WR #	GSCN Name	Effective Date
21-000289	National Healthcare Reimbursement Number (NHRN) AI for US FDA National Drug Code (NDC)	Dec-2021

Associated Work Request (WR) Number:

N/A

Background:

The U.S. Pharmaceutical industry and their collective global supply chains are approaching the final enforcement milestone of the Drug Supply Chain Security Act (DSCSA), November 2023. The DSCSA has requirements on the content of data carriers, which to use, the human readable text adjacent to the carriers, and the format of the text. Industry long supported standards-based solutions to enacting traceability for DSCSA requirements. Considering the impact to manufacturing processes, industry is submitting this request now to provide ample time to transition practices to include this additional AI on the label and in the data carrier.

Disclaimer:

GS1 General Specifications Change:

2.1.5 Healthcare primary packaging (non-retail trade items)

Application description

Healthcare primary packaging trade items are pharmaceutical and medical products or their packages presented to support the point-of-care (direct consumption based on right product, dose, and route of administration). Because the product is never scanned at retail POS, the use of symbologies beyond EAN/UPC and the use of GTIN-14 data structure is permitted.

These products, which may be packaged in a sterile packaging system or in a non-sterile packaging system, are only marked when the package is intended for dispensing to the consumer in a hospital or equivalent facility (e.g., field hospital, nursing home, home healthcare).

See section 4.16.1 *Multiple barcode management practices for consumer trade items – all sectors* and section 4.16.3 *Multiple barcode management practices for healthcare* if the product is intended for scanning at general retail and also must meet regulatory requirements for this application section based on multiple market use. If an item is a regulated healthcare retail consumer trade item and also a non-retail trade item then the barcode marking for regulated healthcare retail consumer trade items is required at a minimum.

GS1 key

Required

The allowed key formats for this application are:

- GTIN-8
- GTIN-12
- GTIN-13
- GTIN-14

Rules

All the GTIN rules described in section 4.

If the regulated healthcare retail consumer trade item to be marked on the primary packaging does not also have secondary packaging, then the primary packaging markings in this section do not apply and are replaced by the required markings in the secondary packaging section (2.1.6).

> ***Example:*** *a bottle of 50 pharmaceutical tablets (the primary package) is not enclosed into a carton (which would represent the secondary packaging). In this instance, the secondary packaging markings are required on the primary packaging level.*

If the required AIDC marks are placed directly on the part, then those AIDC marks (e.g., barcode, human readable interpretation) satisfy the requirements for primary package marking. If those marks are functional (scannable) through the primary packaging, then no additional AIDC marks are required on the primary package.

If the product to be marked has primary packaging that is a blister pack containing several individual pharmaceutical items, for instance a blister pack of 12 pills or tablets, the following rules apply:

- GTIN is the only required mark.
- In addition to the GTIN rules described in section 4, see section 4.3.7 for rules on deploying GTIN-8.

Attributes

Required

Figure 2.1.5-1. Overview of required attributes

AIDC marking level for regulated healthcare trade items	Key	Batch/lot number - AI (10)	Expiration date – AI (17)	Serial number – AI (21)	Other
Minimum (pharmaceutical only)	GTIN-8, GTIN-12, GTIN-13, or GTIN-14	No	No	No	None
Enhanced (med device only)	GTIN-8, GTIN-12, GTIN-13, or GTIN-14	Yes	Yes	No	None
Highest – pharmaceutical brand owner AIDC marking	GTIN-8, GTIN-12, GTIN-13, or GTIN-14	No	No	No	None
Highest – medical device - brand owner AIDC marking	GTIN-8, GTIN-12, GTIN-13, or GTIN-14	Yes	Yes	Yes	Active potency, AI (7004), for kits with pharmaceuticals
Highest – hospital AIDC marking of pharmaceutical	GTIN-8, GTIN -12, GTIN -13, or GTIN -14	No	Yes, Expiration date and time, AI (7003), if needed for short life items	Yes	None
Highest – hospital AIDC marking of certain medical devices (see section 2.1.8)	GRAI, AI (8003), or GIAI, AI (8004), is optional if GTIN, AI (01), + serial number, AI (21), is not marked on the product.	No	No	GRAI, AI (8003), or GIAI, AI (8004), is optional if GTIN, AI (01), + serial number, AI (21), is not marked on the product.	

To manage healthcare data requirements within GS1 EPC/RFID tags, see section 3.11 and the most recent version of the *EPC Tag Data Standard*.

Optional

For compliance with a national/regional regulatory or industry requirement where the GTIN will not meet the need, a regulated healthcare trade item may be identified with GTIN and AI (710), AI (711), AI (712), AI (713), AI (714), and AI (7154) National Healthcare Reimbursement Number, see section 3.8.18.

Rules

All the GTIN rules described in section 4.

National Healthcare Reimbursement Number AI (710), AI (711), AI (712), AI (713), AI (714), and AI (7154) must always be used with the GTIN.

Human readable interpretation

For human readable interpretation rules see section 4.15. For HRI rules specific to regulated healthcare retail consumer trade items, see section 4.15.1.

AIDC marking level for regulated healthcare trade items	Key	Batch/lot number - AI (10)	Expiration date – AI (17)	Serial number – AI (21)	Other
Highest – Brand owner AIDC marking	GTIN-8, GTIN-12, or GTIN-13	Yes	Yes	Yes	Potency AI (7004) (for pharmaceutical, and for medical device kits with pharmaceuticals)
Highest – Hospital AIDC marking of pharmaceuticals	GTIN-8, GTIN-12, or GTIN-13	No	Yes, AI (7003) if needed for short life items	Yes	None
Highest - Hospital AIDC marking of certain medical devices (see section 2.1.8)	GRAI, AI (8003), or GIAI, AI (8004), is optional if GTIN, AI (01), + serial number, AI (21), is not marked on the product.	No	No	GRAI, AI (8003), or GIAI, AI (8004), is optional if GTIN, AI (01), + serial number, AI (21), is not marked on the product.	

To manage healthcare data requirements within EPC/RFID tags, see section 3.11 and the most recent version of the *EPC Tag Data Standard*.

Optional

For compliance with a national/regional regulatory or industry requirement where the GTIN will not meet the need, a regulated healthcare trade item may be identified with GTIN and AI (710), AI (711), AI (712), AI (713), AI (714)$_7$ and AI (7154) National Healthcare Reimbursement Number. See section 3.8.18 for details on the use of AI (710), AI (711), AI (712), AI (713), AI (714)$_7$ and AI (7154).

Rules

National Healthcare Reimbursement Number AI (710), AI (711), AI (712), AI (713), AI (714)$_7$ and AI (7154) must always be used with the GTIN.

Data carrier specification

Carrier choices

See the "data carrier specification carrier choices" recommendations on preferred options, options in addition to the barcode and other acceptable options found at the end of section 2.1.5.

Symbol X-dimensions, minimum symbol height, and minimum symbol quality

For regulated healthcare consumer trade items scanned in retail pharmacy and general distribution or non-retail pharmacy and general distribution see section 5.12.3.8, *GS1 symbol specification table 8*.

For regulated healthcare retail consumer trade items not scanned in general distribution see section 5.12.3.10, *GS1 symbol specification table 10*.

Symbol placement

All the symbol placement guidelines defined in section 6.

Unique application processing requirements

For a description of processing requirements, see section 7.

AI	Data Content	Format [1]	FNC1 required [4]	Data title
7010	*Production method: AI (7010)*	N4+X..2	(FNC1)	PROD METHOD
7020	*Refurbishment lot ID: AI (7020)*	N4+X..20	(FNC1)	REFURB LOT
7021	*Functional status: AI (7021)*	N4+X..20	(FNC1)	FUNC STAT
7022	*Revision status: AI (7022)*	N4+X..20	(FNC1)	REV STAT
7023	*Global Individual Asset Identifier of an assembly: AI (7023)*	N4+X..30	(FNC1)	GIAI – ASSEMBLY
703s [8]	*Number of processor with three-digit ISO country code: AI (703s)*	N4+N3+X..27	(FNC1)	PROCESSOR # s
7040	*GS1 UIC with Extension 1 and Importer index: AI (7040)*	N4+N1+X3	(FNC1)	UIC+EXT
710	*National Healthcare Reimbursement Number (NHRN) – Germany PZN: AI (710)*	N3+X..20	(FNC1)	NHRN PZN
711	*National Healthcare Reimbursement Number (NHRN) – France CIP: AI 711)*	N3+X..20	(FNC1)	NHRN CIP
712	*National Healthcare Reimbursement Number (NHRN) – Spain CN: AI (712)*	N3+X..20	(FNC1)	NHRN CN
713	*National Healthcare Reimbursement Number (NHRN) – Brasil DRN: AI (713)*	N3+X..20	(FNC1)	NHRN DRN
714	*National Healthcare Reimbursement Number (NHRN) – Portugal AIM: AI (714)*	N3+X..20	(FNC1)	NHRN AIM
715	*National Healthcare Reimbursement Number (NHRN) – United States of America NDC: AI (715)*	N3+X..20	(FNC1)	NHRN NDC
... [5]	*National Healthcare Reimbursement Number (NHRN) – Country "A" NHRN*	N3+X..20	(FNC1)	NHRN xxx
723s [6]	*Certification reference: AI (723s)*	N4+X2+X..28	(FNC1)	CERT # s
7240	*Protocol ID: AI (7240)*	N4+X..20	(FNC1)	PROTOCOL
8001	*Roll products - width, length, core diameter, direction, splices: AI (8001)*	N4+N14	(FNC1)	DIMENSIONS
8002	*Cellular mobile telephone identifier: AI (8002)*	N4+X..20	(FNC1)	CMT No
8003	*Global Returnable Asset Identifier (GRAI): AI (8003)*	N4+N14+X..16	(FNC1)	GRAI
8004	*Global Individual Asset Identifier (GIAI): AI (8004)*	N4+X..30	(FNC1)	GIAI
8005	*Price per unit of measure: AI (8005)*	N4+N6	(FNC1)	PRICE PER UNIT
8006	*Identification of an individual trade item (ITIP)* piece: AI (8006)	N4+N14+N2+N2	(FNC1)	ITIP
8007	*International Bank Account Number (IBAN): AI (8007)*	N4+X..34	(FNC1)	IBAN
8008	*Date and time of production: AI (8008)*	N4+N8+N..4	(FNC1)	PROD TIME
8009	*Optically readable sensor indicator: AI (8009)*	N4+X..50	(FNC1)	OPTSEN
8010	*Component/Part Identifier (CPID): AI (8010)*	N4+X..30	(FNC1)	CPID
8011	*Component/Part Identifier serial number: AI (8011)Component/Part Identifier serial number: AI (8011)*	N4+N..12	(FNC1)	CPID SERIAL
8012	Software version: AI (8012)	N4+X..20	(FNC1)	VERSION
8013	*Global Model Number (GMN): AI (8013)*	N4+X..25	(FNC1)	GMN
8017	*Global Service Relation Number to identify the relationship between an organisation offering services and the provider of services: AI (8017)*	N4+N18	(FNC1)	GSRN - PROVIDER

Figure 3.8.17-1. Format of the element string

GS1 Application Identifier	GS1 UIC with Extension 1 and Importer index		
	GS1 UIC	Extension 1	Importer index
7 0 4 0	N_1X_2	X_3	X_4

The data transmitted from the barcode reader means that the element string denoting a Unique Identification Code has been captured.

When indicating this element string in the non-HRI text section of a barcode label, this element string in the non-HRI text section of a barcode label, the following data title SHOULD be used: **UIC+EXT**

3.8.18 National Healthcare Reimbursement Number (NHRN): AIs (710), (711), (712), (713), (714)~~,~~ and (7154)

The GS1 Application Identifiers (710), (711), (712), (713), (714)~~,~~ and (7154) indicate that the GS1 Application Identifier data field contains a National Healthcare Reimbursement Number, from the NHRN GS1 Application Identifier series, associated to the Global Trade Item Number (GTIN) of the trade item. The GS1 Application Identifiers (710), (711), (712), (713), (714)~~,~~ and (7154) indicate a specific NHRN from within the assigned series.

Use of the NHRN GS1 Application Identifier, associated to the GTIN of the trade item, is needed for compliance with a national/regional regulatory or industry requirement where the GTIN will not meet the need.

GTIN is the GS1 identifier for pharmaceutical and medical device trade items. The GS1 Application Identifier for National Healthcare Reimbursement Number is provided to meet regulatory or industry requirements until they are amended to accept the GTIN as a compliant identifier.

Within this application are the rules and recommendations for the association of NHRNs to the Global Trade Item Number (GTIN) where regulatory requirements require an NHRN for product identification, registration or reimbursement purposes.

There are a number of known NHRNs but at this time not all are required to be encoded within the data carrier found on the trade item. Flexibility for additional assigned NHRN AIs has been provided if required.

The National Healthcare Reimbursement Number GS1 Application Identifier is an initial step in a migration path to the most efficient method to identify trade items. GS1 recommends that Healthcare stakeholders faced with national numbers:

a. Use GTIN for all supply chain and reimbursement purposes (GTIN used in the data carrier and as the NHRN) as this is the most efficient and effective way for all stakeholders to identify trade items.

b. Use GTIN, cross-referenced to an NHRN in an existing database, in the case of an existing system of NHRNs (i.e. GTIN used in the data carrier with the NHRN found via cross-reference).

c. Use GTIN with an associated NHRN (GTIN and NHRN both used in the data carrier via the NHRN AI) as an intermediate solution for those who cannot use "a" or "b". GS1 only recommends this as a migration path to noted options "a" or "b".

Important:

- There is a mandatory association of the National Healthcare Reimbursement Number Application Identifier with the GTIN.
- The NHRN is usually assigned by a national authority to healthcare brand owners for specific trade items and SHALL only be used for compliance to regulatory requirements where the GTIN alone will not meet the requirements.
- Additional individual NHRN AIs can only be assigned by GS1 and only in response to a work request being submitted through GSMP.

- The GTIN and all associated NHRNs SHOULD be concatenated into a single data carrier (i.e. single GS1-128, GS1 DataMatrix).
- Use of NHRN on the item is controlled by and subject to the rules and regulations of national/regional agencies. Those rules and/or regulations may supersede these recommendations.
- More than one NHRN may need to be associated with a given GTIN.

The general format of an NHRN GS1 Application Identifier is:

Figure 3.8.18-1. Format of the element string

GS1 Application Identifier	National Healthcare Reimbursement Number
n n n	X_1———variable length———›X_{20}

When an NHRN AI is approved, the overall variable length (i.e. allowable number of characters) is specified by the national authority, with a twenty (20) character maximum as noted in the general format above if applicable.

The GS1 Application Identifiers used with this element string, their specific format and associated regulatory body or assigning organisation, are shown in the figure below:

Figure 3.8.18-2. Overview of NHRN Application Identifiers

GS1 Application Identifier	National Healthcare Reimbursement Number			Organisation
710	X_1	variable length	X_{20}	Germany IFA
711	X_1	variable length	X_{20}	France CIP
712	X_1	variable length	X_{20}	Spain National Code
713	X_1	variable length	X_{20}	Brazil ANVISA
714	X_1	variable length	X_{20}	Portugal INFARMED
715	X_1	variable length	X_{20}	United States of America FDA
nnn (*)	X_1	variable length	X_{20}	Country "A" NHRN Authority
(*) An example to illustrate future additional NHRNs. If additional NHRN AIs are required, a request for a new NHRN AI SHALL be made through GSMP.				

Companies wishing to apply one of the listed NHRN AIs will need to associate that NHRN AI to the trade item's GTIN according to the NHRN AI rules and should contact their GS1 Member Organisation for further considerations of use.

The data transmitted from the barcode reader means that the element string denoting a National Healthcare Reimbursement Number has been captured. This element string is an attribute of a trade item and must be processed together with the GTIN of the trade item to which it relates (see section *4.14 Data relationships*).

When indicating this element string in the non-HRI text section of a barcode label, the data title listed in figure *3.2-1* SHOULD be used.

3.8.19 Certification reference: AI (723s)

The GS1 Application Identifier (723s) indicates that the GS1 Application Identifier data field contains a reference to a product certification. The certification reference is an attribute of a trade item or an individual asset.

As multiple certificates may be present, each with an individual certification reference, the fourth digit of the AI (s in the figure below) indicates the sequence of the certification references.

The general structure of AI (723s) is:

- Certification scheme (2 characters) defined by GS1. The following code values are currently allowed:

If element string		Then mandatory associated element string	Rule
AI	Designation	AI	
4313	Return-to address line 2	4312 AND 00	Return-to address line 2 SHALL occur in combination with line 1 of a return-to address
432N	Service-related GS1 application identifiers for transport process	00	Service-related GS1 application identifiers SHALL occur in combination with an SSCC
7001	NATO stock number	01 XOR 02 XOR 8006 XOR 8026 ***	The NATO stock number SHALL occur in combination with: ▪ a GTIN; or ▪ a GTIN of contained trade items; or ▪ an ITIP ▪ an ITIP of contained trade item pieces
7002	UN/ECE meat carcasses and cuts classification	01 XOR 02	The UN/ECE meats carcasses and cuts classification SHALL occur in combination with: ▪ a GTIN; or ▪ a GTIN of contained trade items.
7003	Expiration date and time	01 XOR 02	The expiration date and time SHALL occur in combination with: ▪ a GTIN; or ▪ a GTIN of contained trade items.
7004	Active potency	01 AND 10	The active potency SHALL occur in combination with the batch/lot number and the GTIN.
7005	Catch area	01 XOR 02	The catch area SHALL occur in combination with: ▪ a GTIN; or ▪ a GTIN of contained trade items.
7006	First freeze date	01 XOR 02	The first freeze date SHALL occur in combination with: ▪ a GTIN; or ▪ a GTIN of contained trade items.
7007	Harvest date	01 XOR 02	The harvest date SHALL occur in combination with: ▪ a GTIN; or ▪ a GTIN of contained trade items.
7008	Species for fishery purposes	01 XOR 02	The species for fishery purposes SHALL occur in combination with: ▪ a GTIN; or ▪ a GTIN of contained trade items.
7009	Fishing gear type	01 XOR 02	The fishing gear type SHALL occur in combination with: ▪ a GTIN; or ▪ a GTIN of contained trade items.
7010	Production method	01 XOR 02	The production method SHALL occur in combination with: ▪ a GTIN; or ▪ a GTIN of contained trade items.
703(s)	Number of processor	01 XOR 02	The number of processor SHALL occur in combination with: ▪ a GTIN; or ▪ a GTIN of contained trade items.
710, 711, 712, 713, 714, 715	National Healthcare Reimbursement Number	01	National Healthcare Reimbursement Number(s) SHALL occur in combination with the GTIN.
7020	Refurbishment lot ID	(01 XOR 8006***) AND 416	The refurbishment lot ID SHALL occur in combination with the GLN of production/service location and: ▪ a GTIN; or ▪ an ITIP

7.3 Validation of the electronic message regarding system consistency

The GS1 system enables system users to process scanned data without human intervention. This implies that the electronic message generated from data scanned and transmitted from data carriers needs to substitute for all human activities during a particular transaction. In other words, the transmitted data must provide all information required for its correct processing.

The GS1 system is designed to fulfil these requirements. Section 4 describes the association of element strings to form valid messages.

Validation of system consistency refers to the verification of the correct composition of the electronic message by a system processing the transaction messages. Whether the message is adequate in business application terms is dealt with by the application software.

Only messages containing a valid set of element strings defined in the GS1 system can be unambiguously processed. The processing of invalid messages may lead to data file errors because the meaning and relationship of the element strings are not defined. This is illustrated in figures 7.3-1 and 7.3-2.

Figure 7.3-1. Examples of valid messages

Element strings in message			Comment
AI 00	AI 33nn		Identification of a logistic unit + logistic weight
AI 00	AI 01		Identification of an entity as a logistic unit and as a fixed measure trade item
AI 00	AI 01 '9'	AI 31nn	Identification of an entity as a logistic unit and as a variable measure trade item
AI 00	AI 02	AI 37	Identification of a logistic unit and its contained fixed measure trade items
AI 01	AI 10	AI 15	Identification of a trade item + lot number + best before date
AI 00	AI 401		Identification of a logistic unit as part of a consignment
AI 01 '9'	AI 31nn	AI 33nn	Identification of a variable measure trade item + logistic weight
AI 00	AI 01	AI 33nn	Identification of an entity as a logistic unit and a fixed measure trade item; the logistic weight is associated with the identification number of the logistic unit
AI 01	AI 710		Identification of a trade item + National Healthcare Reimbursement Number
AI 01	AI 711		Identification of a trade item + National Healthcare Reimbursement Number
AI 01	AI 712		Identification of a trade item + National Healthcare Reimbursement Number
AI 01	AI 713		Identification of a trade item + National Healthcare Reimbursement Number
AI 01	AI 714		Identification of a trade item + National Healthcare Reimbursement Number
AI 01	AI 715		Identification of a trade item + National Healthcare Reimbursement Number

Figure 7.3-2. Examples of invalid messages

Element strings in message			Comment
AI 00	AI 01	AI 37	Invalid identification of an entity as a logistic unit and as a fixed measure trade item; AI 37 (quantity of items contained) must be used with AI 02 only
AI 01	AI 10	AI 33nn	Invalid identification of a fixed measure trade item + lot number; AI 33nn is incorrect because logistic measures of a fixed measure trade item are fixed attributes stored in the data file
AI 01'9'	AI 33nn		Invalid identification of a variable measure trade item + logistic weight; the mandatory element string with a trade measure is missing
AI 00	AI 11		Invalid identification of a logistic unit; AI 11 is incorrect because a production date must be associated with the identification number of a trade item
AI 00	AI 01	AI 02/37	Invalid identification of an entity as a logistic unit and as a fixed measure trade item; AI 02/37 must not be associated with AI 01
AI 01	AI 30		Invalid identification of a fixed measure trade item; AI 30 must only be associated with the identification number of a variable measure trade item
AI 02	AI 37		Invalid identification of the fixed measure trade units contained in an unidentified logistic unit; AI 00 is missing
AI 00	AI 02		Invalid identification of a logistic unit and of the contained fixed measure trade items; AI 02 requires the mandatory presence of AI 37 to complete the identification of the content

~~7.8.7~~7.8.8 National Healthcare Reimbursement Number (NHRN)

Some national or regional regulatory organisations may require pharmaceuticals and/or medical devices be identified with locally specific National Healthcare Reimbursement Numbers (NHRNs). For compliance with these national/regional regulatory or industry requirements where the GTIN does not meet current need, the trade item SHALL be identified with GTIN and AIs (710), (711), (712), (713)~~,~~ and (714) National Healthcare Reimbursement Number.

One or more NHRNs may be associated with a single GTIN and encoded within the appropriate GS1 Data carrier in order to meet multiple market business needs. See figure *7.8.8~~7.8.7-1~~* for examples of multiple NHRNs.

Additional individual NHRN AIs can only be assigned by GS1 and only in response to a work request being submitted through GSMP.

Figure 7.8.8-1. Examples of valid messages

Element strings in message							Comment
AI 01	AI 710						GTIN Identification of a trade item + Country "A" NHRN
AI 01	AI 710	AI 711					GTIN Identification of a trade item + Country "A" NHRN + Country "B" NHRN
AI 01	AI 710	AI 711	AI 712				GTIN Identification of a trade item + Country "A" NHRN + Country "B" NHRN + Country "C" NHRN
AI 01	AI 710	AI 711	AI 712	AI 713			GTIN Identification of a trade item + Country "A" NHRN + Country "B" NHRN + Country "C" NHRN + Country "D" NHRN
AI 01	AI 710	AI 711	AI 712	AI 713	AI 714		GTIN Identification of a trade item + Country "A" NHRN + Country "B" NHRN + Country "C" NHRN + Country "D" NHRN + Country "E" NHRN
AI 01	AI 710	AI 711	AI 712	AI 713	AI 714	AI 715	GTIN Identification of a trade item + Country "A" NHRN + Country "B" NHRN + Country "C" NHRN + Country "D" NHRN + Country "E" NHRN + Country "F" NHRN

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