The Global Language of Business

GSMP:

General Specifications Change Notification (GSCN)

GSCN #	GSCN Name	Issue Date	Status
WR14-175	**Modification to "Healthcare Human Readable Interpretation (HRI) Decision Tree"**	5 Oct 2015	Ratified

Associated Work Request (WR) Number:

14-000175

Background:

The current Healthcare Human Readable Interpretation (HRI) Decision Tree diagram may be misunderstood to indicate it may be applied to healthcare products independently, and contains all of the HRI rules that apply to healthcare products. Rather, it is intended to be used in conjunction with general and healthcare HRI rules.

Since these rules have regulatory implications, HRI exceptions should be limited to specific circumstances, but the diagram does not indicate its limited application.

The diagram text implies it only applies to medical devices, while it should, in fact apply to all regulated healthcare products.

The home care exception is redundant and may cause manufacturers of those products to misinterpret the HRI rules, and the intent should be that these products do not have different exceptions that other healthcare products.

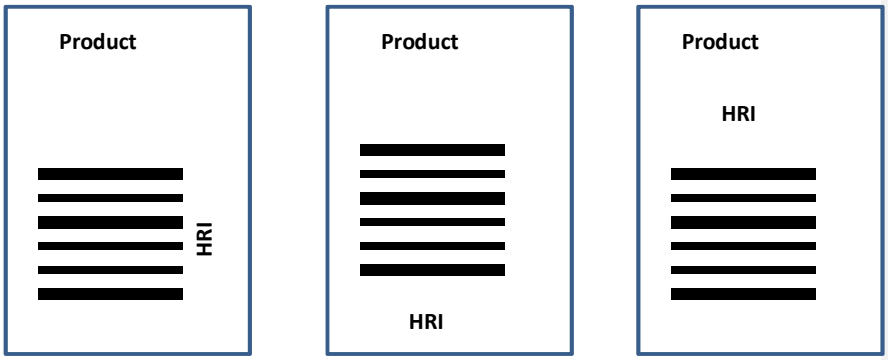
GS1 General Specification Change:

The recommended changes are highlighted in the attached excerpt from the GS1 General Specifications, v15 and include the following changes:

- HRI Decision Tree
  - Add "to be used only when limited space is available" statement above the decision tree
  - Remove text as marked
  - Remove two decision tree components related to home care environment (highlighted in red)
- Add note stating that the decision tree should be used only when not in conflict with regulations

Disclaimer

Figure 4.14-2. Locations of HRI for barcode in ladder orientation



Note: There may be local variants for non-HRI text on the label (e.g., dates, prices) which are formatted based on local practice rather than the way the data is encoded in GS1 AIDC data carriers. In this case, the HRI associated with AIDC shall still be expressed as it is encoded in the GS1 AIDC data carrier encodation (per Application Identifier definition).

9. When AI (8200) appears on the label, the expression of the URL shall not appear in HRI. If it appears in Non-HRI text, it shall be expressed as http://brandownerassignedURL.com/GTIN (where GTIN expressed as 14 digits).

4.14.1. Healthcare Human Readable Interpretation Rules

The GS1 System requires printing both the GS1 AIDC data carrier and the HRI that represents all the information encoded within that GS1 AIDC data carrier.

If the GS1 AIDC data carrier cannot be read or scanned, the HRI should be used as back up information. The GS1 preferred format for HRI when applied on healthcare trade items shall be as noted in the general HRI rules found in Section 4.14.

When considering the practical implementation and application of HRI during the creation of the product packaging, many factors must be taken into account to determine if and how HRI is included with the symbol. These factors may include the type of product being labelled or marked, product use, available space for marking, alternate data availability, regulatory or legal requirements, technical constraints, etc.

However, printing both the GS1 AIDC data carrier and the associated HRI may not be possible due to many factors such as the intended use of the item, available space for marking, etc. Deviation from the HRI format should be minimised and consider impacts to downstream trading partners and users

Typical examples are shown in Figure 4.14.1-1

Figure 4.14.1-1. Preferred HRI Format Examples

If a deviation from the preferred format is required that results in HRI not being printed, then a combination of HRI and Non-HRI Text may be used. When doing so, the following rules apply:

- If the data represented in the Non-HRI Text is exactly as in the HRI, then the appropriate AI shall be printed along with the data title. See figure 4.14.1-2.
- If data represented in the Non-HRI Text does not match the HRI, then only a data title may be used. The AI shall not be printed. This is illustrated in figure 4.14.1-3 by the GTIN and Expiry.
- The selection of data titles may be determined by the manufacturer based on regulatory, local language requirements, relevant standards (e.g. ISO/IEC 15223) or appropriate abbreviations.

Figure 4.14.1-2. Combination of HRI with AIs, Non-HRI Text and data titles

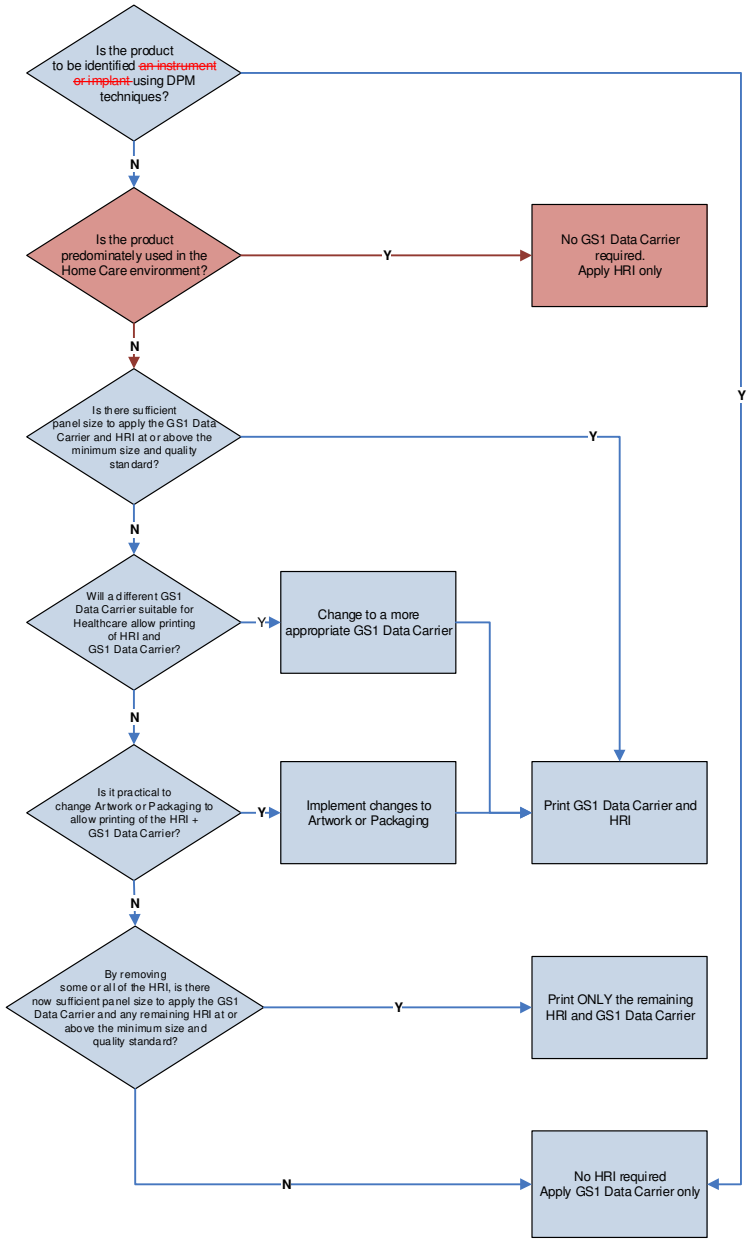
Figure 4.14.1-3. Combination of HRI with AIs, Non-HRI Text (GTIN and Expiry) and data titles

If it is not possible to print both the GS1 AIDC data carrier and the HRI, Figure 4.14.1 – 4 should be used to determine how HRI will be implemented. When it is not possible to print all of the HRI, preference for printing shall be given to the GS1 Key.

Figure 4.14.1-4. Healthcare Human Readable Interpretation (HRI) Decision Tree
(to be used only when limited space is available)

Commented [CJ24]: WR14-175, also changes to diagram and notes

graphic to be updated further prior to publication:
1. red text to be removed
2. red boxes to be removed



Note: Figure 4.14.1-1 is intended for use when there is no regulatory mandate that conflicts with this guidance and where space constraints limit the ability to provide both the GS1 AIDC marking and the associated HRI text—this document does not impact the non-HRI text that is required for compliance with labeling regulations. In all situations, applicable regulatory requirements shall take precedence. Brand Owners are responsible to understand and comply with applicable regulations and to document deviations from those regulations and their justifications for such deviations in the product master record files or other formal document control files.

Note: Active Potency (AI 7004) HRI Rule. Printing of the Active Potency on the item is controlled by regulation. Human readable interpretation of the Active Potency is not required on the trade item.

4.14.2. Manual Date Marking

Where regulations and/or trade partner agreements require applied date markings for stock rotation and manual identification, the ISO standard (8601) for date sequence should be used. The format should be YYYY-MM-DD preceded by the date type short form (See Figure 4.14.2-1 below for respective date types) based on ISO standard abbreviations (15223).

Figure 4.14.2-1. Short forms by date type

Date type	Short form
Production	PROD
Packaging	PACK
Best Before	BEST
Expiration	EXP

AIDC techniques are suggested over any manual process to ensure accurate and timely stock rotation. Every effort should be made to adopt an automated process to increase productivity and date management.

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4.15. Multiple Barcode Management Practices for Consumer Trade Items (cross-sector)

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EAN/UPC symbols have been used for POS/POC and will continue to be used for existing applications however new symbologies have been introduced to support new application requirements. Until all parties can process GTIN using the new technologies, existing technology must be supported while new technology migration occurs. This standard provides a set of management practices intended to permit the use of existing and new technologies on one package. The management practices are designed to ensure brand owners will not carry two different inventories based on technologies.

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In addition to supporting POS/POC and general distribution scanning applications, consumer trade item packages may now support additional business processes using barcodes. For example, support for B2C extended packaging and trade item production control. For this reason, a management practices has been introduced to separate, where possible, symbols for different functions and in the case of production control barcodes, another management practice is introduced to obstruct their supply chain scanning or make them obscure where possible.

The transition to use of additional data beyond GTIN in barcodes is a non-trivial step for the retail and healthcare industry. It means operators must learn to handle the new technologies

