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**Information Technology**

**Serialization Efforts Energize Track-and-Trace Technology**

By: Nicholas Basta    Date: 2010-06-27

*By fits and starts, pharma and healthcare providers are moving ahead on IT technologies to layer track-and-trace capabilities on supply chains*

As promised to Congress, in late March FDA released its guidance on "serial numeric identifiers" (SNIs), which represents FDA's thinking on the topic of putting unique identifiers on unit packages of pharma products going into distribution. That task is a preparatory step to the long-sought capability for "track and trace" in the pharma supply chain. The FDA guidance didn't mandate any steps to be taken immediately; the commitment to provide the guidance itself was a compromise coming out of the 2007 FDA Amendments Act, for which the Congressional debate leading up to its passage was the last time Congress as a whole took a stab at track-and-trace legislation.



FIGS. 1-2. THE BRAND LOYALTY & INTEGRITY SERVICE OF COVECTRA (SOUTHBOROUGH, MA) IS COMBINING ENABLES SMARTPHONE CONFIRMATION OF BARCODES. credit: Covectra

Track-and-trace, in turn, was the foundational step toward "e-pedigree" as defined by the California legislature, containing the elements of SNIs (applied by the manufacturer), and data collection by trading partners, as a means of preventing counterfeit or diverted products from being passed along pharma supply chains. The California e-pedigree movement came to a halt in September 2008, when the California Board of Pharmacy, pressured by the governor's office, decided to postpone its implementation until 2015 at the earliest, citing a lack of technology readiness, and strong resistance from retail pharmacies. The California effort (like that of many other states) was only occurring because FDA itself had been unable to develop (or convince Congress to legislate) a national pedigree program. And that, in turn,

History		COVECTRA
05 JULY 2009	Received	ATC Pharmacy, Olympia 2, London
30 JUNE 2009	Shipped	Worldwide Wholesalers Ltd.
21 JUNE 2009	Received	Worldwide Wholesalers Ltd.
18 JUNE 2009	Shipped	Healthy Planet Pharmaceuticals Inc.

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reaches all the way back to the Prescription Drug Marketing Act (PDMA), signed into law during the Reagan Administration in 1988.

Despite the 2008 stalemate, serialization and track-and-trace activity is perking along—mostly outside the US, and outside pharma distribution. Versions of track-and-trace are now mandated in Brazil and Turkey, and global pharma companies are making preparations for implementations there. France has a regulation, CIP 13, that will involve track-and-trace principles (but without unique identifiers on packages). And the GS1 organization (US HQ in Lawrenceville, NJ), together with a dozen or so healthcare group purchasing organizations, have banded together to institute “sunrise dates” of December 2010 for the Global Location Number (GLN), and December 2012 for the Global Trade Identification Number (GTIN) for pharma and device distribution within hospitals. GLN is “where” in the pharma supply chain, and GTIN is “what” (product identification). Add serialization to GTIN (often called sGTIN) brings you right back to FDA’s SNI. The GS1 organization’s Healthcare Group—with the participation of many pharma companies—is also hard at work at developing standards for pharma track-and-trace processes.

Manufacturers reviving or extending their track-and-trace activities need to look first at their packaging and shipping processes; then reconcile their enterprise IT infrastructure (ERP systems, warehouse and transportation management, ordering processing and accounting, among others) with the serialization data collection and storage requirements, and finally with the communications and IT capabilities of trading partners, logistics service providers and other contractors. At that level, the national and even global drivers for track-and-trace come into play.

#### **In-line printing**

“Serialization activity slowed but didn’t stop in September 2008,” says Joe Ringwood, chief operating officer for Systech International (Cranbury, NJ), which offers a suite of software tools to manage serialization and other operations on pharma packaging lines. “Some companies continued moving ahead because of international supply-chain concerns; some regrouped to get their global strategy together. To us, it’s starting to look like 2007 again, when everyone was ramping up in anticipation of California’s e-pedigree regulation.”

Systech’s software (Advisor, Senti and Guardian) could be considered a base point for serialization strategy; the products manage the process of imprinting, verifying and then storing serialization data on individual packages, to be “served up” to enterprise IT systems or to databases accessed by trading partners of a manufacturer. Ringwood says that Systech has completed over 150 implementations of its software at multiple manufacturer sites (including over 20 at AstraZeneca alone), and has the process down to as little as a three-day turnaround following initial planning work. “It hinges on the manufacturer’s approach,” he says. “A global solution can be standardized across the enterprise; a plant-by-plant approach that requires customization can take significantly longer.”

Bob Neagle, business unit manager at Videojet Technologies Inc. (Wood Dale, IL), a global supplier of marking and coding systems, agrees that pharma serialization projects are “starting to be rekindled,” and that companies like his have used the downtime to build out their technology offerings. Videojet tries to cover the waterfront in marking technologies, including inkjet, laser, thermal transfer and label applicator systems. Last fall, it acquired Wolke Ink & Printers GmbH (Hersbruck, Germany), which complements and extends Videojet’s technology in high-speed variable-data printing. Videojet offers in-line printing equipment, verification systems and software, including a proprietary algorithm to ensure random code generation.

Systech and Videojet are nominally competitors, at least in the software arena, but the two companies have just announced a partnership to provide comprehensive solution to Brazilian pharma manufacturers preparing for that country’s January 2011 implementation date. Brazil’s ANVISA (the equivalent of FDA) has mandated serialization at the item level, using GS1 standards (including 2D barcodes), combined with pre-printed labels that are to be supplied by the Brazilian Mint. The rule, a subsection of the national law known as RDC 59, is already in effect, with a deadline of 2011 for coding to be performed by manufacturers, and code confirmation at retailers by 2014. The driver is mostly to prevent the intrusion of counterfeits into the national supply chain.

Although it may cause some pharma industry packaging experts to groan in despair, the drumbeat is rising again for RFID (radio-frequency identification), the fingernail-sized tags that can be scanned from a distance by a reader. **Last month**, market-researcher GBI Research (New York) projected that RFID use in pharma will increase 34% annually through 2015, from \$112 million in 2008 to \$884 million. FDA kicked off an RFID boom in pharma in 2004 when it recommended the technology’s use for then-impending tracking rules; dozens of pilot programs were run by manufacturers, wholesalers and others with decidedly mixed results. There are, however, multiple users of RFID today, including Purdue Pharma, Pfizer and others; wholesaler-distributors have consistently advocated for its use because it simplifies the read-out inside a warehouse (no “line of sight” is necessary, as is the case with barcode), while manufacturers and retailers resisted the technology because of implementation costs. RFID never had the same momentum behind it among European manufacturers, and overall the pharma industry is committed to 2D barcode (even packages with RFID tags frequently have barcodes alongside them). Even so, the technology continues to be refined, and there could be sufficient experience, and lower costs, to be had by 2015.

#### **Pre-printing**

“In the US, bigger manufacturers will tend toward in-line code printing, but mid-sized and smaller pharma companies and generic manufacturers are looking closely at the option of using pre-printed, serialized labels,” says Gregg Metcalf, an industry market manager at Nosco (Gurnee, IL). The tradeoff is the higher capital cost and production-management burden with in-line printing, versus the cost of the pre-printed labels. Metcalf says that current label-converting technology can produce high-resolution labels at costs of 0.5-3 cts per label (higher for shorter print runs, lower for extended runs). Nosco has **invested heavily** in new digital-printing technology which makes short print runs more economical. “We can economically provide preprinted labels even for small-volume production runs with this technology,” he says.



FIG. 2. BARCODES CAN BE ON BOTH PRIMARY AND SECONDARY PACKAGING. credit: Nosco

Metcalfe says that some implementations of in-line barcode printing have experienced difficulties in printing and verifying the codes at production line speeds; preprinted labels can be produced with high pixel resolutions that avoid this problem. Pre-printed labels also allow for the use of a wide variety of anti-counterfeiting measures (see box). Advocates of 2D in-line printing, on the other hand, argue that current marking technology can handle variable-data printing even at high production speeds, and that pre-printed labels have their own challenges in matching codes with specific lots as production gets aggregated into cases and pallets during production.

Whichever type of code generation is decided, the majority of projects both inside and outside the US point to 2D datamatrix barcode, which has the advantages of being relatively small yet capable of carrying considerable information. Frequently, the 2D barcode will be accompanied by "human readable" codes, as a backup verification to the 2D matrix. What about the code itself? FDA's March SNI guidance stopped short of recommending the use of the GS1 standards, but the document clearly allows for their use and seems to be tailored to GS1.

Within the GS1 Healthcare Group, the hub of activity has clearly shifted from pedigrees for packages to adopting GLNs and GTINs for supply chain activities flowing through hospital group purchasing organizations (GPOs). GS1 Healthcare US has the participation of most leading GPOs and many of the larger health systems in the US. Cardinal Health, one of the Big Three wholesalers, endorsed the GS1 standards in a statement issued in early March, saying that "industry-wide adoption of these standards will enhance supply chain visibility, drive opportunities for cost savings and improve patient safety."

The GLN/GTIN implementation process is considerably simpler than package track-and-trace, in that suppliers (and customers) only need to file applications with the GS1 organization, and then acquire sufficient numbers to identify products and locations. But it is not without some complexity: large health systems need to identify their locations in a logical manner; manufacturers need to organize their stockkeeping units in the same manner. Any trading partner working with GPOs must modify their order-processing and accounting systems to accept the codes.

It's a fairly straightforward jump (logically, at least) from GTIN for a product to the serialized GTIN (sGTIN) for an individual package, and so the groundwork is being laid for serialization necessary for track and trace. But here is where technological and international paths begin to differ. In Europe, the drive has been for "bookend" authentication, mostly as a way to complete a reimbursement at the retail pharmacy, and also to prevent counterfeit product from being purchased. The number is imposed at the beginning of the supply chain, then authenticated at the end; no intermediate tracking is obligatory. The European Federation of Pharmaceutical Industry Assns (EFPIA; Brussels) ran a largescale pilot program in Sweden during the latter half of 2009 to verify use of 2D codes, in-pharmacy readers, and the online communication system to authenticate product within a few seconds, and was generally satisfied with the process. Aegate Systems (London) has installed similar technology under national contracts in Belgium, Greece and Italy, and a pilot program in Germany will be conducted this year.

(Simultaneously, GS1 Europe is working on standardizing GTINs and other codes in Europe; although barcoding is used extensively, there are a handful of differing standards in place).

In the US, the drive has been for a drug "pedigree" that traces its movement so that each

new recipient can confirm the package's authenticity. GS1 Healthcare US adopted a standard the Drug Pedigree Messaging Standard (DPMS) in mid-decade, and while it has the force of law in many states, many participants (including the biggest wholesalers) have a bye for generating the pedigrees, and no state requires manufacturers' participation (until, and if, the California e-pedigree standard comes into force). More or less simultaneously with the adoption of DPMS, GS1 promoted the development of RFID-based standards and, specific to pharma applications, the Electronic Product Code Information Service (EPCIS), which is also in force but which has parts that are still undefined. One of the advantages of EPCIS is that it is true track-and-trace: Provided that trading partners share the data, a drug's forward path (track) and backward path (trace) can be analyzed.

Dirk Rogers, co-chair of the GS1 Healthcare US Traceability work group, says that DPMS (with which he was involved from an early date) is the only "real" standard in use today, and are being generated routinely in several states. "Any use of the GS1 EPCIS standard to construct a new type of pedigree architecture would result in what's called a 'network-centric' e-pedigree system, but that architecture is at odds with all of the existing US pedigree laws." At his former employer, SupplyScape (now owned by TraceLink—see Pharmaceutical Commerce, April, p. 9), there were over 125 companies that had invested in DPMS systems, and many of these are currently in use. For its part, Woburn, MA-based TraceLink continues to support DPMS clients, but has shifted software development to a network based on social-media tools that will be compatible with the GS1 structure, according to Shabbir Dahod, president.

Another DPMS-certified vendor, rFXcel (San Ramon, CA) says that emerging GS1 standards will be useful not just for drug authentication and supply chain visibility, but also for raw materials and intermediate products going into drug production. That company has also won new DPMS clients for its "active e-pedigree" system, as it calls it, as recently as last month, when OM Healthcare Logistics went live with its new distribution center in Louisville, KY (see p. 9).

In an "unwelcome surprise," as Rogers puts it, GS1 issued a statement in late 2008 signaled that they would stop supporting DPMS and focus all GS1 track-and-trace activity going forward on the EPCIS and related standards. Although there has been no official renunciation of that statement, GS1 officers have indicated that support for DPMS continues, including an effort to essentially blend the two standards into one. GS1 Healthcare has also certified two other software-development organizations for the DPMS standard: the Institute of Logistics Information Technology (Pusan University, South Korea) and Samsung SDS (Ridgefield Park, NJ).

GS1 Healthcare US has been holding online seminars and conference calls during this year to develop life-sciences-related "use cases" of products in transit in the supply chain, and has built a simulation model that manufacturers and others can use to experiment with EPCIS-type supply chain transactions.

A larger group of IT vendors support the EPCIS standard, including IBM (Infosphere Traceability Server) SAP (Object Event Repository) and Axway (Synchrony Track and Trace). Axway has been particularly active with HDMA and GS1 in promoting the development of usable EPCIS standards for the pharma industry; the company's software won an iBusiness award from HDMA last year for its Trade Activity Manager solution, which interoperates with its Synchrony platform. Axway, Samsung and IBM are the only vendors who are certified both for DPMS and EPCIS. "There's still a search for a pragmatic solution between DPMS and EPCIS," says Ruby Raley, director of healthcare solutions at Axway, "but the lack of item-level serialization in DPMS is limiting." Axway's direction, she says, has been to build on EPCIS capabilities and to extend track-and-trace into upstream intermediate products and work-in-process. Its latest Track and Trace version was certified by GS1 in January; the company claims to be the only IT vendor with standardization both around EPCIS and the AS2 communications protocol (an IT standard that provides improved security over conventional network communications).

#### Write more laws

Washington insiders Pharmaceutical Commerce spoke with assert that inside Congressional committees, work is proceeding on re-introducing the Buyer-Matheson legislation of the last Congress, which instructed FDA to mandate item-level serialization, and to establish track-and-trace data storage systems, with a set of deadlines roughly corresponding to the 2015 date of the California e-pedigree rules. This work went on hold during the intense debate over healthcare reform that consumed Congress for most of last year. As yet, however, no new legislation has been introduced.

Last year's debate also featured another hashing-out of "re-importation"—to legalize the import of drugs from abroad that have met some level of FDA quality review, but can be purchased at the lower prices that national governments command from manufacturers abroad. That effort got tabled during the healthcare reform debate as part of the now-infamous deal between the pharma industry and the White House to support reform. But various Congressmen might seek to reopen it, especially if involved supply-chain issues like track-and-trace come to the floor.

In Europe, the European Parliament now appears to have the lead in an effort started in the European Union in 2008 to address pharmaceutical trade and counterfeits. During an April meeting, Environment Committee Ministers advocated "the introduction of mandatory safety features, such as seals or serial numbers, for certain medicines," according to a report issued by the Parliament, as part of a series of discussions over Internet pharmacies and drug marketing. More sessions are to be held on this "pharmaceutical package" this summer.

Globally, a battle royale is building over how the World Health Organisation (WHO) will clamp down on trade in counterfeit products, especially in the developing world. While numerous reports and national studies have shown counterfeit malaria medications, HIV drugs and other product to reach counterfeit levels as high as 60% in some nations, efforts to restrict distribution have come under fire from countries like Brazil and India, claiming that the restrictions have harmed the distribution of what they consider to be legitimate drugs whose market authorizations are under dispute over intellectual-property rights. WHO has been the secretariat for IMPACT (International Medical Products Anti-Counterfeiting Taskforce); during the World Health Assembly in May, Brazil and India advocating the

dissociation of WHO from IMPACT. According to press reports in late May, WHO has set up an intergovernmental group to review both its policy and its ongoing support of IMPACT. PC

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