DRUG PEDIGREE IN THE HEALTH CARE INDUSTRY: BACKGROUND

VERSION 1.Ø

This paper provides the health care industry historical and background information on options and issues for consideration in preparing for the implementation of drug pedigree and traceability in the pharmaceutical supply chain.

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PURPOSE AND SCOPE

The NCPDP Work Group 17 Pharmaceutical Pedigree and Traceability (WG17) Education Task Group developed this White Paper to define the current status of traceability and pedigree within the pharmaceutical supply chain This review is founded on awareness of the proposals for the use of drug pedigrees and traceability functionality in response to the growing concerns for securing the pharmaceutical supply chain against theft and fraud and assuring patient safety.

Within recent years there has been an increased awareness of issues surrounding the security of pharmaceutical products as they move through the supply chain. Concerns include diversion or loss of legitimate products, insertion of fraudulent products and accurate product labeling. There is also a need to ensure that the drug delivered to the patient is indeed the product ordered by the prescriber. This White Paper will provide a discussion of these concerns as well as a review of the regulatory and health care industry responses to this challenge. It is the first step in an effort to arrive at a model for the integration of pedigree and traceability into the pharmaceutical supply chain and health care delivery processes.

DEFINITIONS

The following are the definitions of key terms used in this White Paper:

- Pedigree: The documentation of lineage. In the context of the healthcare supply chain, Pedigree is a process that begins with the serialization of a product by application of a unique identifier at the lowest unit of sale, and then moves through the supply chain with each trading partner authenticating it upon receipt and transfer. Updates are appended as the product is passed to document changes in custody and ownership. Ideally authentication and updates are done through an interoperable electronic interchange.

- Traceability: The ability to track the forward movement of a product through specified stage(s) of the extended supply chain and trace backward the history, application or location of is the product under consideration

- Serialized Product Identifier: A unique character string that identifies a specific instance of a drug packaging or saleable 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).

- Data Carrier or Identification carrier: A mark, tag, label or accompanying document sometimes called "passport" or "identity card" in some industry sectors which can be human readable and/or machine readable. It is applied at the source when the finished goods are created or shipped. Machine readable forms are linear, 2D bar code or RFID electronic tag.

1. THE PROBLEM – PATIENT SAFETY AND SUPPLY CHAIN SECURITY

The enactment of laws governing the traceability of manufactured pharmaceuticals throughout the supply chain dates back to the Prescription Drug Marketing Act (PDMA) of 1987, which became law in 1988. The PDMA contained provisions for what we identify today as ePedigree or "track and trace" technology. Those provisions were enacted to help protect the drug supply from diversion and the American consumer from the risk of counterfeit or altered drug products. The goal was to document the chain of custody of a drug unit from manufacturer to distributor to wholesaler to hospital or pharmacy. Subsequent laws and regulations, including the Prescription Drug Amendments Act of 1992 (PDAA) and recent bills in Congress, all contain varying levels of pedigree, pharmaceutical traceability, drug serialization, and other track and trace requirements.

In September of 2007 the Food and Drug Administration Amendments Act of 2007 (FDAAA) was signed into law. Section 913 of this legislation created section 505D of the Federal Food, Drug, and Cosmetic Act, which requires the Secretary of Health and Human Services to develop standards and identify effective technologies for the purpose of securing the drug supply chain against counterfeit, diverted, sub potent, substandard, adulterated, misbranded, or expired drugs. In March 2010 the Food and Drug Administration (FDA) issued "Standards for Securing the Drug Supply Chain - Standardized Numerical Identification for Prescription Drug Packages" which provides non-binding guidance addressing package level SNI (Serialized Numerical Identifier) to be "applied to a prescription drug at the point of manufacturing and repackaging at the package or pallet level, sufficient to facilitate the identification, validation, authentication, and tracking and tracing of the prescription drug". The standards included in the guidance are based on information received in response to FDA's request for comment and FDA's familiarity with currently utilized standards.

The safety and security of pharmaceuticals continues to remain a key focus of government regulators and industry stakeholders on a global scale. This guidance is the first of several expected guidance and regulation documents that FDA may issue to implement FDAAA.

In addition, recent reports show that there are troubling trends in the pharmaceutical industry with crime targeting pharmaceutical shipments and warehouses. One warehouse robbery reported in the March 17, 2010 Wall Street Journal resulted in a $75 million loss, but it was believed that the tight controls in place in the U.S. pharmaceutical distribution system would make it extremely difficult for stolen product to make it to patients through legitimate channels. However, a theft of insulin, notified by the FDA on 8/26/2009, resulted in multiple FDA warnings after the stolen insulin showed up in a medical center. This indicates that regardless of the existing safeguards, there are still possible illegitimate channel entries into the pharmaceutical distribution supply chain.

There is also concern in the US about unapproved, imported pharmaceuticals whose safety and effectiveness cannot be assured because they originate outside the FDA approval process. In 2003, Congress tasked the Department of Health and Human Services to examine issues related to drug importation. The task force "Report on Prescription Drug Importation" yielded the following the key findings:

- There are significant risks associated with the way individuals are currently importing drugs that violate the Federal Food, Drug and Cosmetic Act.
- The integrity of the distribution system must be ensured.
- It would be extraordinarily difficult and costly ($3 billion a year based on 2003 estimates) for "personal" importation to be implemented in a way that ensures the safety and effectiveness of the imported drugs.

- Overall national savings from legalized commercial importation will likely be a small percentage of total drug spending, and developing and implementing such a program would incur significant costs and require significant additional authority.
- The public expectation that most imported drugs are less expensive than American drugs is not generally true, especially in the case of generic drugs marketed in the U.S.
- Legalized importation of now-unapproved drugs will likely adversely affect the future development of new drugs for American consumers.
- The effects of legalized importation on intellectual property rights are uncertain but likely to be significant.
- Legalized importation raises liability concerns for consumers, manufacturers, distributors, pharmacies, and other entities.

For further information see http://www.fda.gov/Drugs/DrugSafety/ucm169828.htm

1.1 THE REGULATORY RESPONSE

Various efforts at the state and federal level have been undertaken to address supply chain safety through the use of drug pedigrees.

1.1.1 FEDERAL INITIATIVES

The Initial Prescription Drug Marketing Act (PDMA) was enacted in 1988 with the intent to increase safeguards that prevent the introduction into the US drug supply chain and the subsequent retail sale of substandard, ineffective and counterfeit drugs. The Final Rule was enacted in 1999 and the Final Enforcement Rule became effective on December 1, 2006. Since that time, various bills have been introduced that include drug pedigree requirements.

In recent years, several bills requiring electronic pedigree have been introduced in both the House and Senate, however, none of these bills have moved to the legislative reconciliation phase. State regulations requiring electronic pedigree have been pushed into the future to enable federal rules to drive development of the necessary processes, controls and technology. It is likely that some type of drug pedigree requirement will emerge from Congress.

A unique identifier is a prerequisite for electronic pedigree and track and trace of drugs through the supply chain. The FDA has issued Guidance for a Standardized Numerical Identifier (SNI) to address the need for unique identification at the packaging level. The SNI relies upon the existing National Drug Code (NDC) as the base means of product identification plus an alphanumeric serial number not to exceed 20 characters that is unique to each package.

1.1.2 STATE INITIATIVES

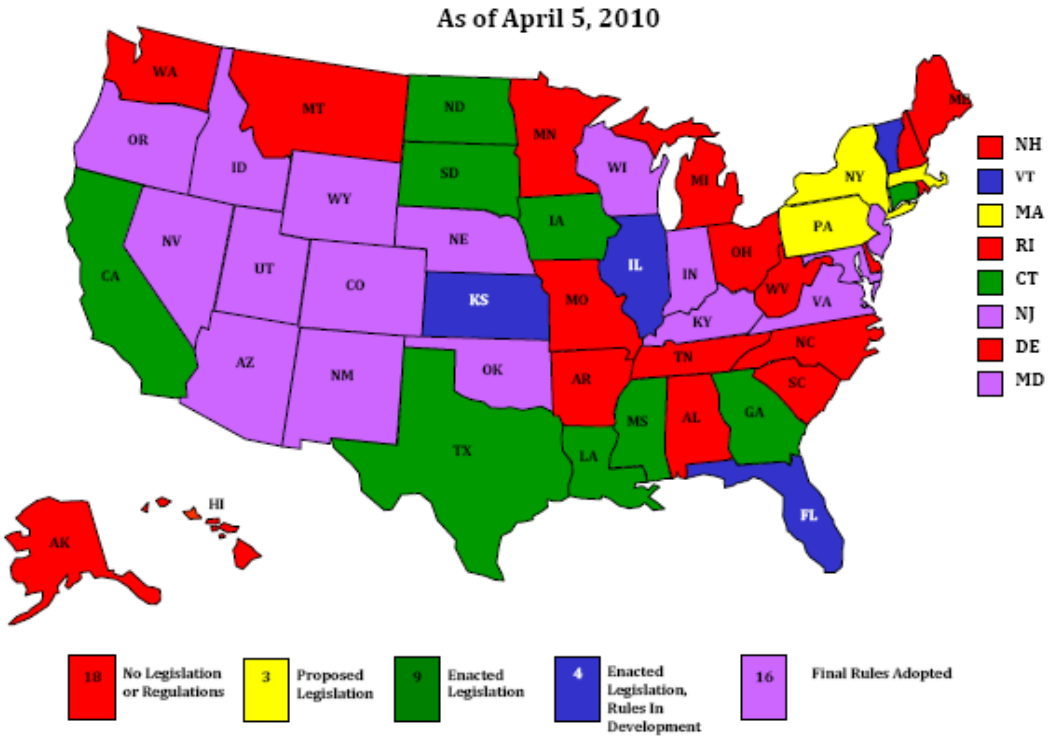
Some states have enacted or proposed legislation that includes the use of a drug pedigree as a means of assuring the safety of the drug supply chain. Many state regulations require a paper pedigree and rely upon the concept of “normal distribution”, as defined in the specific legislation, in determining when a pedigree document is required. The legislative concept of the “normal distribution” channel is intended to reduce the number of instances where a pedigree document must be exchanged. “Normal distribution” channel means a chain of custody during distribution of a prescription drug that goes through authorized distributors of record.

Normal Distribution Channel

The two states whose pedigree laws have received the most attention are Florida and California, but for different reasons. Florida implemented requirements that distributors create pedigree documents. The option of paper or electronic pedigree was supported. Recently Florida legislation was modified so that pedigree is required only for distribution outside the "normal distribution" channel.

The California law is the most comprehensive piece of drug pedigree legislation to date. It includes requirements for an electronic drug pedigree, product serialization, and track and trace from manufacturer to point of sale. The legislation requires a supply chain infrastructure and standards that are not currently in place. As a result, the implementation date of the California regulatory requirements has been pushed back to 2015 – 2017 to allow a phased-in approach with pharmacies implementing on or after July 1, 2017. This time should be used for all members of the supply chain to settle on methods for managing the process. The delay is also stimulating discussion of federal pre-emption in order to standardize requirements across the states. 2015 looks to be a de facto deadline for pedigree standardization and implementation in California, without prior federal intervention and pre-emption.

The following map provided by the Healthcare Distribution Management Association (HDMA) depicts the status of state pedigree requirements as of April 5, 2010. It is expected that state level pressure for electronic pedigrees will intensify should pre-emptive federal legislation not materialize in a timely fashion.



1.2 THE INDUSTRY RESPONSE

In developing this paper NCPDP WG17 researched the publications of various industry stakeholders regarding the need to secure the pharmaceutical supply chain and the potential for use of pedigree. Comments from United States industry groups on track and trace and pedigree contain some similarities in content. While most groups support the eventual implementation of electronic track and trace and/or pedigree systems, they also express concern regarding the viability of moving forward with current technology without an extended period of systems and interoperability testing and pilots. Common topics revolve around such areas as:

- recognition that the process is complex and lengthy,
- formalization and acceptance of standards are necessary before implementation and testing can begin,
- extensive testing and pilots are needed to prove technology prior to a mandate for implementation,
- maintenance of current processes within the typical distribution channel,
- consideration of benefit and cost impact on various areas in the supply chain and
- provision of both human-readable and machine-readable formats.

There are also areas of mixed support among the industry groups. Efforts of the states in implementing pedigree generate varied concern. While the intent behind the efforts is generally applauded, emerging inconsistent state requirements and lack of recognized national standards (formalized through legislation) make it an administrative burden for companies that operate across state lines. There is a lack of consensus in the area of product identification:

- NDC number creation/development and revamping of NDC number formats,
- addition of serialization to product identification,
- need for a central authority for product identification maintenance
- long-term uniqueness (no re-use),

- package/pallet size enumerations, and
- inclusion of lot number and expiration in the unique product ID.

Some industry suggestions include initial implementation of smaller scale programs such as real-time authentication of a serialized product ID at the dispensing location or limitation of pedigree (initially) to a subset of the distribution channels.

In summary, there is consensus that pedigree and track and trace are important in protecting the supply chain and helping to ensure patient safety. However, there is concern about the costs involved in implementation such as the administrative burden, infrastructure requirements, resource limitations, viability/limitations of current technology, and general expense all of which impacts the ability to service patients. For any legislative or regulatory activity in this regard to be truly successful, it is paramount that process flows be developed and standards be identified that are national in scope, scalable, implementable for testing, and sufficiently flexible for long-term use; and that these standards address the concerns of all stakeholders in the supply chain.

2. TECHNOLOGICAL TRENDS AND INITIATIVES

The regulatory and industry responses to the problems associated with pharmaceutical supply chain security and integrity have made clear the need for a standardized way to identify products, to track their progress through the supply chain and authenticate the product upon receipt. GS1 is an international standards development organization that has been supporting efficient, effective supply chain processes for over 30 years. To this end they developed a suite of identifiers, data carriers for the identifiers, and standards for recording and documenting the movement of the item through the supply chain.

2.1 INTERNATIONAL MEDICAL PRODUCTS ANTI-COUNTERFEITING TASKFORCE

There has also been much movement globally driven by concerns of counterfeit and diverted pharmaceuticals. The World Health Organization (WHO) launched the International Medical Products Anti-Counterfeiting Taskforce (IMPACT*) in 2006. One of the 5 workgroups organized to combat counterfeiting is chartered to promote technology solutions. Some of the resulting recommendations have been embedded into their pending Good Distribution Practice (GDP) guideline which discusses traceability and technology. Additional information on the guideline is available http://www.health.gov.il/download/forms/a3040_GDP.pdf.

2.2 EUROPEAN FEDERATION OF PHARMACEUTICAL INDUSTRIES AND ASSOCIATIONS

The European Federation of Pharmaceutical Industries and Associations (EFPIA) recently launched a pilot in Sweden to prove out the effectiveness of a system that allows verification of authenticity as product is dispensed. The EFPIA published results provide the following insights[1]:

Key results of the pilot study show that:

- The model works in practice.
- The system allows for effective identification of fake packs as well as expired or short dated packs and recalled products.
- Availability and performance allow pharmacists to work at normal pace and without significant additional effort.
- The system is easy to use when fully integrated into the pharmacy workflow and existing pharmacy Point of Sales system.

[1] Results extracted from the EFPIA report entitled “EFPIA Product Verification Project”. To obtain the joint final report go to http://www.efpia.eu/Content/Default.asp?PageID=559&DocID=8771.

- The two previous aspects lead to very high user acceptance.

Other findings of the pilot project

- In order to achieve sustained credibility, the system must provide the correct answer to all transaction requests.
- The system should be customised to the existing pharmacy workflow as well as local conditions and regulatory requirements
- The presence of more than one code on the pack causes confusion for the user and will jeopardize user acceptance.
- The necessary data segregation and data security can be technically ensured
- Pharmacists are interested to get expiry date and batch number in machine-readable form.

The European Parliament is working on legislation that will incorporate serialization technology enhanced by the use of tamper-evident packaging and overt/covert authentication.

In addition some individual countries have also initiated legislation. Turkey now requires serialized products using the bar codes and data structure promoted by EFPIA. They started out legislating full track and trace and subsequently reduced requirements to the pharmacies only for their phase one serialization efforts. Brazil is also actively pursuing serialization.

2.3 PRESCRIPTION DRUG MARKETING ACT

With the enactment in 1988 of the Prescription Drug Marketing Act (PDMA) and its requirement of a documented drug pedigree, focus on the healthcare and pharmaceuticals was initiated. This led to the January 2007 publication of the Pedigree Ratified Standard (aka Drug Pedigree Messaging Standard, DPMS) to enable compliance with US federal and state laws. Subsequently workgroups were established both in the United States and globally to analyze and identify gaps in the existing standards and to explore the best ways to communicate and store the information necessary to support GS1 requirements for pedigree and healthcare supply chain traceability. To date these groups have published the Global Traceability Standard for Healthcare (GTSH), the Global Traceability Standard for Healthcare Implementation Guide (GTSH IG), the Healthcare Provider Tool Kit and the Healthcare Supplier Tool Kit. In April 2009 a new GS1 global project, Traceability in Healthcare II, was initiated to develop a suite of Process and Technical standards for global supply traceability that would enable actionable visibility from point of production to point of use.

2.3.1 PEDIGREE

The pedigree is a certified record that contains information about each distribution of a prescription drug. It records the sale of an item by a pharmaceutical manufacturer, any acquisitions and sales by wholesalers or repackagers, and final sale to a pharmacy or other entity administering or dispensing the drug. The pedigree contains product information, transaction information, distributor information, recipient information, and signatures.

Currently states regulating pedigree implementation define an ePedigree as a complete electronic legal document directly containing and signing over pedigree documents created earlier in the chain. This is the approach implemented in the GS1 Pedigree Ratified Standard (DPMS).

A high level, simplified pedigree process would be similar to the following:

- Create pedigree
- Add information to pedigree
- Certify (digitally sign) pedigree
- Send pedigrees for products in shipment to customer

- Receive pedigrees
- Electronically authenticate pedigrees
- Manually authenticate transactions that were not electronic
- Verify products received against authenticated pedigrees
- Certify (digitally sign) pedigree for receipt and authentication.

GS1 Healthcare has proposed an alternate approach where all of the components of an electronic pedigree would be distributed across the network and a single query issued that collects those components into a complete electronic pedigree document for validation.

Part of this approach relies on use of the Electronic Product Code Information Services (EPCIS). EPCIS is a GS1-EPCglobal standard designed to enable EPC-related data sharing within and across enterprises. It has the capacity to record and transmit data needed for the pedigree including product information and chain of custody or ownership. As part of the Traceability in Healthcare II Project it is anticipated that modifications will be made to EPCIS to fully support electronic pedigree update and sharing as well as creation of a pedigree document when needed. Once the planned suite of traceability standards is complete and implemented, GS1 will stop maintenance and modification of the DPMS.

2.3.2 SERIALIZATION

Serialization includes the processes of generating, encoding, and verifying the unique identity of individual physical items. It allows the granular identification of an instance of a product. When combined with track and trace technology, serialization facilitates the tracking of a product through the supply chain and allows for targeted identification of products for recall.

In March 2010 the Food and Drug Administration (FDA) issued guidance regarding the use of serialized identifiers on prescription drug packages. This guidance is based on a serialized NDC (sNDC) that consists of the manufacturer's NDC that corresponds to the specific drug product (including the particular package configuration) combined with a unique serial number generated by the manufacturer or repackager for each individual package. Serial numbers should be numeric (numbers) or alphanumeric (letters and/or numbers). The sNDC conforms to the structure of the serialized Global Trade Item Number (sGTIN) which is the GS1 standard for trade item identification.

2.4 TRADE ITEM IDENTIFICATION

GTIN and sGTIN provide item identification and allow for encoding in automatic data capture technologies such as bar codes and/or RFID for subsequent automated scanning and reading as needed along the supply chain.

Manufacturers, wholesalers and pharmacy chains will need to obtain a full GS1 Company Prefix because it allows them to create all of the GS1 identifiers that they will need to operate. This includes,

- GTIN (Global Trade Identification Numbers)
- SSCC (Serialized Shipping Container Codes)
- GLN (Global Location Numbers)
- GRAI (Global Returnable Asset Identifiers)
- GIAI (Global Individual Asset Identifier)

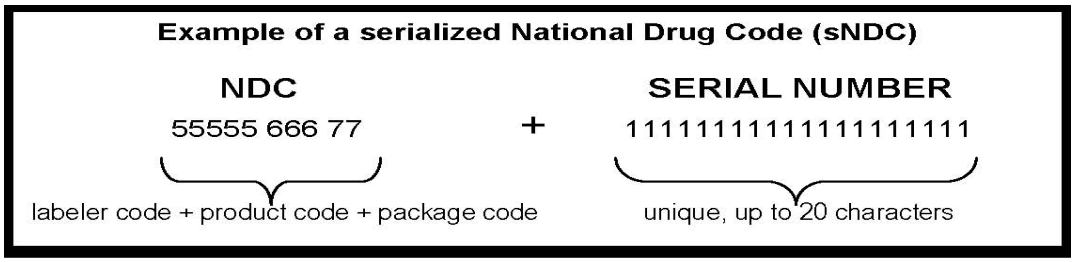
However, many hospitals, independent pharmacies and smaller pharmacy chains will probably not need any of these identifiers except one or perhaps two GLN's. The identifiers related to the pharmacy supply chain are discussed below in subsequent sections.

2.4.1 GLOBAL TRADE ITEM NUMBER (GTIN)

The GTIN is a GS1 defined, globally unique identification number used for trade items or products and services. It is normally constructed from a company prefix assigned by GS1, an item reference number designated by the company and a check digit. The GTIN may be 14 digits, 13 digits, 12 digits or 8 digits. GTIN numbers are assigned by the manufacturer in accordance with the GS1 allocation rules that assure that every variation of a product is assigned a single reference number. Separate GTINs are required for the item, inner pack and case. These are shared with trading partners along the supply chain. (The Universal Product Code (U.P.C.) is a similar product identification system that predates the GTINs. They are fully integrated with the GTIN specifications.)

2.4.2 SERIALIZED GLOBAL TRADE ITEM NUMBER SGTIN

The sGTIN is a number that uniquely identifies a specific instance of a particular trade item. It is created by appending a serial number to the GTIN of the product. In their draft guidance for serialized identifiers prescription drugs, the FDA proposed the use of the NDC (which forms part of the GTIN in the US realm) combined with an eight digit serial number.



2.4.3 DATA CARRIERS

Data carriers are the graphical systems used to represent and convey the product identifiers and associated information in computer and/or human readable format. They are represented by a mark, tag or label applied at the source when goods are created or shipped. Computer readable formats include linear and two dimensional (2D) bar codes, data matrices and radio frequency identifier (RFID) tags.

2.4.3.1 BAR CODE

A bar code is a computer readable representation of data that is presented in widths (lines) and spaces. It may have a single line of encoded data or may be stacked, 2D, to convey more information regarding the product.

2.4.3.2 DATA MATRIX

Data matrix, another form of 2D bar code, uses squares, dots, hexagons and other geometric patterns to represent the data. It is made up of black and white cells arranged in a square or rectangle. A data matrix can store up to 2,335 alphanumeric characters.

2.4.3.3 RADIO FREQUENCY IDENTIFIER

RFID is an identification system using an object or tag applied to or incorporated into a product for the purpose of identification and tracking. The tag has at least two parts:

- an integrated circuit for storing and processing information and modulating a radio-frequency signal
- an antenna for receiving and transmitting signal.

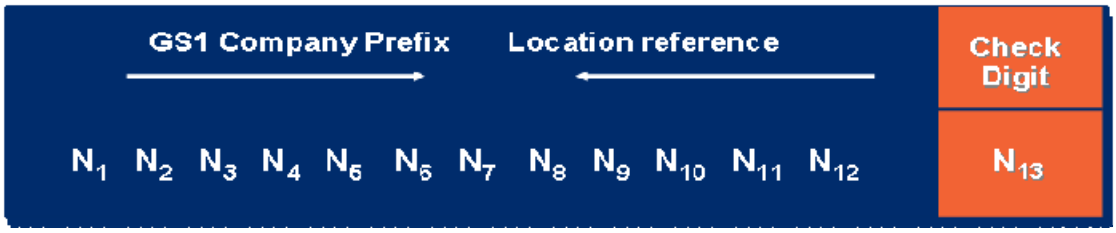
An active tag contains a battery that can transmit autonomously. A passive tag requires an external source to provoke a signal.

2.5 GLOBAL LOCATION IDENTIFIER (GLN)

Global Location Identifier uniquely names a legal entity, physical address and location with a numeric code. This code serves to improve data quality and reduce the size of transmissions and is required in GS1 compliance communications and repositories such as ecommerce, epedigree, GDSN, EPCIS databases, etc. Using this 13 digit code eliminates the need to transmit the full name, street address and so forth in each transmission. The GLN is composed of six numeric digits identifying the legal entity or organization followed by a six digit location reference and a check digit.

The Company Prefix shown below is assigned by GS1 but the location reference is assigned by the company. If the company moves to a new location, is bought or sold to another organization or out sources part of its supply chain, then a new GLN Company Prefix is required.

A location extension that may be kept private or shared with others can be used to identify dock doors, aisles, bins, departments, etc. at the organization's discretion. The use of the location extension can make it easier to route messages, and manage the flow of products.[2]



3. TRACEABILITY

Traceability is a system and process to allow the tracking of a product as it moves forward along the supply chain from the manufacturer to the end user and to trace a product backwards through the changes of ownership and custody to ascertain its authenticity and usability. It requires the use of standard identifiers for products and standardized messages between trading partners.

3.1 MASTER DATA

Master data is used to reduce the size of transmissions and improve data accuracy of shared information. Use of master data identifiers such as GS1's GLN and GTIN in business electronic documents and messages requires agreement between trading partners on exactly what each identifier means and what they reference. The complete set of data associated with each identifier is normally not carried within these electronic documents and messages but it is necessary that all parties have it and that it is exactly the same everywhere. This data is known as "master data" and rarely changes.

[2] http://www.gs1.org/1/glnrules/ for examples and explanations of when to request a new GS1 Company Prefix including a very useful storyboard with real world use cases.
or http://healthcareportal.gs1us.org/glnregistry/Home/tabid/36/Default.aspx This is the home of the GLN Registry for HealthCare in the US.

For a specific GLN, the master data could include such information as the company name, address, geographic coordinates, contact person(s), phone number(s), email address(es), license numbers, etc. For a specific GTIN master data could include product name, NDC, strength, form, active ingredient(s), package size, manufacturer identification, etc.

Currently in the pharmaceutical supply chain, master data is collected and maintained independently by each trading partner on an ad hoc basis. This inefficient approach frequently results in differences and gaps in the information used by each trading partner. A more efficient and accurate method for communicating, updating and establishing in advance the exact master data for each identifier is the GS1 Global Data Synchronization Network (GDSN) services. Adoption of a service such as GDSN within a given supply chain only makes sense when a large number of the trading partners commit to its use at the same time. The pharmaceutical supply chain has not yet made that jump, but with the trend toward the use of GLN's and GTIN's, it is increasingly likely. For more information about GDSN, see Global Data Synchronization Network® (GDSN®)

3.2 MAINTENANCE OF AND ACCESS TO PEDIGREE INFORMATION

Pedigree is being proposed by regulatory bodies as a means to secure the drug supply chain and enhance patient safety. It is essential that the pedigree information be maintained in a manner that allows ready access to all legitimate interested parties while not overburdening trading partners with unmanageable data maintenance requirements.

3.2.1 DPMS

DPMS is designed so that the full documentation of pedigree is passed along with every change of ownership and change of custody. The pedigree is initiated and signed by the manufacturer. When the product moves from the manufacturer to the distributor, the distributor verifies that the product received matches the pedigree received and adds identifying and authenticating information to the pedigree. It is this augmented pedigree that is passed to the next trading partner. This model is commonly referred to as the Russian Doll as the initial pedigree is nested under each successive pedigree. By the time this reaches the final trading partner, the pedigree is likely to have grown quite large which could impact both transmission and storage of the electronic document.

3.2.2 EPCIS

EPCIS is a repository with standardized services/interfaces that allows the recording of the movements of an item through the supply chain. With EPCIS an actual pedigree document is not created, but can potentially be produced by the aggregation of the separate events recoded for each change of location, custody or ownership. The manufacturer is responsible for the creation of the first event to identify and authenticate the serialized product and assure that the affixed tag is readable. Separate events are recorded in the EPCIS repository to reflect every movement of the product along the supply chain. No one trading partner holds the entire history of the product. Instead the entity only has access to the event information received from the prior trading partner, his own receipt and authentication event data and the event he created for transfer to the next trading partner.

4. CONCLUSION

The pharmaceutical industry recognizes that compliance to emerging serialization and pedigree legislation can benefit the pharmaceutical supply chain through the increase of data sharing to

provide operational efficiencies, improved patient safety and brand protection, expiration and inventory management, targeted recall, and management of cost diversion.

For any legislative or regulatory activity in this regard to be truly successful, it is paramount that process flows be developed and standards be identified that are national in scope, scalable, implementable for testing, and sufficiently flexible for long-term use; and that these standards address the concerns of all stakeholders in the supply chain.

Future white papers will deal with the impact and potential benefits of traceability implementation at the retail pharmacy level and in facilities, the technological challenges, implementation dependencies and barriers, and with associated costs.