

DRUG PEDIGREE, MESSAGING AND TRACKING

GLOSSARY OF TERMS

This document provides the definitions for acronyms and terms used with drug pedigree and supply chain processes and tracking. The content is a compilation of terms identified by NCPDP WG17 Pedigree and Traceability,

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Acronyms

3PL	Third Party Logistics Provider - An entity that picks, packs and ships as an agent of the manufacturer. They do not have ownership of the product.
AI	Application Identifier - The field of two or more characters at the beginning of an Element String that uniquely defines its format and meaning. Valid values: <ul style="list-style-type: none"> • 00 SSCC • 01 GTIN • 10 Lot/Batch • 17 Expiry • 21 Serial Number • 30 Quantity
ADR	Authorized Distributor of Record - Those distributors with whom a manufacturer has established an “ongoing relationship” to distribute manufacturer’s products.
API	Active Pharmaceutical Ingredient - The substance in a drug that is pharmaceutically active . (active ingredient (AI), also active pharmaceutical ingredient (API) or bulk active,) The traditional word for the API is pharmacon (from Greek: φάρμακον), adapted from pharmacos which originally denoted a magical substance or drug . The term is similarly used in pesticide formulations where active substance is also used. Some medications may contain more than one active ingredient.
ASN	Advanced Shipping Notice - This is a type of EDI transaction (ASC X12 Ship Notice/Manifest transaction set (856)). The 856 contains detail information about a shipment). The ASN contains information regarding a specific shipment of product from a seller to a buyer and is transmitted prior to the arrival of the shipment. The fields, data and level of granularity (shipment, pallet, case, etc.) are determined by the trading partners
BoP	Board of Pharmacy - The state regulatory authority governing the pharmacy industry within the state.
CMS	Centers for Medicare & Medicaid Services – The division of the US Department Health and Human Services providing governance for the Medicare and Medicaid programs.
DC	Distribution Center - A distribution center for a set of products is a warehouse or other specialized building , often with refrigeration or air conditioning , which is stocked with products (goods) to be re-distributed to retailers , wholesalers or directly to consumers. A distribution center is a principle part, the " order processing " element, of the entire " order fulfillment " process. Distribution centers are usually thought of as being " demand driven ". A Distribution center can also be called a warehouse, a DC, a fulfillment center, a cross-dock facility, a bulk break center, and a package handling center. The name by which the distribution center is known is commonly based on the purpose of the operation. For example a "retail distribution center" normally distributes goods to retail stores, a "order fulfillment center" commonly distributes goods directly to consumers, a cross-dock facility stores little or no product but distributes goods to other destinations.
DEA	Drug Enforcement Administration - The mission of the Drug Enforcement Administration (DEA) is to enforce the controlled substances laws and regulations of the United States and bring to the criminal and civil justice system of the United States, or any other competent jurisdiction, those organizations and principal members of organizations, involved in the growing, manufacture, or distribution of controlled substances appearing in or destined for illicit traffic in the United States; and to recommend and support non-enforcement programs aimed at reducing the availability of illicit controlled substances on the domestic and international markets.
ECC200	Data Matrix Version – The latest version of Data Matrix Bar Code Font and Encoder Standard supports advanced encoding supporting error checking and correction algorithms . ISO/IEC16022 version ECC200.

EDI	Electronic Data Interchange –The structured transmission of codified data between organizations by electronic means, for instance, organizations might replace bills of lading and checks with appropriate EDI messages. It also refers specifically to a family of standards used to enable this communication of information, such as the ASC X12 standards. It is based on ASCII -formatted single messages.
EMA	European Medicines Agency - an EU regulatory agency for the evaluation of medicinal products.
EPC	Electronic Product Code™ (EPC) - A globally unique serial number that identifies an item in the supply chain. The EPC is a fundamental element of the EPCglobal Network.
EPCIS	EPC Information Services – An EPCglobal standard designed to enable EPC-related data sharing within and across enterprises. The EPCIS standard defines standard interfaces to enable EPC-related data to be captured and subsequently to be queried using a set of service operations and an associated data model.
EU	European Union - A political and economic union of 27 member states , located primarily in Europe . It was established by the Treaty of Maastricht in 1993 upon the foundations of the pre-existing European Economic Community .
FDA	Food and Drug Administration - The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation’s food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.
FIPS	Federal Information Processing Standards - Federal standards for information processing. As it relates to pedigree, these are the Federal standards for cryptographic, digital signature, and hashing technology and processing and may be specified by some state laws.
GLN	Global Location Number - The globally unique GS1 System Identification number for legal entities, functional entities, and physical locations. The Global Location Number is 13 digits, comprised of a variable length GS1 Company Prefix, Location Reference, and Check Digit.
GPC	GS1 Global Product Categorization - It provides the required global framework for trade item categorization supporting global data synchronization.
GS1	GS1 is a global organization dedicated to the design and implementation of global standards and solutions to improve the efficiency and visibility of supply and demand chains globally and across sectors.
GTIN	Global Trade Item Number - The GS1 system used to uniquely identify trade items. The GTIN is comprised of a GS1 or UPC Company Prefix followed by an Item Reference Number and a Check Digit. They may be 8 digits, 12 digits, 13 digits, or 14 digits in length. They are represented as right justified 14 digit fields with 0 fill to left as needed. In the GTIN-14 the first digit is an indicator digit.
HDMA	Health Distribution Management Association – Mission Statement: Protect patient safety and access to medicines through the safe and efficient distribution of healthcare products and services. Create and exchange industry knowledge and best practices to enhance the value of the healthcare supply chain. Advocate for standards, public policies and business processes that produce safe, innovative and cost-effective healthcare solutions.
HIPAA	Health Insurance Portability & Accountability Act 1996 no general definition.
HLS	Health and Life Sciences Industry - A subdivision of EPCglobal dealing with standards for the health care industry.
IATF	Industry Adoption Task Force – An EPCglobal HLS work group.

NDC	National Drug Code - A three-segment product identifier used in the United States to identify drug products. The FDA enters the full NDC into a database known as the Drug Registration and Listing System (DRLS). The segments of the NDC identify the manufacturer, the product and the saleable unit package size.
OMS	Orders Management System - Is a computer software system used in a number of industries for order entry and processing.
PDMA	Prescription Drug Marketing Act 1987 – no general definition
PKI	Public Key Infrastructure - A framework for creating a secure method for exchanging information based on public key cryptography. The foundation of a PKI is the certificate authority (CA), which issues digital certificates that authenticate the identity of organizations and individuals over a public system such as the Internet. The certificates are also used to sign messages which ensure that messages have not been tampered with or otherwise compromised
PLN	Principal Location Number - It is the GLN of the legal entity owning the GCP.
RFID	Radio Frequency Identification The product identification tag used in the tracking system based on the electromagnetic or electrostatic coupling in the RF portion of the electromagnetic spectrum to transmit signals. An RFID system consists of an antenna and a transceiver , which read the radio frequency and transfer the information to a processing device ; and a transponder , or tag, which is an integrated circuit containing the RF circuitry and information to be transmitted.
SDO	Standards Development Organization - Any entity whose primary activities are developing, coordinating, promulgating, revising, amending, reissuing, interpreting, or otherwise maintaining standards that address the interests of a wide base of users outside the standards development organization.
SGTIN	Serialized Global Trade Item Number – The combination of the GTIN and a unique serial number. The SGTIN consists of the Company Prefix, Item Reference and Serial Number.
SKU	Stock Keeping Unit - An item level product identifier used for inventory and sales
SSCC	Serial Shipping Container Code - The GS1 Identification Key used to identify logistics units. The key is an 18 digit number with an initial indicator digit followed by of the variable length GS1 Company Prefix and Serial Reference, and ending with a Check Digit.

Terms

Aggregation	The establishment of containment relationships to support and facilitate inference: defines unit to container association and container to container association.
Authenticate	Affirmatively verify that each previous transaction listed on the pedigree has occurred and that the previous signatures or certifications are complete.
Auto-ID	Any technology that encodes information on a product for automatic/machine identification. It is not designed To be read by humans. Examples of Auto-ID include the linear/ 2D Barcode or RFID which, when applied on the individual package, store the unique identifier of this package to allow for a link between the product and its Electronic Pedigree.
Bar Code	A symbology consisting of a precise arrangement of parallel lines (bars) and spaces that varies in width to represent data.
Certificate Properties	Typically includes the public key being signed, a name, which can refer to a person, a computer or an organization, a validity period, and the location URL of a revocation center.
Certification	A sworn statement that the pedigree is complete and accurate and that prior sales and distributions have been authenticated. It is used if required by regulation.
Commissioning	The act of creating a pedigree for an item. Associates units, repackaged items, and/or kits to drug characteristics and the source of drug information.
Dangerous Drug	A designation assigned by California law (Senate Bill 1307) to all prescription drugs.
Data Matrix	A standalone two dimensional matrix symbology (Barcode-standalone, two)-that is made up of square modules arranged within a perimeter finder pattern. Data matrix ISO version ECC200 is the only version that supports GS1 System identification numbers, including Function Code 1. Data Matrix Symbols are read by two-dimensional scanners or vision systems.
Digital Signature	A method for authenticating digital information analogous to ordinary physical signatures on paper, but implemented using techniques from the field of public-key cryptography. A digital signature method generally defines two complementary algorithms, one for signing and the other for verification, and the output of the signing process is also called a digital signature. The term electronic signature, although sometimes used for the same thing, has a distinct meaning in common law: it refers to any of several, not necessarily cryptographic, mechanisms for identifying the originator of an electronic message.
Digitally Signed	Digitally signed data is data that has been stored with the "identity" of an entity, and a digital signature intended to prove that the entity is the source of the data. The data has been digitally signed using the entity's private key (see "PKI") in an attempt to make it practically impossible to forge or modify the data. In this document this refers to a digitally signed pedigree xml record.
Disaggregation	Alteration of unit to container or container to container relationships.
Dosage Form	Is the physical form of a dose of medication , such as a capsule or

	<p>injection. The route of administration is dependent on the dosage form of a given drug.</p> <p>Various dosage forms may exist for the same compound, since different medical conditions may warrant different routes of administration. For example, persistent vomiting may make it difficult to use an oral dosage form; in this case, it may be advisable to use either an injection or a suppository. Also, specific dosage forms may be warranted for certain medications, since there may be problems with stability, e.g. insulin cannot be given orally since it is digested by the gut.</p>
Downstream Trading Partners	Customers of the current holder of the pedigreed drug product and their customer's customers.
Drug Pedigree	A record of each distribution of a prescription drug from the sale by a Manufacturer through acquisition and sale by any Wholesale Distributor until final sale to a Pharmacy or other authorized person administering or dispensing the Prescription Drug.
Drug Pedigree Laws	State and / or federal laws that require a record of a drug product's chain of custody. These laws apply to specific jurisdictions and may vary from jurisdiction to jurisdiction.
Electronic Pedigree	An electronic record containing all data and information required by one or more pedigree laws, including any necessary certifications. The Pedigree Standard defines the requirements for the standard representation and exchange of pedigree information through EPCIS events.
Electronic Verification	The process of determining the pedigree and each signature or certification is genuine, true and unaltered through the use of electronic technology such as digital signatures, hashing and public and private electronic code pairs. See "signature" and "PKI".
EPCglobal	A SDO set up to achieve world-wide adoption and standardization of Electronic Product Code (EPC) technology in an ethical and responsible way.
EPC Event	The documented What, When, Where and Why of an item or container movement that enables track and trace processes. Event types include commissioning of units, repackaged items or kits; shipping; receiving; aggregation and disaggregation; change in custody; change in ownership; etc.
EPC Reader	An RFID reader that complies with EPCglobal standards.
EPC Tag	An RFID tag that complies with EPCglobal standards containing an Electronic Product Code.
ePedigree	See "Electronic Pedigree"
Expiration Date	The date printed on the drug label by the manufacturer up to which time the manufacturer guarantees the full potency and safety of the drug.
Grandfathering	An exception which would permit transfers without pedigrees of prescription drugs that otherwise require pedigrees for some time (and / or quantity) after the effective date of the law.
Inference	To infer the serialized number based on information provided by the upstream supply chain, reasonable inspection of the product, and application of Serialized Inference rules by the shipping and receiving partners. GS1/EPCglobal.

Interoperability	The ability of different information technology systems and software applications to communicate; to exchange data accurately, effectively and consistently; and to use the information that has changed.
Item	The lowest level of packaging that manufacturers offer a prescription product (bottle, vial, box, etc.) This typically does not refer to the unit dose that would be prescribed or administered to the patient or consumer (pill, milliliter, etc). It generally means "Saleable Item" from the point of view of the manufacturer.
Item Reference	The part of the Global Trade Item Number (GTIN) allocated by the user to identify a trade item for a given GS1 Company Prefix.
License	A company's or individual's commercial license issued by a regulatory body to manufacture, package, sell, store, transport, buy or receive prescription drugs. Licenses are issued by the state and federal governments. An entity may have multiple licenses depending upon the jurisdictions in which they are conducting commerce and what function they are providing/performing.
Lot	A distinct group of inventory of a given drug. A drug's lot number is assigned by the manufacturer or by a repackager (See "Repackaging"). An individual lot number is assigned to drugs that are produced in a particular time period, on a particular manufacturing or packaging line, or that contain the same genealogy of ingredients.
Message Digest	The output of cryptographic hash function which takes a message of any length as input and produces a fixed length string as output.
NDC Masking	The process of replacing the Item Reference portion of the SGTIN with zeros to avoid divulging the underlying NDC number.
Non-Repudiation	Ensuring that parties to an event, transaction or legal document cannot later disclaim involvement.
Package Size (Pack Size)	The number of individual units of a drug product (pill or tablet count, milliliters or "cc", grams, etc.) included in each item (bottle, vial, box, etc.) See "Item".
Partial Receipt	Receipt of only part of a shipment of a specific drug from a supplier for a specific sale or transfer. For example, a supplier provides a pedigree for single shipment of 100 units of a drug. 50 units are received on day one by the purchasing organization; the remaining 50 units are received on day four. Both receipts are partial receipts.
Pedigree	Pedigree is a process that begins with the serialization of a product with a unique identifier down to the lowest unit of sale, then moves through the supply chain with each trading partner authenticating it upon receipt and transfer, with updates appended as the product is passed to the next receiver, in an interoperable electronic interchange.
Pedigree Envelope	A document that encloses one or more pedigrees in a shipment
Product Information	Information required in a pedigree related specifically to the identity of the drug. Requirements vary from state to state. Data may include the name of the prescription drug, National Drug Code, package size, quantity, dosage form and strength, the expiration date(s) and the lot number
Product Label	The label applied to an item package by the manufacturer or

	repackager. The contents and characteristics of this label must meet strict guidelines and regulations set forth by the FDA.
Publish	A term used to describe the process of transmitting EPCIS events from an EPCIS server to an EPCIS.
Pure Identity	The identity associated with a specific physical or logical entity, independent of any particular encoding vehicle such as a RF tag, bar code or database.
Quarantine	The act of holding an item/container out of the supply chain or inventory until an appropriate, authentic pedigree is received.
Repackager	A business entity that buys finished products from the manufacturer in the manufacturer's packaged form and repackages it into quantities to serve market requirements. For example, a repackager may buy 1,000 pill count bottles and repackage them into 10 count blister packs. A repackaged product may or may not be assigned its own NDC number, different from the original NDC number.
Radio Frequency Identification	A data carrier technology that transmits information via signals in the radio frequency portion of the electromagnetic spectrum. A RFID system consists of an antenna and a transceiver, which read the radio frequency information to a processing device, and a transponder, or tag, which is an integrated circuit containing the radio frequency circuitry and information to be transmitted.
Radio Frequency-Active Tag	A RFID tag with its own power source, usually a battery. Most active RFID tags use replaceable batteries – usually button batteries – but some do not. A battery in the tag can enable one or more of the following: longer range, on-tag diagnostics (such as temperature recording) and better performance in difficult environments – such as with metals and fluids. Active tags can also be used to enable real time locating of the items they are connected to. Some active tags can work over existing standards and networks such as Wi-Fi and Zigbee.
RFID Passive Tag	RFID where the tag does not contain its own power supply. It only returns an appropriate signal that is directed at it. Most RFID employs passive tags.
Saleable Item	The lowest packaging unit a wholesaler would ship a drug to fill and order. See "item".
Serialization	Serialization is the process of generating, encoding, and verifying unique identities on physical items.
Serialized Inference	The process a supply chain partner uses to ensure there is enough evidence to infer the serialized number without physically reading all serialized numbers within a packaging unit. Specific parameters are defined by trading partner agreement. GS1/EPCglobal
Serial Number	A unique character string that identifies a specific instance of a drug packaging unit (case, inner pack, bottle, vial, box, etc.) from all other instances of that drug in the same packaging unit (serialized cases, serialized bottles, serialized vials). Few drugs contain serial numbers at the bottle, vial or item level (see item definition) today.
Signatures	The representation, in any acceptable media, by an individual or corporation that they are swearing or affirming that the information contained on the pedigree is accurate and complete. Each signature has a context and a finite scope.

Signer	The person authorized to bind the company by oath on legal documents.
Strength	The amount of active ingredient in the drug product. Each NDC has either one specific strength or a specific combination of strengths. This is also referred to as potency.
Standing Queries	Used by EPCIS to obtain query results from an EPCIS repository. Created when EPCIS subscribe to queries available on an EPCIS repository.
Trace	The capability to identify the historical locations, the records of ownership, and the packaging for a particular traceable item. Trace answers questions such as “where has the item been”, “who has previously owned the item”, and “in what packaging hierarchy did the product exist at various locations”. The EPCglobal Pedigree Messaging Standard is one example of a Trace mechanism. Trace back or upstream in the supply chain.
Track	The capability to identify the current (and at time of shipment the intended future) location, ownership, and packaging hierarchy of a traceable item through the supply chain as it moves between parties. Track addresses both forward and reverse logistics operations. Track answers the questions such as “where is the item currently”, “who is the next intended recipient”, and “what is the current packaging hierarchy of this item”. Track forward or downstream the supply chain.
Traceability	Traceability is the ability to track forward the movement through specified stage(s) of the extended supply chain and trace backward the history, application or location of that which is under consideration
Trace and Track	The combined capabilities of “Trace and Track”.
Transaction Information	Typically refers to mandatory information related to each transaction (sale, movement, return, transfer) of a pedigreed drug’s distribution.

Modification History

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