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Adoption of GTIN-14 Product Coding, November 2017: How HDA's "Origin", an Industry Master Rx GTIN Repository, will help.

www.HDAOrigin.com

The Drug Supply Chain Security Act (DSCSA) was enacted in 2013 to improve the safety and security of Rx distribution and dispensing in the United States, by keeping illegitimate product out of the supply chain. Its detailed, phased implementation is changing many of the ways that transactions happen, from manufacturers to the wholesale channel, and finally to points of dispensing and patients. There are many incremental steps along the path to full adoption, which began in 2013 and completes in 2023. The next step is the requirement for manufacturers to apply serial numbers to all packages and send all transaction information exclusively electronically, beginning November 27, 2017.

This document contains two sections: the first explains the terms used and the issues faced by the industry, specifically leading into November 2017. The second part explains how **HDA's** "**Origin**" master reference data service will help address these issues for manufacturers, wholesalers and dispensers.

Part 1: Understanding the Issues

The traceability system the DSCSA mandates will require a massive amount of frequent and accurate data exchange. To accomplish this data exchange, the DSCSA and FDA both point to the need for the industry to use standards that comply with a form and format developed by a widely recognized international standards development organization. Many in the pharmaceutical industry are supporting standards developed by GS1, including using EPCIS for the data exchange the DSCSA requires. In turn, GS1's EPCIS standards will require assignment of GTINs to each pharmaceutical product at each level of packaging (i.e., bottle, inner pack, case, and pallet). For pharmaceuticals, the GTIN-14, subject to GS1's international standards, is the identifier that links a scan of a product to the master data associated with that product, including the NDC number, package size, quantity and more. GTINs must be up-to-date and accurate for the data exchange between trading partners to function smoothly and efficiently. It is critically important to ensure that all GTINs are consistent with GS1 standards and that each NDC number for a pharmaceutical is incorporated into an appropriate GTIN.

A GTIN repository provides a uniform method for manufacturers to share consistent and accurate product master data with downstream supply chain trading partners and relieves them of the burden of sharing the same data multiple times with multiple trading partners. Manufacturers would submit their GTINs to the central repository which could become a reliable source for the GTIN and important associate product information.

This repository is an important building block, foundational for the next DSCSA milestone, in November 2019, when wholesalers will be allowed only to transact with serialized product. The repository will also keep the industry on track and aligned with the FDA's guidance for SNI: Standard Numerical Identification for Prescription Drug Packages[1]. Come 2023, in the absence of any other widely recognized international standard, EPCIS data standards will need to be fully implemented as a part of the methodology for transacting data as the DSCSA requires. The GTIN-14 is a key part of that standard, and will need to be used in all transactions as product moves through the supply chain.

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1 Guidance for Industry: Standards for Securing the Drug Supply Chain - Standardized Numerical Identification for Prescription Drug Packages
https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM206075.pdf

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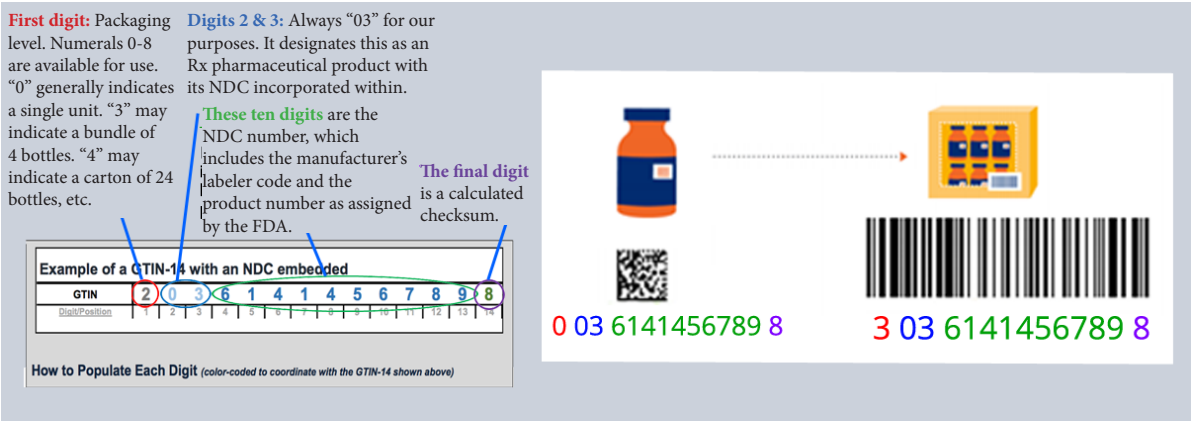
Decoding the GTIN-14

GTIN stands for "Global Trade Item Number". In this application, it is a 14-digit number that incorporates, among other elements, the familiar NDC number for the product and a newly added packing level indicator (unit, carton, case). It is important to understand that a product's GTIN-14 number does not incorporate a package serial number, nor would a database of GTIN-14 numbers include any package serial numbers or transaction data.

The definition of what is inside the GTIN-14 is managed by GS1, the global standards setting organization. The GTIN-14 methodology defines a highly detailed standard identification code format. GS1 has developed general GTIN formats useable by most industries, and highly specific ones to satisfy the individual requirements of several industries, including healthcare.

The GTIN-14 standard adopted for the pharmaceutical industry is a 14-digit product identification code. The code contains important identifiers that tell who has made the item, the specific identification number of the item, and the container package size of the item. It also contains a calculated checksum digit that is used to ensure accuracy in transmission.



GS1 does not track or store GTINs. GS1 establishes the code's format and requires all companies using GTINs to sign up for a company specific **Labeler Code**. GS1 offers a subscription service called DataHub which performs the task of assigning a perfectly formed GTIN-14, which includes the labeler code, the product (NDC) number and calculates the checksum; however, constructing a GTIN-14 manually is quite easy. The **Indicator Digit** is user-defined (importantly, GS1 does not dictate what the Indicator Digit means. The definition is up to the manufacturer.) Once manufacturers license their labeler code and have their NDC number, there is a free online utility that calculates the checksum.

More information can be found here: http://www.gs1.org/GTIN

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How does using GTIN-14 change standard practices in the supply chain?

Prior to GTIN-14, there has been no universal standard for the identification of "unit" within a package in the supply chain. Supply chain participants within the industry have had to develop extensive normalization formulas to accurately and consistently record the quantity of an "each" that is received when reading the information contained in a Transaction Statement. Maintaining inventory accuracy has remained a challenge. Now, with the inclusion of the GTIN-14, the first digit in the code is reserved to indicate the package size (defining the packing levels contained within). *However, the exact meaning of the numerical digit used in the code is not regulated and will vary from manufacturer to manufacturer.*

Scanning the entire GTIN-14 provides the following information to the receiver:

1. The exact product that is being received. The product number must exist and be registered as "real" before anyone can receive the product.
2. The nested quantity that is contained within a pack, carton, or pallet.

This is where ***Origin*** comes in, to record and decode the meaning of every GTIN-14.

Part 2: The Role of HDA's "Origin"

Origin is designed to be a central data repository for the pharmaceutical supply chain that will contain the master list of all GTIN-14s, as well as the key to every product's "pack size" indicator digit. ***Origin*** also incorporates a data investigation service designed to assist immediately in the event of data mismatches, serving as a single point of contact between distributors and manufacturers to correct database errors as quickly as possible.

Across its distribution centers, a typical large wholesaler might receive 3 million units each day, from 600 manufacturers. In the US, there are approximately 200 distribution centers of all sizes. Besides receiving new product, these same wholesalers handle about 274,000-unit product returns each working day[2].

Industry stakeholders would be challenged to build and staff an infrastructure for manual and one-to-one queries and data sharing to manage master data for each GTIN. Any errors in communicating GTINs and associated data could result in downstream trading partners not being able to scan barcodes or exchange data electronically in transactions for those products. An inability to match a product with associated data creates a difficult and labor intensive exception handling process.

A product GTIN-14 may also be scanned by wholesalers at the time of shipment to dispensers. In most instances, the wholesaler will have broken down the cases and cartons into smaller, saleable units. Therefore, the GTIN-14s being shipped will be different from the ones that had been scanned on receipt; those GTIN-14s on and for the full cartons. These GTINs can be checked against ***Origin*** as they are being readied for shipment.

2 HDA Foundation: FactBook, 87th edition, 2016

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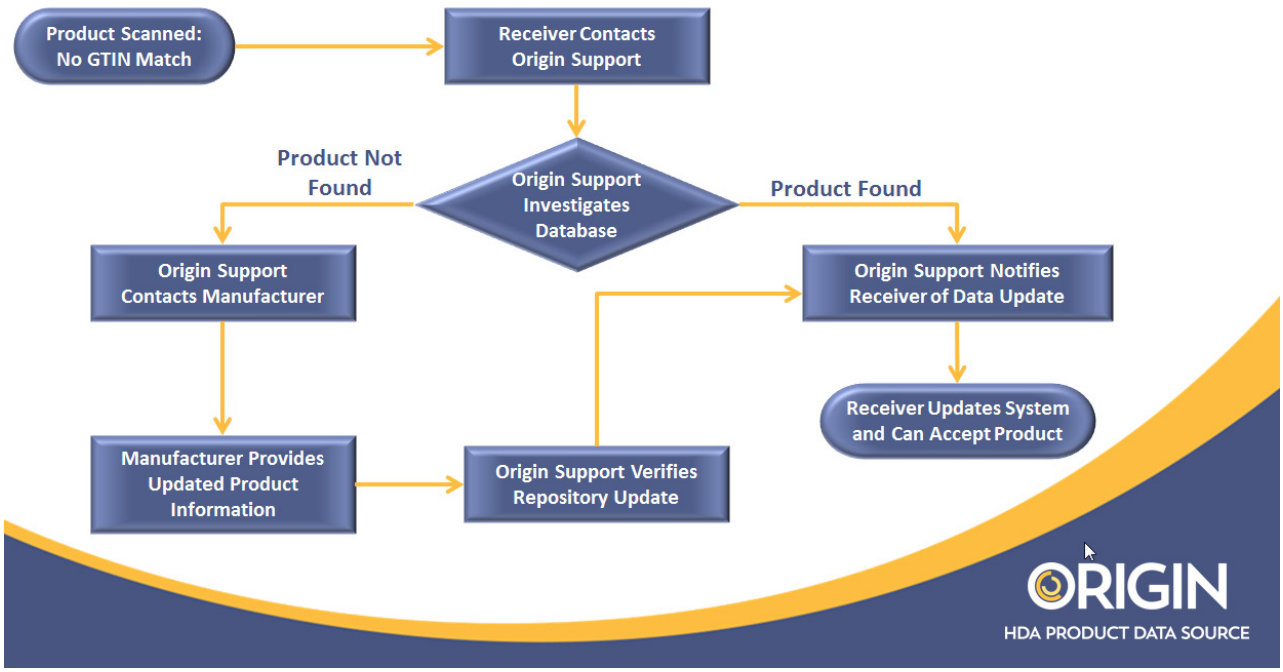
Origin allows for industry collaboration in the following ways:

1. Subscribing manufacturers upload their GTIN-14 catalog into ***Origin***. This source of master data is a trusted location for trading partners to obtain valid GTIN-14 data and saves subscribing manufacturers the burden of providing all of their GTIN-14 catalog to every trading partner and updating it when it changes.
2. Each subscribing wholesaler regularly downloads the universal list of GTIN-14s from this single trusted location to populate its local, internal database.
3. At loading docks, wholesalers use their scanners to record the GTIN-14 data found on incoming shipment product labels. The data are matched against the universe of GTIN-14s from ***Origin*** that are stored locally in each wholesaler's system.
4. In the event of scanning an unknown number, the wholesaler alerts the ***Origin*** team, who opens an investigation into the unknown GTIN-14.
5. The ***Origin*** administrator contacts the manufacturer that shipped the product.
6. The manufacturer corrects the problem with the master data and enters the changes in ***Origin***.
7. Subscribers are notified of the correction. The revised/corrected database in ***Origin*** is made available to all subscribers, for download to their local systems or available on the user portal.

Support Scenario: No GTIN Match



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Deeper Dive: How will HDA's Origin decode GTIN-14 pack quantities, allowing accurate calculation of "received" quantities?

The first digit of the GTIN-14 is a packaging indicator, and this digit is self-assigned by the manufacturer. ***Origin*** is a single place of record where this digit's meaning is stored and can be decoded, allowing wholesalers to easily and uniformly calculate the number of dispensable unit items received within.

The table below shows five different GTIN-14s for a single drug. The first four columns are data that the manufacturer would enter into the ***Origin*** master data repository. The final column can be calculated by the receiver and used in managing inventory.

The five (5) different GTIN-14s below all represent possible sellable configurations of 100mg capsules of a drug, starting with the lowest dispensable unit, a single bottle of the pills, shown **in red**.

The last column on the right, shows how the receiver can easily calculate how many of the lowest sellable unit they have received into stock.

Product	GTIN-14	Description	What GTIN-14 is contained inside this package?	What is the contained quantity of that GTIN-14?	Calculated: # of Individual Sellable Units Contained within
XazzoMax Capsule 100mg	**0 03 6140528891 5**	Bottle of 100 capsules	None; this is the lowest sellable unit	1	1
XazzoMax Capsule 100mg	**3 03 6140528891 2**	Bundle of (4) 100-Capsule bottles	**0 03 6140528891 5**	4	4
XazzoMax Capsule 100mg	**4 03 6140528891 7**	Carton of (24) 100-Capsule bottles	**0 03 6140528891 5**	24	24
XazzoMax Capsule 100mg	**5 03 6140528891 1**	Carton of (10) Bundles of 100 Capsule bottles	**3 03 6140528891 2**	10	40
XazzoMax Capsule 100mg	**8 03 6140528891 6**	Case of (20) cartons of the above	**5 03 6140528891 1**	20	800

When the shipper indicates electronically that its shipment includes a box of:

(1)- **8 03 6140528891 6** (as shown in the final row of the table above),

it is easy for the receiver to scan this GTIN-14 and to know that, inside this case there are a received quantity of (20) cartons, each containing (10) bundles of (4) bottles. Using HDA's ***Origin*** database as reference, the automated inventory system at the receiver knows what to enter into stock, without human error. And at its deepest level, the receiver's inventory system can calculate that this represents 800 individual bottles of 100 pills.

It is important to note that in the new product numbering system, any change in package quantity results in the need for the manufacturer to assign a new GTIN. If a manufacturer starts to ship in bundles of six bottles instead of bundles of four, a new GTIN is needed. Likewise, if the manufacturer decides to offer a bottle of 50 capsules, it must get a new GTIN-14 to differentiate it from the 100 capsule bottles.

This hierarchy discipline has been designed and implemented to create a reliable uniformity in the way quantities are expressed in shipping notifications, making wholesaler inventory management consistently more accurate.

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