

The Fall issue of BrandSecure News focuses on recent developments in the pharmaceutical industry. The need to secure pharmaceuticals against counterfeits in the global marketplace has never been greater. In this issue, we provide updates of industry news and perspectives on proactive measures to combat counterfeit drugs.

Proactive Measures to Combat Counterfeit Drugs

Threat of Counterfeit Drugs

The global supply chain and the continued growth of the Internet have provided a worldwide marketplace where finished drugs and Active Pharmaceutical Ingredients (APIs) are sourced and sold. The growth of counterfeit drugs generates a significant threat to consumer safety and company reputation. The U.S.-based Center for Medicine in the Public Interest (CMPI) projects that counterfeit sales will skyrocket to \$75 billion by 2010, nearly double the rate of 2005 activity.

“Counterfeit sales are increasing at nearly twice the rate of legitimate pharmaceutical sales and they are a money machine.”

Peter Pitts, CMPI president, 2008

Complexity of the Pharmaceutical Supply Chain

The source of counterfeit drugs can be tracked through a series of twisted channels along the pharmaceutical supply chain. The relative ease in which tainted ingredients infiltrate the legitimate supply chain is shown by the wide availability of illegitimate drugs sold on B2B online trade boards across China, India, Eastern Europe, and Latin America.

Formulate a Proactive Strategy

The global nature of pharmaceutical sales blurs geographic boundaries and complicates enforcement, responsibility and applicable laws. As a result, pharmaceutical companies seek to identify the most effective strategies to protect consumers and their brands from undue risks.

- **ANALYZE the market landscape to evaluate fraud exposure** – An online assessment provides a quantifiable measurement of risk. Product availability across trade boards, online pharmacies and other e-commerce platforms provides intelligence on buyers and sellers in the global supply chain.

- **APPLY product authentication as an anti-counterfeiting measure** – Deploy multi-layer security onto pharmaceutical products as a seal of authenticity and deterrent to counterfeiting. A broad portfolio of overt, covert, and tamper-evident technologies is available.

- **ASSESS the implementation of a product traceability system** – Define relevant scope for a track and trace solution to provide supply chain visibility. Evaluate the need for “in/out” verification vs. full traceability, and keep abreast of industry pilot projects.

- **ADAPT enforcement strategies to changing market forces** – Continuously monitor marketplace exposure in order to respond to market dynamics. Leverage the concerted efforts of law enforcement, field investigations, and online monitoring to identify and link suspicious counterfeit activities.

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Leverage an Integrated Solution

Companies need a multi-pronged brand protection strategy that addresses the key risks of patient health and safety, non-compliance (e.g. order fulfillment, cold chain requirements), grey market activity, and intellectual property infringements. For example, companies that authenticate and track their pharmaceutical drugs through a central database can purchase products from online entities to investigate their authenticity and product origin.

An integrated strategy that incorporates product authentication, supply chain tracking, and Internet monitoring provides a comprehensive solution to combat counterfeit drugs. The size and worldwide scope of the counterfeit drug business compel attention and action.



EFPIA Launches Anti-Counterfeit Product Identification Pilot Project

The European Federation of Pharmaceutical Industry Associations (EFPIA) has announced its pilot project to demonstrate a practical and effective solution for product identification of medicines from point of manufacture to point of dispensation. The pilot project of its 2D data matrix barcode system is being conducted in Sweden in partnership with Swedish retail pharmacy chain Apoteket AB and local wholesalers Tamro and KD.

The data matrix code will contain the product code, batch number, expiry date, and a unique serial number. Manufacturers will generate and apply the codes on each item-level pack, and store on a central database. Before dispensing to patients, pharmacists will check each individual pack against the database. Any duplication of data on packs will trigger the system to immediately alert the pharmacist to the possibility of a counterfeit product. The system will also give alerts for expired products, recall notices, or reimbursement fraud.

Part of the reason for the pilot project is to bring some harmonization of product codes used in countries across Europe. At present, there are at least 10 different national coding systems deployed for mass serialization of medicines. EFPIA is using the most widespread coding system, the GS1 GTIN (Global Trade Item Number) code carried within a standard ECC200 serialized data matrix. A harmonized coding solution is important for the practical adoption of a standardized and interoperable system throughout Europe.



EFPIA is implementing a verification model that provides checks at the point of manufacture and at the point of dispensation. It has deemed that a full track and trace or electronic pedigree project where each pack is scanned at each point in the supply chain (including distributors and wholesalers) was not necessary to adequately ensure patient safety. It was also not practical because of the complex logistics and incompatible systems currently in use across Europe.

The pilot project is expected to start in August, involve 30-50 Swedish pharmacies and 100,000 coded packs, and take three to four months to complete. The goal is to develop an effective anti-counterfeiting solution that allows manufacturers, pharmacists, and patients to verify the authenticity of each unit from manufacture to dispensation.

Source: www.EFPIA.eu

EU Bridge Project Successfully Demonstrates Full Traceability

The EU-funded Building Radio frequency Identification solutions for the Global Environment (BRIDGE) project has successfully demonstrated the feasibility of full product traceability across an open, cross-border supply chain in the European pharmaceutical sector.

The purpose of the three-year initiative was to demonstrate the effectiveness and interoperability of using mass serialization, RFID, and open systems standards (GS1 for data matrix barcodes and EPCglobal for RFID tags). The BRIDGE pilot involved pharmaceutical manufacturers, distributors, transport companies, wholesalers and pharmacies. The project tracked 15 different types of drugs in various packaging forms in a live operating environment. The drugs were monitored from manufacturing and packaging plants in Ireland and the Netherlands to their point of dispensation in the pharmacies at St. Bartholomew's Hospital and the London NHS Trust in London, UK.

Mass serialization was implemented at

every distribution node in the supply chain. Patient packs were marked with data matrix only, while cases and pallets were marked with both data matrix and RFID tags. Each pack was associated with a data set containing the product code, unique serial number (GTIN), batch number, and expiry date.



The pilot implementation demonstrated the required traceability for electronic pedigree which is expected to reduce medication errors, provide an effective means of product authentication, reduce the threat to patient safety, and improve supply chain visibility. The integration of traceability data also supported applications for recall, inventory

management, and financial reconciliation. In addition, the pilot project highlighted issues that will require solutions prior to future live implementations, as well as suggestions for ongoing development of GS1 and EPCglobal standards.

The BRIDGE project provided a valuable business case for the feasible implementation of full supply chain traceability. However, it required a high level of commitment, tight system integration, robust processes, and full collaboration. The significant investment of effort and resources must be evaluated in terms of practical application. The "in/out" approach taken in the EFPIA pilot in Sweden may be a more viable model.

In summary, the BRIDGE project has shown the value of a traceability system on improving patient safety and reducing the threat of counterfeit drugs.

Sources: www.bridge-project.eu &



OpSec Study Finds Increased Risks of Sourcing Bulk Pharmaceuticals Online

OpSec Security conducted a two-year study which shows substantial trends of increased illicit behavior by trade board sellers that offer bulk pharmaceuticals and active pharmaceutical ingredients (APIs) to buyers and intermediaries, and Internet pharmacies that sell drugs directly to consumers.

Increase in Trade Boards Offering Suspect Bulk Pharmaceuticals

The study revealed a 30% rise in the number of listings offering bulk pharmaceuticals and APIs across multiple highly trafficked B2B trade boards. As highlighted in The New York Times "The Toxic Pipeline" investigative series, trade boards are often used as a platform for the sale and distribution of counterfeit pharmaceutical products. The OpSec study found listings of zolpidem tartrate, the API for a popular prescription sleep aid, advertised in 25 kilogram drum quantities. A single drum can be used to produce 2.3 million sleep aid pills with a retail value of \$32 million.

The availability of bulk pharmaceuticals on B2B trade boards, which are unregulated environments, provides a global sourcing platform for buyers and intermediaries in the pharmaceutical supply chain. None of the pharmaceutical wholesalers mentioned pedigree information, even when offering to ship to the United States where the FDA requires pedigree tracking by each entity in the distribution chain.

Rise in Suspicious Online Pharmacies

In addition to offering significant discounts, 33% of the Internet pharmacies in the research exhibited all four of the following signs of "highly suspicious behavior" indicative of illicit drug sales.

- Internet pharmacies registered in regulated regions that do not require a



prescription, or require only an online consultation

- Internet pharmacies that mask their WHOIS location and contact details
- Internet pharmacies included on the NABP's "Not Recommended" List
- Internet pharmacies registered outside the U.S., but targeting a U.S. consumer

Over the two-year period, a growing number of Internet pharmacies have abandoned the basic requirement of a valid prescription. The number of Internet pharmacies that do not require a prescription or only require an online consultation grew by 65%, while those that required a prescription decreased by 55%.

From 2007 to 2009, there was a 65% increase in non-accredited Internet pharmacies that required no prescription or only an online consultation.

Greater Discounts Entice Consumers to Buy Drugs Online

The study noted a 300% increase in Internet pharmacies offering 60-80% discounts below retail prices from 2007 to 2009. Of the hundreds of unaccredited Internet pharmacies researched, the average price of prescription drugs across a representative sampling of top-selling

drugs was 78% below the average price on the National Association of Boards of Pharmacy's (NABP) Verified Internet Pharmacy Practice Sites (VIPPS) accredited sites.

In addition, consumers are often targeted with potentially dangerous promotions offered when buying drugs online. One network of sites offered free erectile dysfunction pills with any purchase. For patients taking medications to prevent a heart attack or stroke, this promotion would be especially dangerous as they are advised not to take drugs that increase their heart rate and blood flow.

Trends Highlight Escalated Risks of Online Drugs

The continued rise of these trends reveals increasing risks to consumers who buy drugs and companies that source pharmaceutical products online. Unfortunately, the easy anonymity, lax regulations, and global reach of the Internet allow counterfeit drugs to enter into the legitimate supply chain.

Consumers enticed by the deep discounts offered online should be aware of the potential danger of counterfeit or standard drugs on unaccredited Internet pharmacy sites. Likewise, pharmaceutical companies and governments need to address the widespread availability of suspect pharmaceutical products and their infiltration into the legitimate supply chain.

Merck KGaA Benefits from Internet Intelligence for Online Enforcement

As a leading company in the pharmaceutical industry, Merck faces the challenging market dynamics of the Internet. It is an important channel for business and communications, and a global platform to buy and sell a wide variety of goods. In Europe, each member state may enact its laws within the general guidelines of the EU. As a result, pharmaceutical manufacturers must sort through the various applicable laws governing the import of pharmaceuticals and medical products sold on e-commerce platforms.

Unfortunately, not every seller complies with the law. Manfred Bernau, Senior Security Manager at Merck KGaA knows this for a fact. Pharmaceutical products are often repack-

aged in new packs for international shipment to another location in the world. While repackaging is not necessarily illegal, it becomes an infringement of European law if it is done without the consent of the manufacturer. Repackaging to send counterfeit pills in disguise to anywhere in the world increases the potential risks to the end consumer.

“At Merck, we want to be active in monitoring e-commerce platforms to understand the online marketplace,” said Mr. Bernau. “We looked for a company with experience in the Internet sector. For three years now, OpSec has supported our anti-counterfeiting efforts. As a result of our partnership with OpSec, we have created a very successful work process which enables us to quickly gather relevant market information. The data is processed for use as evidence for further investigation by enforcement authorities.”

“OpSec does the research for us on the Internet, and delivers detailed intelligence about dubious sales channels, and their roots and networks. To some extent, we are surprised by the naivety of consumers to respond to such dubious Internet offers. Thanks to the undercover investigations of OpSec, we have full knowledge of the various offers, options, and decoys. In some cases, we are able to have an informative dialogue with the online sellers.”

“In the end, we benefit from a comprehensive assessment across e-commerce platforms, a thorough understanding of the sales and delivery channels, and key insights on the “schemes” of many vendors. New methods of e-commerce will emerge, that’s a fact. Together with OpSec, however, we are confident that we will continue to have a successful program of online enforcement.”



Bio

Mr. Manfred Bernau has been employed at Merck Germany for the past 17 years. In his current position, he is Senior Security Manager, and is responsible for Merck’s Anti-Counterfeiting program and strategy worldwide.

Events

2009 IACC Annual Fall Conference *October 14-16, 2009 Atlanta, Georgia*

OpSec is attending this event.

For more information, please visit www.iacc.org

Frankfurt Book Fair 2009 *October 14-18, 2009 Frankfurt*

OpSec is attending this event.

For more information, please visit www.buchmesse.de/en/

Licensing Market 2009 *November 4, 2009 Munich*

OpSec is attending this event.

For more information, please visit www.lima-verband.de

Fifth Global Congress Combating Counterfeiting & Piracy *December 1-3, 2009 Cancun, Mexico*

OpSec is attending this event.

For more information, please visit www.ccapcongress.net

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