GS1 HEALTHCARE US

Marking Pharmaceuticals & Medical Devices for the 2012 GTIN Sunrise

EXPECTATIONS FOR 2012 AND BEYOND
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About GS1®

GS1 is a neutral, not-for-profit organization dedicated to the design and implementation of global standards and solutions to improve the efficiency and visibility in supply chains. GS1 is driven by more than a million companies, who execute more than six billion transactions a day with the GS1 System of Standards. GS1 is truly global, with local Member Organizations in 111 countries, with the Global Office in Brussels, Belgium.

About GS1 US™

GS1 US is the Member Organization of GS1 that serves companies in the United States. As such, it is the national implementation organization of the GS1 System dedicated to the adoption and implementation of standards-based, global supply chain solutions in the United States. GS1 US currently serves over 200,000 U.S. member companies -- 16,000 of which are in healthcare.

About GS1 Healthcare

GS1 Healthcare is a global, voluntary healthcare user group developing global standards for the healthcare supply chain and advancing global harmonization. GS1 Healthcare consists of participants from all stakeholders of the healthcare supply chain: manufacturers, wholesalers & distributors, as well as hospitals and pharmacy retailers. GS1 Healthcare also maintains close contacts with regulatory agencies and trade organizations worldwide. GS1 Healthcare drives the development of GS1 Standards and solutions to meet the needs of the global healthcare industry, and promotes the effective utilization and implementation of global standards in the healthcare industry through local support initiatives like GS1 Healthcare US in the United States.

About GS1 Healthcare US®

GS1 Healthcare US is an industry group that focuses on driving the adoption and implementation of GS1 Standards in the healthcare industry in the United States to improve patient safety and supply chain efficiency. GS1 Healthcare US brings together members from all segments of the healthcare industry to address the supply chain issues that most impact healthcare in the United States. Facilitated by GS1 US, GS1 Healthcare US is one of sixty-six local GS1 Healthcare user groups around the world that supports the adoption and implementation of global standards developed by GS1.
Executive Overview

Industry associations, advocacy groups, organizations and companies throughout U.S. healthcare have announced their support to adopt GS1 Standards to improve patient safety. In order to accelerate wide-scale adoption and implementation, industry accepted “sunrise dates” were established. The 2012 GTIN Sunrise calls for the adoption of GS1 Global Trade Item Number® (GTIN®) in lieu of custom product numbers by December 31, 2012 in order to standardize healthcare product identification.

The 2012 GTIN Sunrise includes six goals, one of which is to mark appropriate packaging levels with their GTINs. This document was developed by the GS1 Healthcare US® Product Identification Workgroup to help articulate the expectations of the U.S. healthcare industry with regard to the product marking goal of the 2012 GTIN Sunrise initiative. It describes the expectations of suppliers and receivers of both medical devices and pharmaceuticals. In addition, it presents other regulatory and customer marking requirements for the supply chain to consider for beyond the 2012 Sunrise. To that end, this document provides:

- an explanation of the product marking goal of the 2012 GTIN Sunrise initiative,
- additional considerations for marking and receiving healthcare products after the sunrise, and
- examples of automatic identification data capture (AIDC) of GTIN product identifiers and common healthcare production data.
Document Information

This document was prepared by GS1 Healthcare US to assist suppliers and receivers of pharmaceuticals and medical devices in the U.S. It is based on the GS1 General Specification, and was developed using information obtained from all members of the healthcare supply chain from manufacturers to providers.

Purpose

The purpose of this document is to describe the expectations of the U.S. healthcare industry regarding what it means to satisfy the product marking goal of the 2012 GTIN Sunrise initiative, and to present other regulatory and customer marking requirements for the supply chain to consider for beyond the 2012 Sunrise.

Audience

- Providers (Hospitals)
- Manufacturers
- Distributors
- GPOs
- Regulators
- Solution Providers

Scope

This document describes the expectations of suppliers and receivers of both medical devices and pharmaceuticals with regard to the product marking goal of the 2012 GTIN Sunrise initiative. It introduces the GTIN, GS1 Application Identifiers and GS1 barcodes, and explains how these standards are applied to satisfy the 2012 GTIN Sunrise marking goal, as well as other regulatory and customer marking requirements for beyond the 2012 Sunrise. In order to illustrate this application of GS1 Standards, this document presents examples of GS1 barcodes encoding GTIN product identifiers and common healthcare production data. The GS1 General Specification should be consulted for additional information.

Note: This document presents the expectations of the healthcare industry, not mandatory requirements. GS1 standards are voluntary.
2012 GTIN Sunrise

The industry established the 2012 GTIN Sunrise initiative to secure the benefits of standardized product identification throughout the U.S. healthcare system. The 2012 GTIN Sunrise calls for the adoption of GTINs in lieu of custom product numbers across U.S. healthcare by December 31, 2012. The initiative also includes the use of the GS1 Global Data Synchronization Network (GDSN) to store and communicate the associated product attributes of each GTIN. The six goals of the 2012 GTIN Sunrise are:

- GTINs are assigned to healthcare products
- GTINs are marked on appropriate packaging levels
- GTINs are used in business transactions
- GTINs are scanned at points-of-delivery to enhance clinical process
- GTINs are used in product returns and recalls
- GTINs are registered in a GS1 GDSN-certified Data Pool

Together, these goals support a standardized approach to identifying, capturing and sharing precise product information across U.S. healthcare.

How should GTINs be stored and represented in software applications?

GTINs can be assigned as 8 digits, 12 digits, 13 digits, or 14 digits in length, depending on the needs of the manufacturer/brand owner. The length of the GTIN when it is encoded in a barcode can also vary depending on the specific barcode used.

Regardless of the length of the GTIN as assigned or the type of barcode used, GTINs should always be stored/represented in software applications as 14 digits by right-justifying and zero-filling to the left as appropriate. In order to preserve any leading zeros that may be present, it is also recommended that the GTIN field be represented in a database as a text field, not as a numeric field. This information should be provided to systems engineers as they prepare to integrate GTINs into IT systems.
Sunrise Product Marking Goal

One of the 2012 GTIN Sunrise goals is to “mark appropriate packaging levels with their GTINs.” Table 1 further clarifies the three components of this goal:

### Components of the Product Marking Goal

<table>
<thead>
<tr>
<th>Component</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1: “mark”</td>
<td>affix a GS1 barcode</td>
</tr>
<tr>
<td>2: “appropriate packaging levels”</td>
<td>example: the box of 200 tongue depressers, not the individual tongue depressers inside the box</td>
</tr>
<tr>
<td>3: “GTIN”</td>
<td>GTINs can be assigned as 8 digits, 12 digits, 13 digits, or 14 digits in length, depending on the needs of the manufacturer/brand owner. Any/all of these GTIN lengths/formats satisfy the 2012 GTIN Sunrise goals.</td>
</tr>
</tbody>
</table>

Table 1: Components of the Product Marking Goal

Thus, in order to satisfy the product marking goal, manufacturers must encode the GTIN for each appropriate packaging level into barcodes, and then affix a barcode to each appropriate packaging level.

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**Whose GTIN should be on the product in a contract manufacturing scenario?**

One common question asked by companies that use contract manufacturing is: “Whose GTIN should be on the product: mine or the contract manufacturer?” The simple answer is: the company whose name is on the product. In the GS1 System, the company whose name is on the product is called the “brand owner”. The brand owner is responsible for allocating GTINs (under their own GS1 Company Prefix) for any trade items sold under their name.

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**Introduction to GS1 Barcodes**

Product identification information (e.g., GTIN, serial number, expiration date, etc.) can be encoded into barcodes and then affixed to products. Barcodes provide symbolic representations of product identification information that facilitate automatic identification and data capture (e.g., the black bars and spaces on the barcode). In addition, most barcodes include a human readable version as well to facilitate manual data entry when necessary (e.g., the numbers below the black bars of the barcode).

![Barcode Symbol & HRI](image)

Figure 1: Barcode Symbol & HRI

GS1 System includes seven different barcodes in order to support a variety of applications and environments. All GS1 barcodes can carry the GTIN. Some GS1 barcodes can carry the GTIN plus additional information (e.g., expiration date; lot number; batch number; etc.). When encoding a barcode that can carry additional information, each data element in a barcode (e.g., GTIN, serial number, expiration date, etc.) is denoted through the use of GS1 Application Identifiers.
Application Identifiers (AIs) are a finite set of specialized identifiers embedded within numerical string of a barcode. Each AI has a two-, three- or four-digit numeric prefix that appears in parentheses to signal a certain type of data in the barcode numerical string (i.e., indicate what data appears in the next segment of the barcode sequence). For example, the AI for GTIN it is (01). Thus, when “(01)” appears in the numerical string, it means a GTIN follows in the next segment. The AI for lot/batch number is it is (10). When “(10)” appears in the numerical string of a barcode, it means a lot/batch number follows in the next segment.

There are approximately 100 AIs in total, including one AI for each GS1 identifier (e.g., GTIN, GLN, SSCC, etc.) as well as numerous AIs for item-specific information (e.g., expiration date; lot number; batch number; etc.). The complete definitions for all of the Application Identifiers reside in the GS1 General Specifications. The GS1 AI’s commonly used in U.S. healthcare are shown in Table 2 below:

<table>
<thead>
<tr>
<th>GS1 AIs Commonly Used in U.S. Healthcare</th>
</tr>
</thead>
<tbody>
<tr>
<td>AI (10)</td>
</tr>
<tr>
<td>AI (17)</td>
</tr>
<tr>
<td>AI (21)</td>
</tr>
</tbody>
</table>

Table 2: GS1 AI’s Commonly Used in U.S. Healthcare

Additional GS1 AI’s that are used less frequently in U.S. healthcare include:

- **AI (30) - Variable Count**: AI (30) indicates a data field representing the number of items contained in a Variable Measure Trade Item. This Element String is used to complete the identification of a Variable Measure Trade Item and therefore should never be applied in isolation. This field represents the quantity contained in the respective trade item. It is of variable length and may have up to eight digits.

- **AI (11) - Production Date**: AI (11) indicates a data field representing 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.

- **AI (20) - Product Variant**: AI (20) is used to distinguish a variant from the usual item for that GTIN if the variation is not sufficiently significant to require a separate GTIN and the variation is relevant only to the brand owner and any third party acting on its behalf. This AI is only for use by the brand owner and any third party acting on its behalf and not for dealings with any other trading partners. The product variant shall not be used where the variation would trigger the allocation of a different GTIN per the GTIN Allocation Rules.

- **AI (240) - Product Identification Assigned by the Manufacturer**: AI (240) indicates a data field representing additional item identification. The purpose of this Element String is to enable identification data other than the GTIN to be represented in a GS1 System data carrier. It is a cross-reference to previously used catalogue numbers. The additional item identification is considered an attribute of the GTIN (e.g., it facilitates migration to the GS1 System during a transitional period). However, it must not be used to replace the GTIN. The additional item identification field is alphanumeric. Its content and structure are at the discretion of the company applying the Element String.
Barcode Options for the 2012 GTIN Sunrise

The 2012 GTIN Sunrise only calls for the marking of GTINs at appropriate level of packaging. It does not call for a production identifier (PI) or any additional information (e.g., batch/lot number; etc.). Because all GS1 barcodes can carry GTINs, any of the GS1 barcodes can be used to satisfy the product marking goal (i.e., GTIN only). However, some manufacturers already mark their products with GTIN plus a production identifier and/or other additional information. Those manufacturers are urged to continue this practice (the rationale for which is explained below in the Barcode Options for Beyond the GTIN Sunrise section). If you are currently marking with GTIN plus secondary information or are anticipating doing so in the near future, you will need to use only GS1 barcodes that are capable of carrying GTIN plus secondary information. The tables below delineate the options available for (1) barcodes that carry GTINs only and (2) barcodes that carry GTIN plus secondary (AI) information. For each option, the table indicates whether that type of barcode is approved for retail/point-of-sale (POS) and the type(s) of scanner required to read that barcode.

GS1 Barcodes that Carry GTIN Only (no secondary information):

<table>
<thead>
<tr>
<th>Barcode</th>
<th>Approved for POS</th>
<th>Scanner Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>GS1-12 (UPC)</td>
<td>• Approved for POS</td>
<td>• Read by laser scanner</td>
</tr>
<tr>
<td>GS1-13 (EAN 13)</td>
<td>• Approved for POS</td>
<td>• Read by laser scanner</td>
</tr>
<tr>
<td>ITF-14</td>
<td>• Not approved for POS</td>
<td>• Read by laser scanner</td>
</tr>
</tbody>
</table>

**NOTE:** All of these linear barcodes are limited to carrying only the GTIN. However, GS1 Standards provide the option to add an additional data carrier to carry secondary information (i.e., AIs) alongside these linear barcodes. The additional data carrier is called a Composite Component®. Unlike other stand-alone symbologies such as the UPC barcode (which carries only the GTIN) or the DataMatrix (which carries both the GTIN and other AIs), the Composite Component is a two-dimensional symbol designed to be used as a companion to a GS1 linear symbol. With Composite Component, the GTIN is carried by the host linear symbol and the additional AI information is carried on the Composite Component. The Composite Component provides an alternative for users who prefer or require one of these linear barcodes, but need to add secondary AI information at some point.
GS1 Barcodes that Carry GTIN plus Secondary Information (shown encoding GTIN only):

**Figure 5: GS1-128**
- Not approved for POS
- Read by laser or image scanner

![ GS1-128 Barcode ](image)

**Figure 6: GS1 DataMatrix**
- Not approved for POS
- Only read by image scanner

![ GS1 DataMatrix ](image)

**Figure 7: GS1 Databar Expanded**
- Approved for POS
- Read by laser or image scanner

![ GS1 Databar Expanded Barcode ](image)
Barcode Options for Beyond the GTIN Sunrise

Although manufacturers/brand owners need only encode the GTIN to meet the goals of the 2012 GTIN Sunrise, it is highly recommended that manufacturers look beyond the 2012 Sunrise and encode additional production data on their products to honor other industry marking requirements and/or prepare for other pending requirements. For example:

- customer requirements for production information (PI)
- industry requirements (e.g., Global Harmonization Task Force UDI Recommended Guideline [http://www.ghtf.org/])
- U.S. Food and Drug Administration pending regulations [e.g., Unique Device Identifier (UDI) for medical devices (http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0090-0001); Standard Numeric Identifier (SNI) for pharmaceuticals (www.fda.gov/RegulatoryInformation/Guidances/ucm125505.htm)]
- the California pedigree regulation

To include any additional information beyond the GTIN, you will need to use only GS1 barcodes that are capable of carrying GTIN plus secondary information. GS1-128, GS1 Databar, and GS1 DataMatrix barcodes can all carry AI secondary information, and more than one AI can be carried in one barcode. When encoding the barcode, each data element is preceded by its AI (as shown in the examples below).

GS1 Barcodes that Carry GTIN plus Secondary Information:

**Figure 8: GS1-128**
(encoding GTIN, Expiration Date, Lot, and Serial Number)

**Figure 9: GS1 DataMatrix**
(encoding GTIN, Expiration Date, Lot, and Serial Number)

**Figure 10: GS1 Databar (Limited) & Composite**
(encoding GTIN, Expiration Date, Lot, and Serial Number)

**Figure 11: GS1 Databar (Stacked) & Composite**
(encoding GTIN, Expiration Date, Lot, and Serial Number)
U.P.C. (GTIN-12), EAN 13(GTIN-13), and ITF barcodes cannot carry secondary information. However, GS1 Standards provide the option to add an additional data carrier to carry secondary information (i.e., AIs) alongside these linear barcodes. The additional data carrier is called a Composite Component.

Unlike other stand-alone symbologies such as the U.P.C. barcode (which carries only the GTIN) or the DataMatrix (which carries both the GTIN and other AIs), the Composite Component is a two-dimensional symbol designed to be used as a companion to a GS1 linear symbol. With Composite Component, the GTIN is carried by the host linear symbol and the additional AI information is carried on the Composite Component.
References

- GS1 General Specification v12 January 2012
  Available at http://www.gs1us.org/resources/standards/standards-library (see the bottom of the page).

- GS1 AIDC Healthcare Implementation Guide Issue 1.1 Dec-2010
  Available at http://www.gs1us.org/hctools

- GTIN Allocation Rules
  Available at http://www.gs1us.org/hctools

- GS1 Healthcare US GTIN Tool Kits
  Available at http://www.gs1us.org/hcsuptoolkit

- GS1 Healthcare US GDSN Tool Kits
  Available at http://www.gs1us.org/hcsuptoolkit
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