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80 Must-Know Serialization Terms for U.S. Wholesale Distributors

The 2019 DSCSA deadline for wholesale distributors is fast approaching, and it's going to require far more than tracking lot numbers. In order to be compliant, wholesalers will need to buy and sell only serialized products and verify their product identifiers at the homogenous case level or saleable unit level. Serialization requirements bring along a number of abbreviated words, acronyms, and regulatory distinctions that will become part of your day-to-day life.

What, for example, is the distinction between an electronic product code (EPC) and an external product identifier? And what does GTIN even mean? As you begin to plan your serialization strategy, use this glossary as your go-to reference guide. The sooner you master these basic definitions, the faster you can achieve your goals of preparing for a serialized supply chain.

GET GLOSSARY

#

3PL—Third-Party Logistics. A contracted company that provides distribution services of finished goods on behalf of another company. A 3PL never takes ownership of the product although the product is in its possession.

A

ADR—Authorized Distributor of Record. A wholesale distributor that a manufacturer designates or authorizes to distribute its products.

ASN—Advanced Ship Notice. A notification of pending deliveries, usually in an electronic format. ASN is the common name for the EDI 856 transaction.

Aggregation—The process of recording the serial number of a container along with the serial numbers of its contents; often referred to as a parent/child relationship, or a serialized container-to-content relationship.

Authenticate—The practice of checking a unique identifier against a set of captured serialized data to determine its authenticity.

B

B2B—Business-to-Business. Interactions that support the transfer of standardized interchange files up to an enterprise's EDI system. B2B interactions are not integrated with manufacturing, warehouse, or other backend business systems.

C

Case—A container of product cartons which may or may not be bundled.

Chargeback—A difference in expected vs. unexpected cost that must be reconciled and reimbursed. For example, when a wholesale distributor charges a manufacturer for cost and labor when a product does not meet agreed business specifications (box size, position, on time, or labeled, for example). A chargeback may also be warranted when a customer buys product at a cost that is less than the distributor's cost.

Commission—Process of associating a unique identifier to a particular object (product, shipment, asset, or container).

Counterfeit—An imitation usually created with the intent of fraudulently passing it o as genuine, often to take advantage of the established worth of the imitated product. The word counterfeit frequently describes the forgeries of currency and documents, and the imitations of clothing, software, pharmaceuticals, jeans, watches, electronics, and company logos and brands. In the case of goods, it results in patent infringement or trademark infringement.

Cycle Counting—The periodic (daily, weekly, monthly, annual) manual counting of inventory in order to verify what quantities are in the warehouse against a business system to determine a financial value. Some edge solutions have a counting capability for lot count that gets bundled as part of a serialization solution to expedite cycle counting.

D

DC—Distribution Center. A warehouse stocked with goods to be redistributed to retailers, wholesalers, or customers.

DQSA—The Drug Quality and Security Act. U.S. Federal legislation passed in November 2013. DSCSA is a section of DQSA.

DSCSA—The Drug Supply Chain Security Act, which is Title II of DQSA. DSCSA mandates a full supply chain traceability system from pharmaceutical manufacturer to pharmacy dispenser for prescription drugs being distributed in the United States. The law was signed by President Obama in November 2013, providing a national standard for drug security and replacing the patchwork of state-level pedigree regulations that were in place.

Damaged—Reflects an inventory status in which damage has occurred to product packaging or labels, prompting a distributor to contact the supplier and return the product.

Decommission—The process of removing a unique identifier from a product or container so it is no longer tracked. Unlike the business process known as destroying, the item may still physically exist after decommissioning even though it no longer carries serialized identification.

Destroy—In instances where a product or container no longer exists, the process of removing a unique identifier from that item so it is no longer tracked.

Disaggregation—Removing products or containers from their associated parent container. The serial numbers of the contained items are no longer associated as children of the parent container.

Disposition—The state of a serial number, such as commissioned or decommissioned.

Dispenser—A retail pharmacy, hospital pharmacy, group of chain pharmacies, or any other person authorized by law to dispense or administer prescription drugs. Under DSCSA, an entity is not considered a dispenser if it acts as a wholesale distributor or dispenses products only used for animals.

E

EDI—Electronic Data Interchange. The electronic transfer of data between computer systems in a standardized message format.

EPC—Electronic Product Code. A unique number that identifies a specific item in the supply chain. Also known as a serial number.

EPCIS—Electronic Product Code Information Services. A GS1 EPCglobal standard designed to enable EPC-related data sharing within and across enterprises. This data sharing is aimed at enabling participants in the EPCglobal Network to obtain a common view of the disposition of EPC-bearing objects within a business context. (More at www.gs1.org/epcis).

ERP—An Enterprise Resource Planning system. Business process management software used to manage and automate back-o ice operations.

Each—An individual saleable unit entering the supply chain, such as a finished goods bottle or unit carton.

Edge Data—Data captured on a scanning device at different operational hand-off points (edges) of an enterprise, often to determine the status of a product in the supply chain. Examples include capturing product or carton data at a shipping or receiving dock or at the point of dispensing a drug to a patient in a hospital/clinical setting.

Edge Solution—A software solution configured with a company's scanning devices to capture information about physical product as an extension of existing WMS and ERP systems to provide instantaneous feedback and identify and correct potential exceptions. An edge solution can be used to capture a unique product identifier and

communicate with serialization repositories to verify a serial number.

Exception Management—Defines how warehouse operations address exceptions to business processes such as shortages, overages, and damages.

Exclusive Distributor—A wholesale distributor that directly purchased a product from a manufacturer or other channel and is the sole distributor of that manufacturer's product to a subsequent repackager, wholesale distributor, or dispenser.

Expiration—Date of expiration for an item, or the last day the item should be used.

External Product Identifier—A standards-based product code, such as a Global Trade Item Number (GTIN), or a market-specific product code used to identify the product in the external supply chain. This is specifically not a manufacturer SKU, which is not regulated or standardized.

G

GLN—Global Location Number. A unique 13-digit number containing a GS1 company prefix, a location reference, and a check digit, used to uniquely identify a physical location or legal entity in the supply chain. The GLN makes possible the unique and unambiguous identification of those locations and entities.

GS1—A leading global organization dedicated to the design and implementation of global standards and solutions, to improve the e□iciency and visibility of supply and

demand chains globally and across sectors. The GS1 system of standards is the most widely used supply chain standards system in the world. (More at www.gs1.com).

GS1 Datamatrix—A two-dimensional matrix barcode consisting of black and white "cells" or modules arranged in either a square or rectangular pattern. The information to be encoded can be text or raw data. Usage is granted to organization members of GS1.

GTIN—Global Trade Item Number. An identifier for trade items, developed by GS1. Such identifiers are used to look up product information in a database, often by inputting the number via a barcode scanner pointed at an actual product. The uniqueness and universality of the identifier is useful in establishing which product in one database corresponds to which product in another database, especially across organizational boundaries. Usage is granted to organization members of GS1.

Grandfathering—A provision in which some pre-existing situations are not subject to a new rule or regulations. An example is the FDA grandfathering guidance, which states that a package or homogenous case not labeled with a product identifier will be exempt from the manufacturer serialization requirements if there is documentation that it was packaged by the manufacturer prior to November 27, 2018. The major implication of the guidance is that distributors can continue to buy/sell drug product without a product identifier past November 27, 2019, up until expiration date, as long as the product was packaged prior to November 27, 2018.

H

HDA—Healthcare Distribution Alliance. The national association in the U.S. representing primary, full-service healthcare distributors. HDA member companies deliver more than nine million prescription medicines and healthcare products to more than 165,000 settings including chain and community pharmacies, hospitals, nursing homes, physician offices, and clinics in every state and territory.

Homogeneous Case—A sealed case containing only product with a single national Drug Code (NDC) and a single lot. Under DSCSA, a homogeneous case produced by a packager must display a unique product identifier that corresponds to the product it contains.

I

Illegitimate Product—Defined by the FDA as a product for which credible evidence shows that it (a) is counterfeit, diverted, or stolen, (b) is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans, (c) is the subject of a fraudulent transaction, or (d) appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans.

Inbound—The step in which product is received at the warehouse prior to subsequent putaway and pick-pack-ship steps. Under DSCSA, wholesale distributors are not

required to capture serialized information when received on the inbound, although some companies make the decision to implement inbound tracking to record receipt. See Outbound.

Inference—The technique of assuming the serial numbers within a sealed container based on previous observation, and not by directly reading each serial number. Inference is accomplished using data systems or documents and is controlled through validated procedures.

Inquiries—Inquiries may be performed by an FDA or state official to verify product and transaction information under request for information and verification requirements in DSCSA. Official verification inquiries will be held if there is suspicion of counterfeit, diversion, or other illicit activity with a drug product. Request for information inquiries may also be initiated in the event of a product recall.

Inspections—Inspections may be performed to verify compliance with DSCSA rules and regulations. The FDA has the responsibility for implementation of DSCSA and jurisdiction over monitoring compliance. But wholesale distributors could be inspected for DSCSA by a variety of officials. The FDA could perform a random compliance check. State officials may also inspect a business if DSCSA compliance is a precondition for their licensure. And if you are VAWD-accredited, the National Association of Boards of Pharmacy (NABP) may inspect you; their expectation is that VAWD members comply with DSCSA.

Interoperability—The ability of technology systems to exchange information accurately, efficiently, and consistently in a usable format.

L

LPN—License Plate Number. See SSCC.

M

Master Data—Data representing a company's details, global identifiers, products, and trading partners. Particular types of data are required for serialization and global compliance reporting.

O

Outbound—The step in which product is shipped from the warehouse after the pick-pack-ship step. Under DSCSA, wholesale distributors are required to capture serialized information before product leaves the warehouse and a change of ownership occurs. See Inbound.

Overage or Over—Occurs when a customer receives extra product than what was ordered from the supplier, prompting the need to return such product or, if product is retained, to initiate exception processing to ensure receipt of the required DSCSA documentation for the additional product.

P

Pallet—A pallet is assembled at the tertiary level and may contain multiple cases or multiple shipping containers. This level of packaging is rarely covered under explicit serialization regulations.

Picking—The process of collecting items in a warehouse to fulfill a customer order.

Pick-Pack-Ship—The warehouse process of fulfilling an order. Options include picking by order/sequence until complete or verifying at pick by using a scanning-enabled system such as a WMS or edge solution to scan and confirm correct products and quantities.

Putaway—The activities that occur between the time that product is received at the warehouse and when it is stocked in inventory.

R

RMA—Return Material Authorization. Initiates the business process of returning product due to damage, incorrect quantity, or other order fulfillment exception for the purpose of refund or replacement.

Recall—The removal of a drug product from the market. In the U.S., recalls fall under three classifications: Class I is for those products that can probably lead to adverse health e□ects or death; Class II is for drugs that can cause temporary or reversible health e□ects; and, Class III relates to instances where the drug is not likely to cause adverse health e□ects.

Receiving—The process of receiving a product order (PO) from an upstream supplier and then unloading, inspecting, verifying, sorting, staging, and putting product away. See Inbound.

Relabel—Product may be re-labeled if it is being repackaged or being distributed under a different trade name. For wholesalers, relabeling is usually the result of damage to the original label or assigning a new serial number to a container to preserve existing aggregations.

Repackager—The business of repackaging involves taking the originally manufactured product, and then repackaging or relabeling it for resale in the supply chain. Under DSCSA, any U.S. wholesale distributor that purchases drugs from a repackager on or after November 27, 2018, must ensure that the packages are properly serialized.

Replenishment—The manual process of restocking warehouse inventory when a WMS indicates low supply. Automated replenishment through edge solution integration with a company's WMS can be implemented to boost both floor efficiencies and back-office warehouse management processes.

Returns—Typically, product deemed non-saleable due to exceptions such as damage, expiration, or overstocking. The product is returned to a manufacturer or wholesale distributor for credit. A Saleable Return is returned to a supplier and is subject to DSCSA regulations when it re-enters the market.

Rework—Any process exception that touches product during post-packaging and interrupts the business-as-usual operations of a warehouse, such as damaged product or sampling.

S

SNI—Standardized Numerical Identifier. A standard identifier a□ixed to a prescription drug package.

SSCC—Serial Shipping Container Code. A GS1 standard used in logistic encoding and communications. The SSCC ensures that logistic units are identified with a number that is unique worldwide. An SSCC is essentially a pallet level serial number.

Saleable Return—Product that may be resold once the product identifier has been verified against a pharmaceutical manufacturer's data. Per DSCSA Chapter II "…a wholesale distributor may accept returned product from a dispenser or repackager only if the wholesale distributor can associate returned product with the transaction information and transaction statement associated with that product. For all transactions after such date, the transaction history, as applicable, of such product shall begin with the wholesale distributor that accepted and verified the returned product."

Serial Number—In addition to the GTIN, lot number, and expiration date, a component of a Unique Identifier (UID). Also known as a serial reference.

Shipping Container—See Pallet.

Shipping Verification—The process of verifying the contents of an order against the picking ticket to ensure accuracy prior to shipping the order.

Shortage or Short—Occurs when a customer receives an order that is missing products, lots, quantities, or SSCCs. This status prompts the customer to contact the supplier and either ask for additional product or void the transaction and reissue an ASN.

Smallest Saleable Unit—Each individual package of drug product, also known as the primary package level. The sealed homogeneous case in which smallest saleable units are packaged is the secondary package level.

T

T3—Under DSCSA, the combination of Transaction Information (TI), Transaction History (TH), and the Transaction Statement (TS) for a drug product as it moves through the drug supply chain.

TH—Transaction History. A record of transaction information for each change of ownership within the supply chain, starting with the manufacturer.

TI—Transaction Information. A comprehensive set of details about each product included in a transaction, including product name, National Drug Code (NDC) number, strength and dosage form, size and number of containers, lot number, date of transaction, and the names of the companies involved in the transaction.

TS—Transaction Statement. A statement confirming that trading partners are authorized by law to transfer ownership of product, have received transaction documentation, have systems in place to comply with verification requirements, and did not knowingly ship suspect product or provide false information.

Transaction—As defined by DSCSA, the transfer of product where a change of ownership occurs. Exemptions: intercompany distributions, distribution among hospitals under common control, public health emergencies, dispensed pursuant to a prescription, product sample distribution, blood and blood components for transfusion, minimal quantities by a licensed pharmacy to a licensed practitioner, charitable organizations, distributions pursuant to a merger or sale, certain combination products, certain medical kits, certain IV products, medical gas distribution, approved animal drugs.

Track and Trace—The process of tracking drugs through the supply chain using serialization data. Track and trace systems begin with serialization but generally include additional components such as product tracing or tracking, verification, and/or reporting.

U

UID—Unique Identifier. A string of numbers and characters that is unique within a given system. Examples include GS1 GTIN and GS1 identifiers.

V

VAWD—Verified-Accredited Wholesale Distributors. An accreditation for pharmaceutical wholesale distribution facilities. VAWD accreditation indicates that a wholesale distributor is in compliance with state and federal laws as well as the U.S. National Association of Boards of Pharmacy's VAWD criteria.

VRS—A Verification Router Service helps facilitate the verification of a Product Identifier under DSCSA by capturing verification requests and routing them to a system of record that contains product information provided by a manufacturer or repackager.

Verification Request—A request to verify a product identifier for a pharmaceutical pack affixed by the manufacturer or repackager against a pharmaceutical manufacturer's data. The term 'verification' or 'verify' means determining whether the product identifier affixed to, or imprinted upon, a package or homogeneous case corresponds to the standardized numerical identifier or lot number and expiration date assigned to the product by the manufacturer or the repackager.

W

WMS—Warehouse Management System. A software application that supports the day-to-day operations of workers within a warehouse. A WMS supports the centralized management of tasks such as tracking inventory levels and stock locations.

Wholesale Distributor—A licensed company that purchases (takes ownership of) products from a supplier and then sells them to an entity in the supply chain other than a consumer or patient.

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