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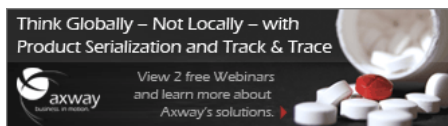
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Business and finance

2008 Product Security Perspective: Protecting the Brand

By: Nicholas Basta Date: 2008-09-30

While pedigree implementation deadlines have faded in importance, the business value of anti-counterfeiting and serialization systems become clearer

Students of military history will recall that in the early stages of WWII, there were armies in the field, declarations of war—but no battles. The “phony war” lasted for several months and then commenced and ground on for the next five years.

Something of a phony war is going on in U.S. pharmaceutical distribution today. Just about all involved parties agree that distribution channels are under attack, and supply chains will need to be reinforced. But the latest actions have been decisions not to act. The California e-pedigree law, which at the beginning of this year had been scheduled to go into effect in January 2009, got pushed out to 2011. At presstime, new state legislation may shove it even farther out—to 2015 for manufacturers, and 2016 for wholesaler-distributors. Federal legislation is sitting in committee, and is likely not to be addressed until after the election.

The picture is only slightly more dynamic outside the United States. The European Federation of Pharmaceutical Industry Assns (EFPIA; Brussels) is about to let a contract for a fairly comprehensive product serialization project—but that will take a couple years to be conducted, analyzed, and for recommendations issued (see p.18). Meanwhile, the World Health Organization International Medical Products Anti-Counterfeiting Taskforce (IMPACT) program, an effort begun in 2005 to add muscle to international anticounterfeiting efforts, hit a wall at mid-year, when an effort to put a resolution on the agenda of the World Health Assembly was stopped by nations (India and Brazil, among others) that objected to unlabeled drugs (which may or may not be the actual medicine) being defined as counterfeit. According to a statement attributed to a representative from India, “Counterfeiting is an issue of trademark violation and has no bearing on public health.”

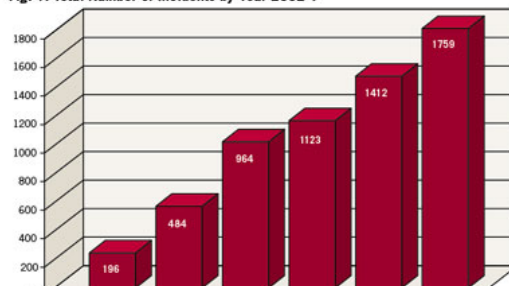
The IMPACT program goes on (its next meeting is in October in Tokyo) and counterfeiting is expected to be on the agenda of the World Health General Assembly when it convenes again in January. But the difficulties of getting governmental bodies to even agree what the problem is indicative of what the pharma industry faces in global trade. Within the United States, which lacks a central purchasing authority for pharmaceuticals (as most European nations possess), and where distribution channels are differentiated by discounts, the problem of diversion represents a significant financial risk to manufacturers.

And for the healthcare providers of all nations, the problem of medication errors due to misidentified medication is endemic. Healthcare providers are gradually getting their arms around identification and tracking processes to reduce error, and have been joining the GS1 organization, the leading standards-setting body for product identification. Progress—while measurable—is slow.

Tracking illicit trade

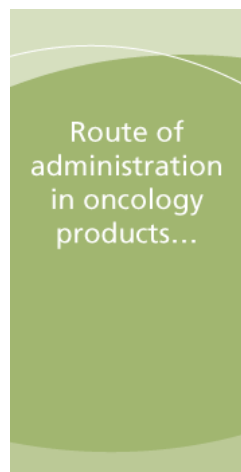
Meanwhile (of course), counterfeiters and diverters are not sitting around waiting for legislative activity to guide them. According to data released by the Pharmaceutical Security Institute (PSI);

Fig. 1. Total Number of Incidents by Year 2002-7



Washington, DC), there was a 24% increase in the number of reported counterfeit, stolen or illegally diverted drugs from 2006 to 2007 (Fig. 1). These incidents occurred in 112 countries and involved 639 branded, generic and OTC products.

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SPECIAL FOCUS REPORT

2008 Product Security Supplement

This is the 4th Annual Pharmaceutical Product Security Report. When we did the first one, in 2005, I recall advocates of anti-counterfeiting and pedigree systems saying that they had to overcome a key question of legislators and others about the topic: Where are the dead people whose lives would have been saved by these measures? Well, this year it happened:

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continued its efforts in tracking illicit drug trade, although the pace fell off from the prior year (Fig. 2). Both FDA and PSI caution that arrests or incident reports are not themselves a measure of the volume of counterfeit or diversion activity (the reports depend as much on how aggressively law enforcement investigates as the volume of activity).



But another, scarier, indicator comes from organizations tracking Internet-based pharmaceutical commerce. An April field test by the European Alliance for Access to Safe Medicines (Cardiff, UK) found that 62% of prescription medicines ordered over the Internet in Europe were counterfeit, substandard or unapproved generics (i.e., produced without the a license from the patent holder). In the U.S., Mark Monitor, an online protective services company, found that "cybersquatting" (unauthorized use of a brand in a website URL) for pharmaceutical products was up 38% in the past year. As consumers grow more comfortable with online e-commerce, the presence of bootleg websites selling pharmaceuticals under false pretenses has skyrocketed.

Mark Monitor also found 229 websites selling bulk active pharmaceutical ingredients (APIs), along with a lively trade in selling commercial quantities of finished products.

The National Assn. of Chain Drug Stores (NACDS; Alexandria, VA) has steadfastly resisted efforts to legislate track-and-trace systems for pharmaceutical distribution over the past year. It lauded the California Board of Pharmacy's decision (last spring) to delay e-pedigree implementation. This summer, it issued a study that claimed that the counterfeit problems that do exist "largely are fueled by illicit internet sites," and that "since 2005, changes in the way that manufacturers, wholesalers, and pharmacies obtain and purchase prescription drugs may be responsible for the low number of reported counterfeit incidents in the United States." Further, the cost to individual pharmacies for implementing track-and-trace systems was estimated at \$84,000 or more per store, and besides, "the ability to move forward with a track and trace system on a large scale will not be in place for many years."

Even so, the study artfully emphasizes the negatives of adopting tracking technologies, while skipping over potential positives like reduced inventory costs or more effective product recalls. In recent months, state pharmacy inspectors have found repeated instances of stores selling expired products—a problem that a track-and-trace system could address. Also, the exclusive emphasis on counterfeits sidesteps issues of product diversion—which might be of little consequence to pharmacies, but does matter to manufacturers.

APIs sourced from questionable e-commerce websites connects with what has been the most dramatic counterfeiting episode in recent years: the introduction of adulterated heparin into legitimate supply chains early this year. Heparin, an anti-coagulant needed by, among others, dialysis patients, is implicated in killing 149 patients from January to the end of May in the U.S. (as indicated by an allergic reaction); similarly adulterated product showed up in Europe as well. Baxter Healthcare, Covidien and others had to issue multiple recalls during the February-March period. The flaw in the supply chain with this incident was that manufacturers were unable to identify the adulteration of API it received from China. Subsequent FDA analysis pointed to an intentional masking of test results by means of the adulterant chosen, a finding that Chinese officials disputed.

In May, Kevin Nicholson, R.Ph., J.D., VP of Pharmacy Regulatory Affairs for NACDS, testified before a Congressional hearing that "the FDA recall process was immediate, robust and effective." But that claim is belied by the facts that multiple recall notices had to be issued, and by the experience of the California Board of Pharmacy, which found that through May, 18% of the 500 hospitals it examined in the state still had unrecalled heparin on their shelves. More alarmingly, some of the heparin had been returned to wholesalers and then sent out again.

Chain drug stores might be considered just one of many interested parties in the pharmaceutical security debate, except that, together with wholesalers and manufacturers themselves, they represent a crucial link in the "normal distribution channel." Absent one party from a track-and-trace system for that channel, and the whole scheme comes crashing down, since the track-and-trace process depends on the active participation of all of the channel partners.

At least one major chain, Walgreen's, is taking a different perspective. In mid-September, it announced that it was deploying a full-blown track-and-trace system within one of its major distribution centers (Anderson, SC), deploying over 170,000 RFID-enabled assets (such as shipping docks, dollies and workstations) to track the movement of 80,000 cases of products daily to over 700 Walgreens stores in the Southeast. RFID readers and monitors are to be linked by an "edge data management system" from Blue Vector (Palo, Alto, CA). The deployment is not specifically an anti-counterfeiting measure—Walgreens goal is to achieve 100% shipping accuracy and higher productivity—but the tracking technology will certainly reinforce the DC's product security performance.

Pharmaceutical Commerce's Serialization Survey (see p. 11 in this supplement) produced a surprising result: the No. 1 benefit of serialization and product-tracking systems, according to industry respondents, is to "enhance our reputation with customers and the public." Perhaps the one company that has taken that goal most literally is specialty pharmaceutical

distributor FFF Enterprises, which has built up, on its own initiative, both an authentication system (Verified Electronic Pedigree) and a product-tracking system (Lot-Track) to ensure the integrity of the vaccines, blood products and other specialty drugs it handles. Even while both manufacturers and distributors have been wrestling with these technical and regulatory issues, the company has built a solid reputation among its hospital and clinical customers through these measures.

Vested in brand value

Overall, the picture that emerges from the current scene is that manufacturers who care about their brands' integrity, as perceived by consumers, or those who want the business value of better visibility into supply chains, are investing in anti-counterfeiting and tracking technologies. Trading partners like wholesalers or retailers have the liability concerns to address, but are not as vested in the product or supply chain integrity.

The good news here is that suppliers of security products continue to come out with new techniques and new security features, giving customers a broader range of tailored choices. Traditional package protection has involved printing techniques such as optically variable inks, taggants, microprinting or holograms. Over the past several years, these techniques have been advanced with the addition of customized micro-taggants (JDSU; ARmark; Authentix, among others); holography with added optical features (Kurz, H.W. Sands); or new types of security seals for packages or cases (3M, Kodak., Stoeffler Seals).

Industry sources say that only 10-15% of today's pharmaceutical packaging incorporates security features, even though the per-unit cost of these features is fractions of a penny. "In the past 18 months, the overall push for item-serialization has caused anti-counterfeiting to take a back seat," says Greg Metcalf, industry market manager at Nosco. "That said, many are realizing the value of protecting their brands through these techniques." Metcalf adds that biotech manufacturers, who have mostly overlooked brand security until recently, are now getting onboard.

A key element of the use of these anticounterfeiting techniques is that they provide a relatively straightforward way to monitor supply chains when product returns are analyzed. "You don't know that you have a problem unless you're looking for it," says Metcalf, who notes that Nosco has had customers in the past year who found counterfeits or diverted products in the return chain when anti-counterfeiting features were found to be missing. Manufacturers have the option of acquiring such anti-counterfeiting measures for use on their own packaging lines, or having them incorporated into labels, cartons or vials that they purchase from converters, or specify with their contract packagers. Contract packagers have become energetic providers of security features for clients, relieving the manufacturer of the need to analyze the wealth of technical options available.

Another new technology, being offered by Cortegra Group, is, in effect, a carton fingerprint. Working with a French optics firm, Signoptic (Le Bourget du-Lac), the company is commercializing a system that reads the surface characteristics of a carton (or other surface) and stores a digital fingerprint of that section. There is a one-in-1027 chance of duplicating this fingerprint. By storing the fingerprint, and then retrieving it when performing a forensic check, the authenticity of the package can be confirmed. Cortegra says that the visual record of the package can be generated at conventional packaging line speeds, and is working with Signoptic to develop a handheld field device to do the check.

On-dose security



Other security vendors point out that you can do all the package security you want, but true authentication looks at the pharmaceutical product itself. "There are many good technologies to use for packaging security, but relatively few for on-dose security," says Dean Hart, SVP at NanoGuardian, who points out that product security is compromised whenever the actual product is separated from its packaging.

With the NanoGuardian system, a proprietary method is used to create multi-layered (overt, covert, and forensic) security features on the dosage surface. These multi-layered security features provide both field level authentication and tracing capability on every single dose. Last summer, a NanoGuardian client in the pharma industry received FDA approval of their Supplemental New Drug Application to utilize NanoGuardian's NanoEncryption technology as a brand protection initiative. The cost of applying NanoGuardian's security features (which can be linked using fairly conventional database technology to a serialization system for use in general pharmaceutical distribution) is said to be less than a penny per pill.

DEAN HART, NANOGUARDIAN

In the near term, Hart envisions manufacturer NanoEncrypting their products, then proactively checking them at reverse logistics facilities to monitor the integrity of the distribution channel. A lab-based authentication system would provide the monitoring, while NanoGuardian's technology could be applied in NanoGuardian facilities or at the manufacturer's packaging line.

Another vendor, XStream Technologies, has adapted what is essentially a laboratory analytical technique, x-ray spectroscopy, to package security. According to the company, the device, the XT250 system, allows a DC manager (or anyone else holding stock of a

pharmaceutical) to put the entire pharmaceutical package in a chamber, and within five minutes receive a chemical assay of the product (Fig. 3). This assay can be compared to stored information to verify the authenticity of the product.



FIG. 3. THE XSTREAM TECHNOLOGIES XT250 ANALYZER

Alan Clock, XStream Technologies SVP, says that it has been tested in the past several months at a major reverse logistics company and a mid-tier wholesaler. In both cases, it was found that product returns contained fake product in numerous instances—indicating that some retailers were improperly seeking refunds for returned product. This is a financial burden for manufacturers, and is of obvious concern if those returned pharmaceuticals are sent back out to retailers.

Techniques like XStream's point to another factor in anti-counterfeiting: how to manage a field-based verification system. Some authentication vendors (Authentix, SICPA, among others) maintain national and even international field services to check products in the supply chain. Manufacturers can also contract with a variety of investigative services to perform these checks.

RFID still in the picture

The ongoing battles among legislators over pedigree systems, the resistance of organizations like NACDS, as well as continued questions over cost and viability have put the push for RFID authentication and tracking into a back seat. There are pharma companies that have continued the march toward full-blown tracking systems, and RFID is now commonplace for tracking cases (as opposed to items) of pharmaceutical shipments. But many manufacturers—especially those working with biologics—remain unconvinced that RFID is the appropriate solution.

RFID, however, is going great guns in many parts of retail and wholesale distribution outside the pharmaceutical arena, and in recent months hospital systems have become more attracted to the benefits of the technology for tracking assets, medical devices and, in some cases, prescriptions. IDTechEx, a London market research company focused on RFID, estimates that 20 million pharmaceutical packages will have been tagged in this year, along with 10 million pallets and cases, says Dr. Peter Harrop, chairman of the firm. Those figures will rise to 7.3 billion and 550 million in 2018 (data from "RFID in Healthcare and Pharmaceuticals 2008-2018," available at idtechex.com).

Pfizer, one of the pharma manufacturers early out of the gate with RFID-tagged products, is continuing its program, and has additional pilots in the works in various parts of the world, and Purdue Pharma, which switched from older RFID technology to Gen 2 devices last year, has continued with its tagging process. Showcase RFID implementations among the Big Three wholesalers at their California distribution centers have been installed and are essentially operational, although relatively little tagged product is entering their facilities.

Meanwhile, RFID vendors continue to push for new adaptations of the technology in various parts of the supply chain in addition to item-level tagging. Mikoh Technologies has combined RFID tags with proprietary adhesive systems so that the tags can simultaneously be an identification system and a tamper-evident seal (Fig. 4). The company can also adapt the adhesive technology to barcoded labels. Matthew Blomfield, Mikoh CEO, points out that it's entirely conceivable for counterfeiters to swipe RFID tags from authentic packages and apply them to fake ones; his technology aims to defeat that. Currently, the tags are being used to secure containers such as diplomatic pouches or military hardware.



FIG. 4. MIKOH TECHNOLOGIES' TAMPER-EVIDENT RFID SEALS CAN BE ADAPTED TO CARTONS AS WELL AS SUPPLY-CHAIN PACKAGING (RIGHT). credit: Mikoh

The grand serialization debate

When FDA, in effect, bolted from the gate in 2004 by strongly recommending that the pharmaceutical industry adopt RFID as an anti-counterfeiting and tracking system, the response that came back from industry was that RFID was still relatively underdeveloped, and that it wasn't inherently an anti-counterfeiting method anyway. Then the debate shifted to pedigree (and e-pedigree) systems, by which tags, barcodes or simple numeric codes would be used to verify shipment origins and destinations. This debate has now shifted in the past year, to track-and-trace systems, highly dependent on IT technology to gather and store identification technology, and produce verifiable records on demand.

A year ago, AstraZeneca announced a broad initiative to build a global database and tracking system for many of its packaging lines around the world. 2D barcode would be the preferred data carrier. That project made a lot of work for Systech, which offers its Guardian technology to collect ID data on packaging lines and serve it up to enterprise systems, and Axway, which provides, via its Synchrony trading-activity platform, a method to store and retrieve the ID data.

Both companies report that the project is well along, with some 45 lines in 12 countries now live or being upgraded, in a project that will ultimately involve 80 lines in 30 countries. "One of the biggest things we've learned in this process is that the internal stakeholders need to be aligned for the project to go forward successfully," says David De Jean, Systech VP. "The manufacturing, packaging, supply chain and brand protection managers need to agree, and this can be difficult." The company now initiates a serialization project with a multi-party requirements training phase, then moves onto execution issues.



Another IT company, Acsis specializes in serialization and pedigree systems for distribution centers. Andre Pino, marketing manager, says that the challenge is not necessarily the technology to read serial numbers on packages, cases or pallets, but to integrate that information with the business processes of the DC. "The challenge is to integrate these processes without slowing down the shipping process," he says. Serialization touches distribution, compliance and IT departments, and these groups need to come together for a successful implementation."

John Pitts, global sales director at Domino Group's Control business unit, points out that serialization and tracking processes could tilt the scales more toward in-house packaging and labeling for manufacturers, and away from using contract packagers or label converters. "Matching up the serial numbers with the

ANDRE PINO, ACSIS

products, while moving them around from one contractor to another, can be a logistics nightmare if not properly handled," he says. Domino, a market leader in product identification technologies, acquired the Control software system last year (it was developed in Germany, and is in use at one manufacturer there) to complement its barcode and other marking technologies, and aims to offer a complete marking and data-storage system to customers.

When manufacturers started shifting their attention from RFID to barcode (especially 2D barcode), the feeling was that they were going from a somewhat underdeveloped technology to one that is well-established and reliable. But at least one barcode marking vendor, Secure Symbology, says that 2D barcoding at production line speeds is a technical challenge of its own. The company has developed a marking system capable of running at 300 items/minute or more, says the company. Catalent Pharma Solutions, a leading contract packager, is in the process of installing the technology at several of its packaging lines. One of the first biopharma customers is Biogen Idec (Cambridge, MA).

To cut through some of the complexity of assembling all the components of an enterprise-level serialization and authentication system, several vendors have grouped themselves as loose consortia that can provide integrated hardware, software and services solutions. The "California Express Solution" (how long will that name linger?) comprises SupplyScape, Nosco, Systech, Acsis and Hewlett-Packard. Another group has come together around Axway, consisting of that firm, Primary Marking Systems, Gephart (a logistics equipment company based in Germany), Domino Group Control, Aegate, and Blue Vector.

Data repositories

If little else, California's insistence on electronic pedigrees (as opposed to paper documents) focused industry's attention on serialization systems, which are inherently a digital technology. Serialization also fits with the direction that Europe is going in, particularly with the emphasis on using serial data to match product, prescription and reimbursement (usually from a government agency). A "bollini" system is now in effect in Italy, involving a government issued serial stamp that is applied to pharmaceutical packages to ensure appropriate reimbursement. Turkey has a goal of establishing a barcode-based tracking and reimbursement system starting in January 2009. Belgium, Greece and other nations have similar programs in various stages of development.

These systems do not inherently provide the track-and-trace capabilities sought by California's proposed e-pedigree system. But, from an IT perspective, a serialization system can provide a triple win: pedigree tracking and tracing (in the U.S.); reimbursement and patient-safety assurance (in Europe); and supply chain visibility for the manufacturer and its trading partners.



Fig. 5. GS1 Healthcare's mid-year roadmap for product identification standards. Credit: GS1 Healthcare

The main stage for working out track-and-trace technology has been at GS1 Healthcare, the healthcare-related component of the international GS1 organization. Over the past year, GS1 Healthcare US (Lawrenceville, NJ) has subsumed the EPCGlobal Healthcare and Life Sciences Group, and now has several workgroups developing standards for item, location and data-synchronization procedures (Fig. 5). Another workgroup is specifically charged with reconciling the Drug Pedigree Messaging Standard (DPMS) originally developed by EPCGlobal, with the Electronic Product Code Information Standard (EPCIS), which defines how data can be exchanged between IT systems. Draft recommendations on this reconciliation are expected by the end of the year, according to Bob Celeste, an industry director at GS1 Healthcare.

Sparks flew over the past year as IT vendors SupplyScape, which was a leader in supporting the development of the DPMS standard, and IBM, which offered a system based on its Websphere RFID Information Center software that has been certified for both DPMS and EPCIS, slugged out the relative benefits of their approaches. (Two other vendors, rfXcel and Axway, also have DPMS-certified software.) That debate has quieted in the face of the delay of the California rules and the GS1-led effort to reconcile the standards.

Data-sharing platforms



SupplyScape, taking advantage of the more-than-100 customers of its pedigree software among manufacturers, wholesalers and retailers, launched a new platform called Nexus last summer. The system, says company president Mark O'Connell, emphasizes data-sharing among trading partners, and includes "on-ramping" tools that allow a SupplyScape user to obtain or deliver data to non-SupplyScape users.

"Visibility into the supply chain is where business value is going to be obtained," says O'Connell. "Anti-counterfeiting is important—and authentication of product is the first objective of our technology—but the cost savings that manufacturers can obtain from more precise reconciliation of chargebacks, or from more accurate product return processes, should draw the attention of pharma CFOs."

MARK O'CONNELL, SUPPLYSCAPE

Paul Fowler, healthcare marketing manager at Axway, couldn't agree more; the company has substantial business in the financial services industry, and recently boosted its capabilities with the acquisition (by Axway's parent, Paris-based Sopra Group) of a data-integrity firm called Tumbleweed. "We think the industry should start thinking about track-and-trace systems as part of a 'financial supply chain,'" he says. "Pharma supply chains are renowned for their inefficiency, with extraordinarily long lead times, slow inventory turns and inaccurate, time-consuming order-reconciliation processes," he says. "The forward-thinking companies will figure out how to protect their brands as a byproduct of gaining better visibility of their distribution channels."

The Center for Healthcare Supply Chain Research (formerly the HDMA Research & Education Foundation) has published two whitepapers this year on the value of the GS1 EPCIS standard as a pathway toward "enormous potential business value." The Center recommends a three-step process for manufacturers, wholesalers and trading partners:

- Level 1: Pedigree compliance
- Level 2: Extensions for on-demand event visibility
- Level 3: Proactive supply chain intelligence

Serialization is a necessary first step along this pathway (the Center is counting on a reconciled DPMS and EPCIS standard being issued by GS1 Healthcare). In August, the Center, working with SAP (whose ERP is commonplace throughout pharmaceutical distribution) that showed how EPCIS will link into SAP's Auto-ID Infrastructure (AII) and Object Event Repository.

Eli Lilly (for one) is already integrating its pedigree system, based on SupplyScape technology, into its global SAP ERP system. Serialization is already being performed at the pallet level; item-level serialization (using 2D barcode) is coming next.

The rationale in all this is to leverage an investment in regulatory compliance (pedigree) to obtain business value that move the pharma supply chain from something the industry usually apologizes for to something that it can be proud of. Just over the horizon is a complementary drive to modernize hospital medication management. But today, that horizon is not getting closer. PC

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