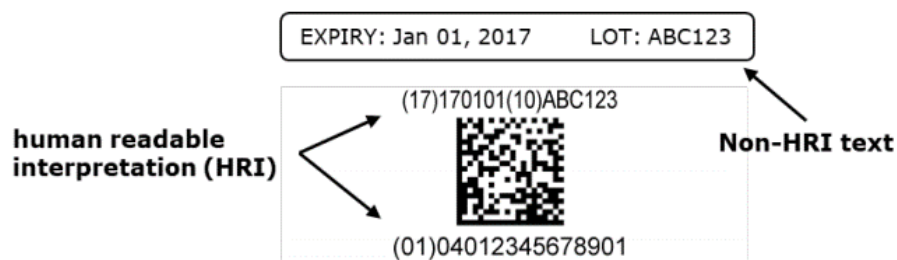
### 6.1 Purpose

The purpose of HRI is to facilitate key entry in the event that a barcode symbol cannot be scanned.

### 6.2 Definition

It is defined as the information below, beside or above a barcode or tag which is encoded in the barcode or tag and represents the same characters as carried in the barcode or tag.<sup>18</sup> While non-HRI text is all other text on package, label or item.<sup>19</sup>

Example:



A HRI has 2 components: (1) a Data Title defined as AI (Application Identifier) which is the indicator of the following encoded data, it may be a number or a descriptive text;<sup>20</sup> (2) a Data Content which is the actual data which will be encoded in a barcode, the format of the encoded data and the Data Content may be different but the values must be the same.

	Example of Expiration Date	Data Title	Data Content	Actual Encoded Data
HRI	(17)210713	(17)*	210713	17210713
Non-HRI	EXP 13 JUL 2021	EXP	13 JUL 2021	17210713

\*(17) is the AI of expiration date.

<sup>18</sup> GS1 AISBL, *GS1 General Specifications* (Release 22.0, Ratified, Jan 2022) 248, s 4.15

<sup>19</sup> Ibidem

<sup>20</sup> Ibidem, 249, Rule 8

## 6.3 Requirement of HRI Format

### 6.3.1 Primacy of Requirement

Although every organization using the GS1 standards is expected to conform fully to the GS1 General Specifications, **applicable regulatory requirements shall take precedence.**<sup>21</sup> This document does not impact the non-HRI text that is not required for compliance with labelling regulations.

### 6.3.2 HA's Requirements of Data Presentation

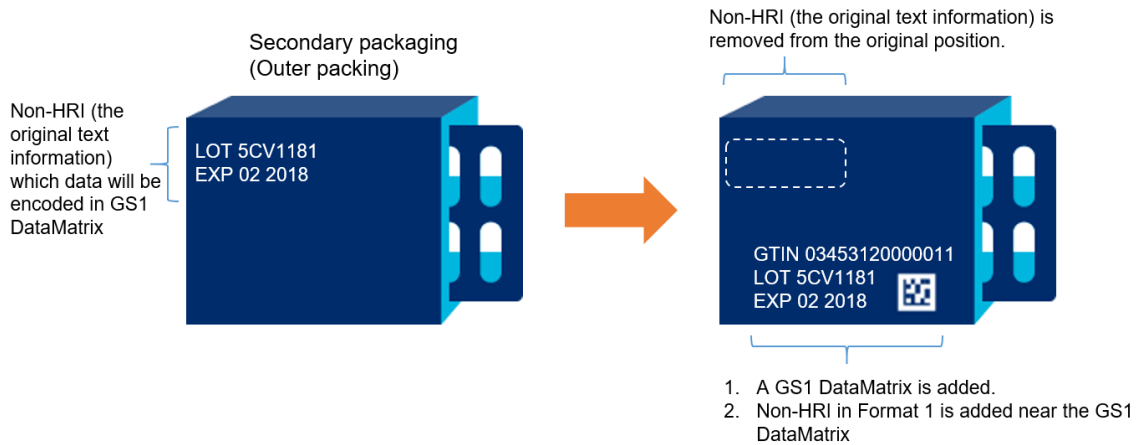
Hospital Authority accepts the Data Presentation formats listed below:

Format 1	All data titles of a non-HRI are in descriptive text, i.e. using word or abbreviation as data title, e.g. Batch: ABC12345. No other text of same values (including different format) to be present.
Format 2	All data titles of a HRI are in numeric value with parentheses, i.e. using application identifiers (AI) number with parentheses as data title, e.g. (10) ABC12345 where (10) is the AI of batch number. Original Non-HRI text is retained.
Format 3	All data titles of a HRI are combining data in descriptive text (e.g. GTIN, SN, batch/lot, expiry) with application identifiers in numeric value [(01), (21), (10), (17)], e.g. Batch (10) ABC12345.

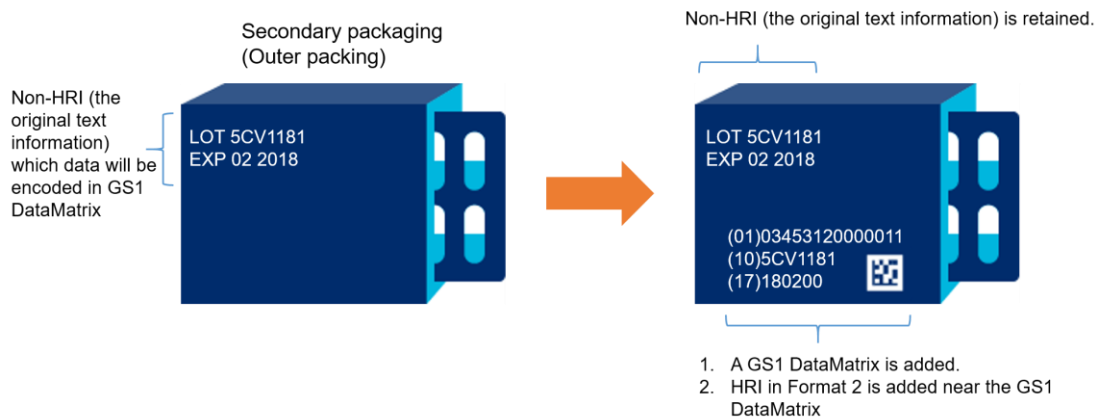
<sup>21</sup> GS1 AISBL, *GS1 General Specifications* (Release 22.0, Ratified, Jan 2022) 252, s 4.15.1

Example for Format 1 with original Non-HRI text removed on secondary packaging

22

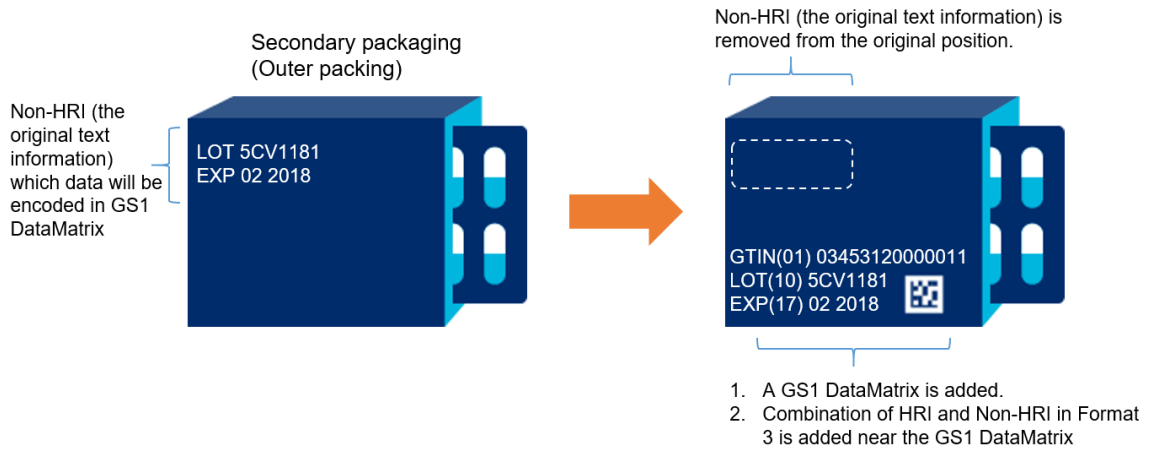


Example of Format 2 with original Non-HRI text retained.



<sup>22</sup> GS1 AISBL, *GS1 General Specifications* (Release 22.0, Ratified, Jan 2022) 510, s 8.1: A level of packaging marked with an AIDC carrier that may contain one or more primary packages each of which may contain a single item or multiple items.

Example of Format 3 with descriptive text combined with AIs in numeric value.



### 6.3.3 GS1's Requirements and Recommendations for HRI

It is recommended to reference section 4.15 and section 4.15.1 of the GS1 General Specifications <sup>23</sup> for full details in relation to HRI and GS1's associated rules.

#### 6.3.3.1 Presence

HRI shall appear unless there are no space of your package for HRI at all.<sup>24</sup>

#### 6.3.3.2 Location & Font

It is recommended to put HRI below the bar code and grouped together wherever physically possible while maintaining the HRI legibility and minimum bar code height. In cases where the HRI must be printed above, to the left, or to the right of the symbol due to packaging or space constraints, HRI shall always be printed adjacent to (obviously associated with) the bar code while protecting Quiet Zones.<sup>25</sup>

A clearly legible font shall be used, such as OCR-B as defined in ISO 1073-2.<sup>26</sup> Alternatively, another clearly legible font can be used.<sup>27</sup>

#### 6.3.3.3 GS1 Preferred Format of HRI

GS1 preferred format means that (1) only AI number is used as the data title; and (2) the value and format of data content is exactly the same as the encoded data. It is suggested to put HRI in GS1 preferred format near the bar code, unless there is prevailing regulatory requirement(s), it is not practical, or the space of packages does not allow. One may NOT need to modify the existing non-HRI. Example of GS1 preferred format.

---

<sup>23</sup> GS1 AISBL, *GS1 General Specifications* (Release 22.0, Ratified, Jan 2022) 248, s 4.15

<sup>24</sup> Ibidem, 249, Rule 8

<sup>25</sup> Ibidem, 248, Rule 1

<sup>26</sup> Ibidem 249, Rule 4

<sup>27</sup> Ibidem





(01)03453120000011  
 (17)191125  
 (10)ABCD1234

### 6.3.3.4 Deviation from GS1 Preferred Format

If deviation from the preferred format is necessary, where AI number may not be used as data title, based on the requirement in Section 6.3.2, only descriptive text shall be used as data title on secondary packaging (outer packing). In this regard, only words or abbreviations which are commonly used or comprehensible should be used, as long as acceptable by the regulatory.

For instance,

Information	Examples of Descriptive Data Title (including but not limited to)
GTIN	GTIN, Product Code, PC
Expiration Date	Expiration Date, Expiry Date, Expiry, EXP.
Batch/Lot	Batch, Lot

Example of deviation:



GTIN: 03453120000011  
 EXPIRY: 2019-11-25  
 BATCH/LOT: ABC1234

### Preferred Format

Information	Encoded Data in Bar code	Presentation
GTIN	0103453120000011	GTIN : 03453120000011
Expiration Date	17191125	EXPIRY: 2019-11-25
Batch/ Lot Number	10ABCD1234	BATCH/LOT: ABCD1234

The preferred option to apply the HRI on the pack is using the data labels and it is accepted also to use of the Application Identifiers data title.

### Accepted Format

Information	Encoded Data in Bar code	Presentation
GTIN	0103453120000011	(01)03453120000011
Expiration Date	17191125	(17)2019-11-25
Batch/ Lot Number	10ABCD1234	(10)ABCD1234

## 6.3.4 Consistency across encoded data, HRI and non-HRI

The data encoded within the barcode, displayed in the HRI and also potentially displayed in non-HRI text shall represent the same data despite the fact that the format of the date when printed for human interpretation may vary from the format used within the bar code. For example, a date that is encoded as 191125 (YYMMDD) in the barcode, may in non-HRI text be displayed as 2019-11-25 or 25 Nov 2019, nevertheless, the overall values is the same.

## 6.4 Expiration Date or Best Before Date, with month and year only, in GS1 preferred format of HRI or its deviation:

To avoid diverse interpretation by different systems and persons along the supply chain of expiration date or best before date with only month and year, it is advised to indicate all of day, month and year in the bar code, whenever possible.

However, in the case that only month and year are practical, then one must encode in the day field in the bar code two zeros "00"<sup>28</sup>. For example, for expiration date Nov 2019, the encoded data should be 191100. The HRI or the deviation should follow one

<sup>2828</sup> GS1 AISBL, *GS1 General Specifications* (Release 22.0, Ratified, Jan 2022) 161, s 3.4.7 and 160, s 3.4.5

the of the following formats:

	Examples of presentation
<b>Data Encoded in Bar code</b>	1911 <u>00</u>
<b>GS1 Preferred Format (accepted by HA)</b>	(17)1911 <u>00</u>
<b>Deviation from GS1 Preferred Format</b>	EXPIRY: 2019-11-00
	EXPIRY: Nov 2019

Please note that HA has advised suppliers to print the full expiry date on the product label / packaging whenever possible for human interpretation purposes. If "00" is encoded as the day of the month value of an expiration date, the HK HA will interpret it as the 1st day of the month.

However, please note that, starting 1 January 2025, the day of the month SHALL NOT be expressed as two zeros<sup>29</sup>. A valid day of the month (e.g., last day of July = 31) SHALL be included.

<sup>29</sup> GS1 AISBL, *GS1 General Specifications* (Release 22.0, Ratified, Jan 2022) 161, s 3.4.7 and 161

The table below lists certain scenarios:

Scenario	Actual expiry Date	Encoded data content in barcode (YYMMDD)	Printed presentation examples of the date	HRI or non-HRI?	Acceptable by HA?	How HA interprets the data?	Preferable Printed presentation Formats by HA	HA Remarks
1	May 13, 2021	210513	210513 Or (17)210513	HRI	Yes	May 13, 2021	13 May 2021	This will be the main preferred format. Note: HRI is aligned with GS1 standards and non-HRI is not covered by GS1 standards. See section 6.2
2	May 13, 2021	210513	13 May 2021 Or 13/05/2021 Or 13-05-21	Non-HRI	Yes	May 13, 2021	210513 051321 130521 13/05/2021 13 05 21 13-4-21	All formats are acceptable provided the date format is clearly defined on the sales pack as YYMMDD, DDMMYY or MMDDYY, to prevent open interpretation of either US/UK formats interchangeably. Where the packaging does not allow printing of the above, vendor must specify via affixing a label or other means to define the expiry date format to avoid confusion.
3	May, 2021	210500	May-21 Or 05 2021	Non-HRI	Yes	May 01, 2021	05 2021	Main Message to vendors: HA will follow GS1 guidelines in inclusion of the exact date within the DataMatrix before official enforcement. As stated in section 6.4, the "00" day code will not be allowed after 2025. However, HA will still accept such format if they are approved by the regulatory.

## 7. Glossary of terms <sup>30</sup>

Terms	Signification
AI (Application Identifier)	GS1 Application Identifier: The field of two or more digits at the beginning of an element string that uniquely defines its format and meaning. For example, 01 for GTIN
Brand owner	The organisation that owns the specifications of a trade item, regardless of where and by whom it is manufactured. The brand owner is normally responsible for the management of the Global Trade Item Number (GTIN).
HRI	Human Readable Interpretation (HRI) Characters, such as letters and numbers, which can be read by persons and are encoded in GS1 AIDC data carriers confined to a GS1 standard structure and format. The human readable interpretation is a one-to-one illustration of the encoded data. However start, stop, shift and function characters, as well as the symbol check character, are not shown in the human readable interpretation.
GTIN	Global Trade Item Number®: The GS1 identification key used to uniquely identify trade items. The key comprises a GS1 Company Prefix, an item reference and check digit. E.g. 4891668000008
GS1 DataMatrix	GS1 implementation specification for use of Data Matrix.
Healthcare secondary packaging	A level of packaging marked with an AIDC carrier that may contain one or more primary packages each of which may contain a single item or multiple items.
Serial Shipping Container Code (SSCC)	The GS1 identification key used to identify logistics units. The key comprises an extension digit, GS1 Company Prefix, serial reference, and check digit.

<sup>30</sup> GS1 AISBL, *GS1 General Specifications* (Release 22.0, Ratified, Jan 2022) 505, s 8.1

## 8. Bibliography

GS1 AISBL, *GS1 DataMatrix Guideline* (Release 2.5.1, Ratified, Jan 2018),

GS1 AISBL, *GS1 General Specifications* (Release 21.0.1, Ratified, Jan 2021),

GS1 AISBL, *AIDC Healthcare Implementation Guideline* (Release 3.0.1, Ratified, July 2015)

## 9. Appendix I

5 printed samples of GS1 DataMatrix were submitted to HA for scanning test on 4 November 2020: The scanner used in the test was able to scan 4 out of the 5 samples. Sample 005 could not be scanned, expectedly, as the sample did not have valid quiet zones.

The x-dimension and symbol size of the 5 samples were 0.4mm and 26 x 26 respectively. The images of GS1 DataMatrix below are for reference only: although they are generated from the same source, they are not the actual tested printing.

Samples scanned successfully:

### Sample 001:

- Non-reversed colour: Black bar code and white space.
- Surrounding white background where quiet zones were protected.



(01) 0 4891668 32668 9 (10) PARA01\_B1 (17) 220930

### Sample 002:

- Non-reversed colour: Black bar code and white space.
- Surrounding black background where quiet zones were protected.



**Sample 003:**

- Reversed colour: White bar code and black space.
- Surrounding black background where quiet zones were protected.



**Sample 004:**

- Reversed colour: White bar code and black space.
- Surrounding white background where quiet zones were protected.



**Sample scanned unsuccessfully:**

**Sample 005:**

- Non-reversed colour: Black bar code and white space.
- Surrounding black background where quiet zones were NOT protected.



**End**