The Global Language of Business

WR #	GSCN Name	Effective Date
21-040	Express expiration and production date day of the month in regulated healthcare products	Mar 2021

Associated Work Request (WR) Number:

20-212

Background: Gen Spec Continuous Improvement

The issue of date formatting and the misalignment with the General Specification was addressed in the previous version of the GTIN allocation Rules for Healthcare. The updated Healthcare GTIN rules addresses the assignment of GTINs however guidance information for other AIs need to be added to the Gen Specs. Patient safety initiatives have defined a best practice on date formatting to include Day Date resolution, to do so requires a valid Day Date to be included in any date representation, meaning the representation of a day as '00' is NOT valid for regulated healthcare products.

GS1 General Specification Change:

The recommended changes are highlighted below, relative to next GS1 General Specification release

Disclaimer

GS1®, under its IP Policy, seeks to avoid uncertainty regarding intellectual property claims by requiring the participants in the Work Group that developed this **General Specifications Change Notification** to agree to grant to GS1 members a royalty-free licence or a RAND licence to Necessary Claims, as that term is defined in the GS1 IP Policy. Furthermore, attention is drawn to the possibility that an implementation of one or more features of this Specification may be the subject of a patent or other intellectual property right that does not involve a Necessary Claim. Any such patent or other intellectual property right is not subject to the licencing obligations of GS1. Moreover, the agreement to grant licences provided under the GS1 IP Policy does not include IP rights and any claims of third parties who were not participants in the Work Group.

Accordingly, GS1 recommends that any organization developing an implementation designed to be in conformance with this Specification should determine whether there are any patents that may encompass a specific implementation that the organisation is developing in compliance with the Specification and whether a licence under a patent or other intellectual property right is needed. Such a determination of a need for licencing should be made in view of the details of the specific system designed by the organisation in consultation with their own patent counsel.

THIS DOCUMENT IS PROVIDED "AS IS" WITH NO WARRANTIES WHATSOEVER, INCLUDING ANY WARRANTY OF MERCHANTABILITY, NONINFRINGMENT, FITNESS FOR PARTICULAR PURPOSE, OR ANY WARRANTY OTHER WISE ARISING OUT OF THIS SPECIFICATION. GS1 disclaims all liability for any damages arising from use or misuse of this Standard, whether special, indirect, consequential, or compensatory damages, and including liability for infringement of any intellectual property rights, relating to use of information in or reliance upon this document.

GS1 retains the right to make changes to this document at any time, without notice. GS1 makes no warranty for the use of this document and assumes no responsibility for any errors which may appear in the document, nor does it make a commitment to update the information contained herein.



AI	Data Content	Format (1)	FNC1 required (4)	Data title
8110	Coupon code identification for use in North	N4+X70	(FNC1)	-
8111	Loyalty points of a coupon: AI (8111)	N4+N4	(FNC1)	POINTS
8112	Positive offer file coupon code identification for use in North America: (AI 8112)	N4+X70	(FNC1)	-
8200	Extended packaging URL: AI (8200)	N4+X70	(FNC1)	PRODUCT URL
90	Information mutually agreed between trading partners: AI (90)	N2+X30	(FNC1)	INTERNAL
91 to 99	Company internal information: AIs (91 - 99)	N2+X90	(FNC1)	INTERNAL

NOTES:

(1): The first position indicates the length (number of digits) of the GS1 Application Identifier. The following value refers to the format of the data content. The following convention is applied:

- n implied decimal point position
- N numeric digit
- X any character in figure 7.11-1
- N3 3 numeric digits, predefined length
- X3 3 characters, fixed length
- N..3 up to 3 numeric digits
- X..3 up to 3 characters in figure 7.11-1
- (2): If only year and month are available, DD must be filled with two zeroes, except where noted.
- (3): The fourth digit of this GS1 Application Identifier indicates the number of decimal places (and in that way the implied decimal point position).

Example:

- 3100 Net weight in kg without a decimal point
- 3102 Net weight in kg with two decimal places
- (4): All GS1 element strings that begin with GS1 Application Identifiers not contained in the predefined table shown in figure 7.8.4-2 SHALL be separated by a separator character unless this element string is the last one to be encoded in the symbol. For details on the separator character see section 7.8.3.
- (5) An example to illustrate future additional National Healthcare Reimbursement Numbers (NHRNs). If additional NHRN AIs are required, a request for a new NHRN AI SHALL be made through GSMP.
- (6) The fourth digit of this GS1 Application Identifier indicates the sequence number, allowing for multiple occurrences of the AI.



3.4 GS1 Application Identifiers starting with digit 1

3.4.1 Batch or lot number: AI (10)

The GS1 Application Identifier (10) indicates that the GS1 Application Identifier data field contains a batch or lot number. The batch or lot number associates an item with information the manufacturer considers relevant for traceability of the trade item to which the element string is applied. The data may refer to the trade item itself or to items contained. The number may be, for example, a production lot number, a shift number, a machine number, a time, or an internal production code. In cases where the same product is manufactured in different locations the brand owner and the manufacturer are responsible for ensuring the non-duplication of batch/lot numbers for a GTIN. For the re-use of batch/lot numbers with a GTIN, sector-specific constraints need to be considered.

The data is alphanumeric and may include all characters contained in figure 7.11-1.



Note: The batch or lot number is not part of the unique identification of a trade item.

Figure 3.4.1-1. Format of the element string

 rigate bills string			
GS1 Application Identifier	Batch or lot number		
1 0	X_1 \longrightarrow variable length \longrightarrow X_{20}		

The data transmitted by the barcode reader means that the element string denoting a batch or lot number has been captured. As this element string is an attribute of a particular item, it must be processed together with the GTIN of the trade item to which it relates (see section <u>4.14.2</u>). When indicating this element string in the non-HRI text section of a barcode label, the following data title SHOULD be used: **BATCH/LOT**

3.4.2 Production date: AI (11)

The GS1 Application Identifier (11) indicates that the GS1 Application Identifier data field contains a production date. The production date is the production or assembly date determined by the manufacturer. The date may refer to the trade item itself or to items contained. The structure is:

- Year: the tens and units of the year (e.g., 2003 = 03), which is mandatory.
- Month: the number of the month (e.g., January = 01), which is mandatory.
- Day: the number of the day of the relevant month (e.g., second day = 02); if it is not necessary
 to specify the day, the field must be filled with two zeroes.
- \bigcirc

Note: When it is not necessary to specify the day (the day field is filled with two zeroes), the resultant data string SHALL be interpreted as the last day of the noted month including any adjustment for leap years (e.g., "130200" is "2013 February 28", "160200" is "2016 February 29", etc.).



Note: How the day of the month is expressed for regulated healthcare products will change starting 1 January 2025. As of that date the day of the month SHALL NOT be expressed as two zeros. A valid day of the month (e.g., last day of July = 31) SHALL be included.



Note: This element string can only specify dates ranging from 49 years in the past to 50 years in the future. Determination of the correct century is explained in section <u>7.12</u>.



When indicating this element string in the non-HRI text section of a barcode label, the following data title SHOULD be used: **BEST BEFORE** or **BEST BY**

3.4.6 Sell by date: AI (16)

The GS1 Application Identifier (16) indicates the date specified by the manufacturer as the last date the retailer is to offer the product for sale to the consumer. The product should not be merchandised after this date.



Note: This AI is to be used in sectors where the manufacturer has agreed to apply the SELL BY date for the customer's use.

The structure is:

- Year: the tens and units of the year (e.g., 2003 = 03), which is mandatory.
- Month: the number of the month (e.g., January = 01), which is mandatory.
- Day: the number of the day of the relevant month (e.g., second day = 02); if it is not necessary
 to specify the day, the field must be filled with two zeroes.



Note: When it is not necessary to specify the day (the Day field is filled with two zeroes), the resultant data string SHALL be interpreted as the last day of the noted month including any adjustment for leap years (e.g., "130200" is "2013 February 28", "160200" is "2016 February 29", etc.).



Note: This element string can only specify dates ranging from 49 years in the past to 50 years in the future. Determination of the correct century is explained in section 7.12.

Figure 3.4.6-1. Format of the element string

GS1	Sell by date		
Application Identifier	Year	Month	Day
1 6	N ₁ N ₂	N ₃ N ₄	N ₅ N ₆

The data transmitted from the barcode reader means that the element string denoting a sell by date has been captured. As this element string is an attribute of a trade item, it must be processed together with the GTIN of the trade item to which it relates (see section <u>4.14</u> Data relationships).

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

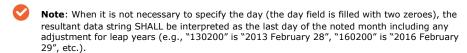
3.4.7 Expiration date: AI (17)

The GS1 Application Identifier (17) indicates that the GS1 Application Identifier data fields contain an expiration date. The expiration date is the date that determines the limit of consumption or use of a product/coupon. Its meaning is determined based on the trade item context (e.g., for food, the date will indicate the possibility of a direct health risk resulting from use of the product after the date, for pharmaceutical products, it will indicate the possibility of an indirect health risk resulting from the ineffectiveness of the product after the date). It is often referred to as "use by date" or "maximum durability date."

The structure is:

- Year: the tens and units of the year (e.g., 2003 = 03), which is mandatory.
- Month: the number of the month (e.g., January = 01), which is mandatory.
- Day: the number of the day of the relevant month (e.g., second day = 02); if it is not necessary
 to specify the day, the field must be filled with two zeroes.





Note: How the day of the month is expressed for regulated healthcare products will change starting 1 January 2025. As of that date the day of the month SHALL NOT be expressed as two zeros. A valid day of the month (e.g., last day of July = 31) SHALL be included.

Note: This element string can only specify dates ranging from 49 years in the past to 50 years in the future. Determination of the correct century is explained in section 7.12.

Figure 3.4.7-1. Format of the element string

GS1	Expiration date		
Application Identifier	Year	Month	Day
1 7	N ₁ N ₂	N ₃ N ₄	N ₅ N ₆

The data transmitted from the barcode reader means that the element string denoting an expiration date has been captured. As this element string is an attribute of a trade item or a coupon, it must be processed together with the GTIN or the GCN to which it relates (see section $\underline{4.14}$ Data relationships).

When indicating this element string in the non-HRI text section of a barcode label, the following data title SHOULD be used: **USE BY or EXPIRY**