

ZAMBIA MEDICINES REGULATORY AUTHORITY



GUIDELINE ON TRACEABILITY OF MEDICINES

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GUIDELINE DEVELOPMENT HISTORY

Author	Date
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ACRONYMS

2D	two-dimensional
AI	GS1 Application Identifier
AIDC	automatic identification and data capture
FNC1	Function 1 Symbol Character
GDSN	GS1 Global Data Synchronization Network
GLN	Global Location Number
GTIN	Global Trade Item Number
HRI	human readable interpretation
MAH	marketing authorization holder
MO	GS1 Member Organization
NPC	National Product Catalogue
SSCC	Serial Shipping Container Code
ZAMRA	Zambia Medicines Regulatory Authority

DEFINITIONS

In this guideline, unless the context otherwise requires -

“**Aggregation**” means the Aggregation defines the hierarchy relationship between the unique identifiers for parent and child packaging hierarchies, where each packaging level will carry a unique identifier encoded in a data carrier. uniquely identified allowing the receiver of the product to scan one code and understand exactly what is in the whole shipment—every case, bundle, or individual carton;

“**Automatic identification and data capture (AIDC)**” means a technology used to automatically capture data. AIDC technologies include barcodes, smart cards, biometrics, and radio frequency identification devices;

“**Barcode**” means a symbol that encodes data into a machine-readable pattern of adjacent, varying width, parallel, rectangular dark bars and pale spaces.;

“**Batch/lot**” means the batch or lot number associates an item with production information that the manufacturer considers relevant for traceability of the trade item. The data may refer to the trade item itself or to items contained in it;

“**Data Matrix**” means a standalone, two-dimensional (2D) matrix symbology that is made up of square modules arranged within a perimeter finder pattern. Data Matrix symbols are read by two-dimensional imaging scanners or vision systems;

“**EAN-13 barcode**” means a barcode of the EAN/UPC symbology that encodes a GTIN for retail purposes;

“**Expiration date**” means the date up until which the drug manufacturer can guarantee that the medicine is fully potent and safe to take based on scientifically-sound product testing;

“**Function 1 Symbol Character (FNC1)**” Means a Function 1 Symbol Character (FNC1) indicates that the barcode is a GS1 symbology so that the scanner understands how to decode it. It is a separator in between different Application Identifiers that do not have a fixed character count (e.g., AI (10) Batch/Lot, AI (21) Serial Number);

“Global Trade Item Number (GTIN)” Means the GS1 identification key used to identify trade items. The key comprises a GS1 Company Prefix, an item reference and check digit;

“GS1” Means a neutral, not-for-profit, global organization that develops and maintains the most widely used supply chain data standards in the world;

“GS1 Application Identifier” Means the field of two or more digits at the beginning of an element string that uniquely defines its format and meaning;

“GS1 Member Organization” Means a member of GS1 that is responsible for administering the GS1 system in its country (or assigned area). This task includes, but is not restricted to, ensuring user companies make correct use of the GS1 system; have access to education, training, promotion, and implementation support; and have opportunity to play an active role in the Global Standards Management Process;

“GS1-128 linear barcode” Means a barcode symbology using bars and spaces in one dimension that leverages a subset of Code 128 that is used exclusively for GS1 system data structures;

“Homeopathic medicine” Means homeopathic medicine, or homeopathy, is a form of complementary and alternative medicine that uses very small amounts of natural substances, which in higher amounts may cause a disease or symptom;

“Human readable form” Means 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 form is a one-to-one illustration of the data encoded in a data carrier. However, start, stop, shift and function characters, as well as the symbol check character, are not shown in the human readable form;

“Marketing Authorisation” Means the authorisation granted under section thirty-nine of the Medicines and Allied Substances Act (No. 3) of 2013 of the laws of Zambia for the placement of a medicine or allied substance on the Zambian Market;

“Label” Means Any tag, brand, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed or impressed on or attached to a container of any medicines and allied substances;

“Logistic unit” Means an item of any composition established for transport and/or storage of pharmaceuticals that needs to be managed through the supply chain. It is identified with an SSCC;

“Marketing Authorization Holder (MAH)” means any legal entity which holds a marketing authorization issued by ZAMRA to distribute and sell its medicine or allied substance in Zambia;

“Master data” means the identification number and descriptive attributes of an object that are static or nearly so that provide more information or characteristics of the object identified;

“Package” means any material that may be used for filling, inserting or wrapping or packing regulated products and includes the immediate container and other wrapping materials;

“Medicine” means a human medicine, veterinary medicine, medicinal product, herbal medicine or any substance or mixture of substances for human or veterinary use intended to be used or manufactured for use for its therapeutic efficacy or for its pharmacological purpose in the diagnosis, treatment, alleviation, modification or prevention of disease or abnormal physical or mental state or the symptoms of disease in a person or animal;

“Primary packaging” means the first level of packaging for the product marked with an AIDC data carrier either on the packaging or on a label affixed to the packaging. For non-sterile packaging, the first level of packaging can be in direct contact with the product. For sterile packaging, the first level of packaging can be any combination of the sterile packaging system and may consist of a single item or group of items for a single therapy such as a kit. For packaging configurations that include a retail consumer trade item, primary packaging is a packaging level below the retail consumer trade item.

“Secondary packaging” means a level of packaging marked with an AIDC carrier that may contain one or more primary packages or a group of primary packages containing a single item.

“Serial number” means a numeric or alphanumeric sequence of maximum 20 characters, generated by a deterministic or a non-deterministic randomization algorithm.

“Serial Shipping Container Code (SSCC)” means the GS1 identification key used to identify logistics units. The key comprises an extension digit, GS1 Company Prefix, serial reference, and check digit.

“Tertiary homogenous pack” means a tertiary pack that consists entirely of the same trade item with the same batch number and expiration date.

“Tertiary mixed pack” means a tertiary pack that contains either more than one unique trade item or entirely the same trade item with different batch numbers or expiration dates.

“Tertiary packaging” means the highest level of packaging that may include a pallet that contains (one or usually) several cases or a case that contains (one or usually) several items in its primary or secondary packaging. Tertiary packaging may refer to either a logistic unit or a trade item.

“Tertiary partial pack” means a homogenous pack of products that is not to be considered a trade item because it is less than full.

“Traceability” means the ability to track forward the movement through specified stage(s) of the extended supply chain and trace backward the history, application or location of a pharmaceutical product.

“Trade item” means any item (product) upon which there is a need to retrieve predefined information and that may be priced, ordered, or invoiced at any point in any supply chain.

“Traditional medicine” means also known as indigenous or folk medicine; comprises medical aspects of traditional knowledge that developed over generations within the folk beliefs of various societies before the era of modern medicine.

“Unique identifier” means a numeric or alphanumeric string captured in a machine-readable data carrier and human-readable form on the label of the pharmaceutical package that is associated with a single product or product group.

1.0 INTRODUCTION

1.1 The Authority

The Medicines and Allied Substances (Marketing Authorisation of Medicines) Regulations, 2019 in particular regulation 20 (j) promulgated under the Medicines and Allied Substances Act No. 3 of 2013, gives the Zambia Medicines Regulatory Authority (ZAMRA) the mandate to enforce a ‘suitable coding’ system for all medicines meant for the Zambian market as part of “Product Labelling and Packaging Requirements”. The Authority adopted the use of the global standards in identification, sharing and capturing of data labelled on medicines as it is widely accepted globally and is robust enough to meet the needs of the Authority and various stakeholders. Therefore, this guideline shall apply to all medicines which are meant for supply to the Zambian market.

1.1 Purpose

Established by the Act of Parliament, the Zambia Medicines Regulatory Authority’s main objective is to ensure that all medicines and allied substances being made available to the Zambian people consistently meet the set standards of quality, safety and efficacy. With this mandate comes a need to provide guidelines for the implementation of existing global standards which provide simplicity and consistency by enabling the identification, automated data capture, and exchange of data about these items in ways that can be used in any industry, in any country, and with any Marketing Authorisation Holder.

By leveraging on existing global standards for labelling and packaging of medicines, ZAMRA hopes to create efficiencies in the public and private health supply chains through standardized identification, automated data capture, and decreased cost in gaining compliance. Specifically, global standards for labelling and packaging are aimed at:

- Supporting interoperability between supply chain information systems;
- Increasing quality of data for decision-making by regulators and supply chain stakeholders.
- Enabling efficiencies across the supply chain;
- Promoting trust in the pharmaceutical sector and healthcare system;
- Creating visibility into and enabling controls to address the pilferage of commodities on the market;

- 33 • Facilitating new controls against substandard and falsified medicines ultimately
34 increasing patient safety

35 This document is intended to provide manufacturers, marketing authorization holders, and/or other
36 supply chain stakeholders seeking to import and distribute pharmaceuticals in Zambia with further
37 information on how to implement labelling requirements as outlined under Regulations 20 (j) of
38 Statutory Instrument No. 79 of 2019 and regulations on traceability and tracking of medicines on
39 the Zambian market.

40

41 **1.3 Scope of the guideline**

42 This guideline applies to all medicines to be placed on the Zambian market with the exception of:

- 43 • Products submitted to the Authority for quality analysis;
- 44 • Whole blood and blood components;
- 45 • Homeopathic medicines and allied substances;
- 46 • Extemporaneous preparations;
- 47 • Medicines imported for personal use only subject to authorization by the Authority;
- 48 • Unregistered medicines imported on special authorization by the authority;
- 49 • Donated medicines imported for emergency cases subject to authorization by the Authority;
- 50 and
- 51 • Products manufactured and labelled prior to their unique identification compliance dates.

52

53 **2.0 Overview of Relevant Global Standards**

54 This guideline is based on the use of the GS1 General Specifications as the primary reference
55 document for technical specifications to implement traceability of medicines in accordance with
56 current GS1 global standards and the GS1 General Specifications.

57

58 **2.1 GS1 Identifier**

59 The GS1 Identifiers (AI) referenced in this section are used for identifying trade items and their
60 locations.

61

62 **2.1.1 AI (00) Serial Shipping Container Code (SSCC)**

63 The GS1 Application Identifier (AI) (00) indicates that the data field contains an SSCC. The SSCC
64 is used to uniquely identify a logistic unit. The SSCC must remain unique and not be reallocated for

65 a minimum of one year from the shipment date of the logistic unit, in accordance with GS1 General
 66 Specifications.

67 The SSCC format is as follows:

68

GS1 Application Identifier	Serial Shipping Container Code (SSCC)			
	Extension digit	GS1 Company Prefix →	← Serial Reference	Extension digit
0 0	N ₁	N ₂ N ₃ N ₄ N ₅ N ₆ N ₇ N ₈ N ₉ N ₁₀ N ₁₁ N ₁₂ N ₁₃ N ₁₄ N ₁₅ N ₁₆ N ₁₇		N ₁₈

69
70

71 For information on how to generate an SSCC and apply it to a logistics label, please refer to the GS1
 72 General Specifications and the following resources:

- 73 • <http://www.gs1.org/barcodes/technical/idkeys/sscc>
- 74 • https://www.gs1.org/docs/tl/GS1_Logistic_Label_Guideline.pdf

75

76 **2.1.2 AI (01) Global Trade Item Number (GTIN)**

77 The GS1 AI (01) indicates that the data field contains a GTIN. The GTIN is the globally unique GS1
 78 identification number used to identify trade items. GTINs are assigned by the brand owner (MAH)
 79 of the trade item and are used to identify trade items as they move through the global supply chain
 80 to the end user.

81 The GTIN may be comprised of 8, 12, 13, or 14 digits. The format of the GTIN-14 is as follows:

GS1 Application Identifier	Global Trade Item Number (GTIN)			
	GS1-8 Prefix or GS1 Company Prefix →	← Item Reference	Check digit	
0 1	N ₁ N ₂ N ₃ N ₄ N ₅ N ₆ N ₇ N ₈ N ₉ N ₁₀ N ₁₁ N ₁₂ N ₁₃		N ₁₄	

82
83

84 For information on how to generate and maintain a GTIN, please refer to the GS1 General
 85 Specifications and the following resources:

- 86 • <http://www.gs1.org/gtin>
- 87 • <https://www.gs1.org/1/gtinrules/en/healthcare>

88

89 **2.1.3 AI (10) Batch/lot**

90 The GS1 AI (10) indicates that the data field contains a batch or lot number. The batch or lot number
 91 field is alphanumeric.

92

93 The format of the batch or lot number is as follows:

94

GS1 Application Identifier	Batch or Lot Number
1 0	X_1 —————> variable length —————> X_{20}

95

96

97 2.1.4 AI (17) Expiration date

98 The GS1 AI (17) indicates that the data field contains an expiration date. The structure of the
99 expiration date should be as follows:

100 Year: the tens and units of the year (e.g., 2003 = 03), which is mandatory

101 Month: the number of the month (e.g., January = 01), which is mandatory

102 Day: the number of the day of the relevant month (e.g., second day = 02), which is optional

103 The format of the expiration date is as follows:

104

GS1 Application Identifier	Expiration Date					
	Year		Month		Day	
1 7	N_1	N_2	N_3	N_4	N_5	N_6

105

106

107 2.1.5 AI (21) Serial number

108 The GS1 AI (21) indicates that the data field contains a serial number. When combined with a GTIN,
109 a serial number uniquely identifies an individual item. The manufacturer determines the serial
110 number.

111 The serial number field is alphanumeric. The character sequence resulting from the combination of
112 the GTIN and the serial number will be unique to a given pack of a trade item at least one year after
113 the pack's expiration date or five years after the pack has been released for sale or distribution,
114 whichever is the longer period.

115 The format of the serial number is as follows:

116

GS1 Application Identifier	Serial Number
2 1	X_1 —————> variable length —————> X_{20}

117

118

119 **2.2 Capture**

120 All tertiary and secondary packages are required to be labelled in accordance with the specified
121 barcode requirement, with relevant GS1 Identifiers encoded and printed in their human readable
122 form.

123
124 All barcode symbols should meet print-quality “Grade C” (1.5 or above). As part of the regular
125 manufacturing or production process, barcode symbol print quality and data content must be verified
126 and graded in accordance with the appropriate sections within the GS1 General Specifications. Many
127 GS1 Member Organizations provide comprehensive barcode verification services to ensure
128 companies are implementing barcode labelling requirements to specification based on optical and
129 data structure requirements.

131 **2.2.1 GS1-128 barcode**

132 A GS1-128 barcode is a linear barcode symbology using bars and spaces in one dimension that
133 leverage a subset of Code 128 that is used exclusively for GS1 system data structures. A linear
134 barcode can be concatenated (i.e., represent all elements of a data string in a single barcode) or non-
135 concatenated (i.e., represent individual elements of a data string over two or more barcodes). The
136 barcode for the logistic unit shall be presented in a concatenated manner only. The barcode for the
137 trade item may be presented in either a concatenated or non-concatenated manner where necessary.

138
139 *Example of a GS1-128 barcode for a logistic unit*



140
141

Example of a GS1-128 barcode for a trade item

Concatenated (preferred)



Non-concatenated (only if necessary)



142
143

144 **2.2.2 GS1 Data Matrix**

145 A GS1 Data Matrix is a two-dimensional matrix symbology that is made up of square modules
146 arranged within a perimeter finder pattern. Two-dimensional imaging scanners or vision systems
147 read Data Matrix symbols.

148

149 *Example of a GS1 Data Matrix for a logistic unit*

150



151 (00) 0 0614141 123452

152

153 *Example of a GS1 Data Matrix for a trade item*

154

(01) 10857674002017
(17) 251231
(10) NYFUL01
(21) 192A837H7



155

156

157

158 **3.0 DESCRIPTION OF PACKAGING LEVELS**

159

160 This section provides for descriptions of each level of the packaging hierarchy for a trade item or
161 logistic unit. Stakeholders should consult the GS1 General Specifications and the GS1 Automatic
162 Identification and Data Capture (AIDC) Healthcare Implementation Guideline, or their GS1
163 Member Organization for additional information.

164

165 **3.1 Tertiary Packaging**

166 Tertiary packaging refers to upper levels of the packaging hierarchy. A tertiary pack may be:

167

- 168 • A pallet that contains one or several cases
- 169 • A case that contains one or several items in the items' primary or secondary packaging

170

171 Tertiary packaging may be used as either a logistic unit or as a trade item. Tertiary packages can be
172 homogenous (i.e., consisting entirely of the same trade item, batch or lot, and expiration date), partial
173 (i.e., consisting of a homogenous pack of items that is not to be considered a trade item because it
174 is less than full), or mixed (i.e., either more than one unique trade item or entirely the same trade
175 item with different batch numbers or expiration dates).

176

177 It is recommended that labels containing the barcode symbols, with associated human readable form,
178 be positioned on two faces of the tertiary packaging to enable ready access for scanning when the
179 trade item or logistic unit is stored, stocked or handled.

180

181 **3.1.1 Logistic Unit**

182 A logistic unit is an item of any composition established for transport and/or storage that needs to
183 be managed through the supply chain. In many instances, the tertiary package logistic unit takes the
184 form of a pallet, an export carton or other specific authorised form.

185 The logistic unit is identified using the serial shipping container code (SSCC). This packaging level
186 is marked with a GS1-128 barcode, with the option to also include a GS1 Data Matrix, either on the
187 packaging itself or on a label affixed to the packaging.
188

189 3.1.2 Trade Item

190 The tertiary package trade item will typically be a case or carton but may also be a shrink-wrapped
191 tray or other configuration.
192

193 A homogenous pack trade item is identified with a GTIN, batch or lot number, expiration date, and
194 serial number. A mixed or partial pack item is considered a logistic unit and identified with an SSCC.
195 This packaging level can be marked with a GS1-128 barcode or a GS1 Data Matrix, with a strong
196 preference for a GS1 Data Matrix, either on the packaging itself or on a label affixed to the
197 packaging.
198

199 Examples of tertiary packaging include, but are not limited to:
200



201
202
203

204 3.2 Secondary Packaging

205 Secondary packaging is a level of packaging that may contain one or more primary packages, or a
206 group of primary packages containing a single item. The secondary pack is always a trade item. This
207 packaging level is marked with a GS1 Data Matrix, either on the packaging itself or on a label
208 affixed to the packaging.
209

210 Examples of secondary packaging include, but are not limited to:
211



212

Group of primary packages containing a single item

One primary package

One or more primary packages

Group of primary packages containing a single item

213
214

215 In-scope commodities can have more than one level of secondary packaging, such as an inner pack
216 (bundles) and intermediate packs (inner case). Identification and marking of inner and intermediate
217 secondary packaging levels is required. Examples of inner or intermediary secondary packaging
218 include, but are not limited to:
219



220
221
222

223 3.3 Primary Packaging

224 Primary packaging is the first level of packaging that is in direct contact with the trade item. This
225 packaging level is marked with a GS1 Data Matrix, either on the packaging itself or on a label
226 affixed to the packaging.

227 Identification and labelling of trade items at this level is a preferred characteristic unless the supplier
228 is providing items in “carton less packaging”, i.e., without a secondary packaging level, in which
229 case it is mandatory. Marking trade items at this level is also recommended where the secondary
230 package will likely be opened or removed before being dispensed to one or several patients (e.g., a
231 display carton is opened, and individual or split blister packs are distributed to patients).

232 Examples of primary packaging include, but are not limited to:

233



234
235
236

237 4.0 REQUIREMENT FOR PHARMACEUTICAL PRODUCT 238 IDENTIFICATION AND LABELLING

239 This section describes how to implement the product identification and labelling requirements. Refer
240 to the GS1 General Specifications and the GS1 AIDC Healthcare Implementation Guideline, or their
241 GS1 Member Organization for additional information.
242

243 4.1 Tertiary Pack Logistic Unit

244 All tertiary pack logistic units must include a GS1-128 barcode encoded with the following
245 information and printed adjacent to the data carrier in human readable form:

246

AI	Description	Required by
00	SSCC	No later than 5 years from date of publication of the guidelines

247 A Serial Shipping Container Code may be re-used after a period of one year, as noted within the
248 GS1 General Specifications.

249

250 An example of this in practice:

251



(00)006141411234567890

252

253

254 Encoded in the data carrier, this example will take on the following format:

255

FNC Opening Character	AI	SSCC
FNC1	00	006141411234567890

256

257 Read via AIDC technology, this example will take on the following format:

258

259]c100006141411234567890

260

261 4.2 Tertiary Pack Trade Item

262 All tertiary pack trade item packages must include a GS1-128 barcode or a GS1 Data Matrix encoded
263 with the following information and printed adjacent to the data carrier in Human Readable form:

264

AI	Description	Required by
01	GTIN	No later than 2 years for imported medicines and 3 years for domestically manufactured medicines from date of publication of the guidelines
10	Batch or Lot	No later than 2 years for imported medicines and 3 years for domestically manufactured medicines from date of publication of the guidelines
17	Expiration Date	No later than 2 years for imported medicines and 3 years for domestically manufactured medicines from date of publication of the guidelines
21	Serial Number	No later than 5 years from date of publication of the guidelines

265

266 An example of this in practice:

267

(01) 10857674002017
(17) 251231
(10) NYFUL01
(21) 192A837H7



268

269



(01)10857674002017(17)251231(10)NYFUL01(21)192A837H7

270

271
272
273
274
275
276

Encoded in the data carrier, these examples will take on the following format:

FNC Opening Character	AI	GTIN	AI	Expiration Date	AI	Batch/ Lot Number	FNC Separator	AI	Serial Number
FNC1	01	10857674002017	17	251231	10	NYFUL01	<GS>	21	21192A837H7

277
278
279

Read via AIDC technology, this example will take on the following format:

280]d201108576740020171725123110NYFUL01<GS>21192A837H7

281

282 The character sequence resulting from the combination of the product identifier and the serial
283 number shall be unique to a given pack of a medicine.

284

285 The Authority shall not stipulate the order in which data is encoded into the data carrier. However,
286 for the most efficient encoding, it is recommended to have fixed-length data elements precede
287 variable-length elements. In this instance where a tertiary pack trade item is also considered a logistic
288 unit, the SSCC can be applied in lieu of the serialized GTIN.

289

290 Stakeholders shall notify the Authority if they need to add information other than the four data
291 elements described above in the unique identifier.

292

293 4.3 Secondary Pack Trade Item

294 All secondary trade item packaging must include a GS1 Data Matrix encoded with the following
295 information and printed adjacent to the data carrier in human readable form:

296

AI	Description	Required by
01	GTIN	No later than 2 years for imported medicines and 3 years for domestically manufactured medicines from date of publication of the guideline
17	Expiration Date	No later than 2 years for imported medicines and 3 years for domestically manufactured medicines from date of publication of the guideline
10	Batch or Lot	No later than 2 years for imported medicines and 3 years for domestically manufactured medicines from date of publication of the guideline
21	Serial Number	No later than 5 years from date of publication of the guideline

297

298 An example of this in practice:

299

(01) 10857674002017
(17) 251231
(10) NYFUL01
(21) 192A837H7



300
301

302 Encoded in the data carrier, this example will take on the following format:

303

FNC Opening Character	AI	GTIN	AI	Expiration Date	AI	Batch/Lot Number	FNC Separator	AI	Serial Number
FNC1	01	10857674002017	17	251231	10	NYFUL01	<GS>	21	21192A837H7

304 Read via AIDC technology, this example will take on the following format:

305

306]d201108576740020171725123110NYFUL01<GS>21192A837H7

307

308 The character sequence resulting from the combination of the product identifier and the serial
309 number shall be unique to a given pack of a medicine.

310 The Authority shall not stipulate the order in which data is encoded into the data carrier. However,
311 for the most efficient encoding, it is recommended to have fixed-length data elements precede
312 variable-length elements.

313 Stakeholders shall notify the Authority if they need to add information other than the four data
314 elements described above in the unique identifier.

315

316 4.4 Primary Pack Trade Item

317 Identification and labelling of trade items at the primary trade item packaging level is a preferred
318 characteristic unless the supplier is providing items in “carton less packaging”, i.e., without a
319 secondary packaging level, in which case it is mandatory.

320 If implemented, the unique identifier for the primary pack must include a GS1 Data Matrix encoded
321 with the following information and printed adjacent to the data carrier in human readable form:

322

AI	Description	Required by
01	GTIN	No later than 2 years for imported medicine and 3 years for domestically manufactured medicines from date of publication of the guideline
17	Expiration Date	No later than 2 years for imported medicine and 3 years for domestically manufactured medicines from date of publication of the guideline
10	Batch/ Lot	No later than 2 years for imported medicine and 3 years for domestically manufactured medicines from date of publication of the guideline
21	Serial Number	No later than 5 years from date of publication of the guideline

323

324 An example of this in practice:

325

(01) 10857674002017
(17) 251231
(10) NYFUL01
(21) 192A837H7



326

327

328 Encoded in the data carrier, this example will take on the following format:

329

FNC Opening Character	AI	GTIN	AI	Expiration Date	AI	Batch/Lot Number	FNC Separator	AI	Serial Number
FNC1	01	10857674002017	17	251231	10	NYFUL01	<GS>	21	21192A837H7

330
331 Read via AIDC technology, this example will take on the following format:
332
333 jd201108576740020171725123110NYFUL01<GS>21192A837H7
334
335 The character sequence resulting from the combination of the product identifier and the serial
336 number shall be unique to a given pack of a medicine.
337
338 The Authority shall not stipulate the order in which data is encoded into the data carrier. However,
339 for the most efficient encoding, it is recommended to have fixed-length data elements precede
340 variable-length elements.
341
342 Stakeholders shall notify the Authority if they need to add information other than the four data
343 elements described above in the unique identifier.
344

345 **5.0 REQUIREMENT FOR MEDICINES AND LOCATION MASTER DATA** 346 **SHARING**

347 This section provides guidance to manufacturers, marketing authorization holders, and/or other
348 supply chain stakeholders on the collection and submission of product and GS1-based trade item
349 master data to the marketing authorization register, National Product Catalogue (NPC)register,
350 including GTINs and relevant Global Location Numbers (GLNs) for medicines procured and
351 supplied to the Zambian market.

352 353 **5.1 ZAMRA Master Data Attribute Requirements**

354 The Attribute List (see Appendix A) is the primary reference document for Marketing Authorization
355 Holders regarding master data attribute requirements. It includes all initial priority attributes to be
356 provided as relevant on trade items supplied to the Authority. For each attribute, the guide provides
357 the category, attribute name, description, and an example.

358 **Attribute Significance**

Attribute Requirement	No. of attributes
Mandatory Attributes that must be populated to share with ZAMRA	13
Optional Attributes that should be populated if available, but not yet mandatory for ZAMRA	52
Total attributes	65

Attribute Grouping	Description
General Item Information	General information about the trade item
Product Description Information	Supplier product descriptions and other descriptive information
Unit Indicators	Supply chain characteristics
Dimensions	Trade item dimensions, weights and measures
Contact/Role Information	Manufacturer, supplier and information provider contact information (name, address and contact method)
Pharmaceutical Information	Information on dosage and route of administration
Hierarchy	Trade item hierarchy (packaging levels) information
Storage, Handling & Shelf Life	Defines the information and processes needed to safely handle the trade item.
Product Classifications	Product classification details
Dangerous & Hazardous Goods Information	Information on dangerous and hazardous goods and waste classification
Referenced Trade Item Identification	These attributes support identification of substitute or alternate trade items from the same brand owner.

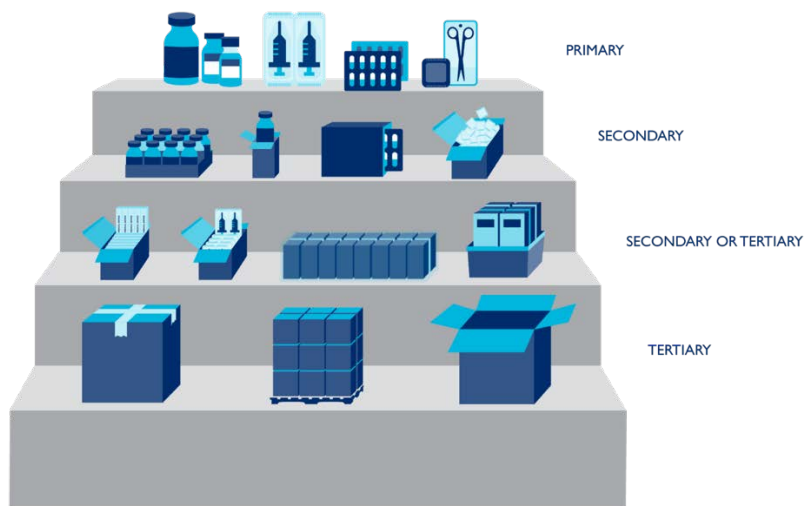
360

361 **5.2 Steps for Sharing Product and Location Master Data with ZAMRA**

362 To synchronize data with ZAMRA, Marketing Authorisation Holders are advised to undertake the
 363 following actions:

- 364 1. Assign a GLN for each of the relevant locations or legal entities, including Marketing
 365 Authorisation Holder and manufacturing site.
- 366 2. Assign a GTIN to each level of the trade item packaging hierarchy (e.g., each, inner, case,
 367 pallet).² An example of a trade item packaging hierarchy in the healthcare context is:

368



369 *Figure 1. Identification at healthcare levels of packaging*
 370
 371

- 372 3. Gather the product and location attribute data on each trade item packaging hierarchy level,
373 per the ZAMRA Product and Location Master Data Attribute Guide (Appendix A). Note that
374 these attributes are based on the GS1 Global Data Synchronization Network (GDSN)
375 standard.
- 376 4. Populate the ZAMRA Product and Location Master Data Submission Form (Appendix A)
377 in Excel format and submit with the marketing authorization application. If submitting an ad
378 hoc request for master data from the ZAMRA or providing an update to data submitted
379 through the marketing authorization process, email your form to pharmacy@zamra.co.zm.
- 380 5. MAHs are expected to ensure that the master data provided for registered products is
381 maintained and updated as necessary. If there are any changes to the master data provided
382 on your products or relevant locations, send an updated template to the Authority within 30
383 days of implementing the change.

384

385 Please note that the Authority seeks to enable direct submission of product and location master data
386 to the NPC over time, either via direct entry or a form of electronic data exchange (e.g. GDSN).
387 This guideline will be updated as those capabilities are developed, tested, and deployed.

388
389

390 **6.0 SUPPORTING RESOURCES**

- 391
- 392 Find a GS1 Member Organization
- 393
- 394 Use this resource to find a GS1 Member Organization to register your company.
- 395 <https://www.gs1.org/contact/overview>
- 396
- 397 GS1 General Specification
- 398
- 399 This resource is the primary document that details the foundational GS1 standards that defines how
- 400 identification keys, data attributes and barcodes must be used in business applications.
- 401 https://www.gs1.org/docs/barcodes/GS1_General_Specifications.pdf
- 402
- 403 10 Steps to Barcode Your Product
- 404
- 405 This resource provides a step-by-step instruction for implementing AIDC on your products.
- 406 <http://www.gs1.org/barcodes/implementation>
- 407
- 408 GS1 GTIN Healthcare Allocation Rules
- 409
- 410 This resource provides the rules for assigning GTINs to trade items in the health sector.
- 411 https://www.gs1.org/docs/gsmf/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf
- 412
- 413 AIDC Healthcare Implementation Guideline
- 414
- 415 This resource provides information on the more technical aspects of implementing AIDC for
- 416 healthcare on various levels of packaging.
- 417 https://www.gs1.org/docs/healthcare/GS1_Healthcare_Implementation_Guideline.pdf
- 418
- 419 GS1 Global Data Dictionary
- 420
- 421 The GS1 Global Data Dictionary (GDD) is a repository of the data elements defined across all GS1
- 422 Standards. Attributes in the GDD are described using data types, some of which may contain code
- 423 lists. Each GS1 Standard is represented in the GDD, sorted by the type of data exchange standard
- 424 including Global Data Synchronization Network (GDSN).
- 425 <http://apps.gs1.org/GDD/SitePages/Home.aspx>
- 426
- 427 Global Standards Technical Implementation Guideline for Global Health Commodities
- 428
- 429 This resource was developed by a set of international procurement agents in the global health
- 430 community to support suppliers in meeting their AIDC requirements. It includes a number of
- 431 technical references and a Frequently Asked Questions section that may be useful to Marketing
- 432 Authorisation Holders in their implementation.
- 433 [http://ghsupplychain.org/global-standards-technical-implementation-guideline-global-health-](http://ghsupplychain.org/global-standards-technical-implementation-guideline-global-health-commodities-v21)
- 434 [commodities-v21](http://ghsupplychain.org/global-standards-technical-implementation-guideline-global-health-commodities-v21)
- 435
- 436

437 **Appendix A. ZAMRA Product and Location Master Data Attribute Guide and**
438 **Submission Form**



439
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441