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Proactive Protection

By Alina Halloran

The number of online pharmacies continues to increase exponentially and the global supply chain is at risk of infiltration by counterfeit ingredients. A more proactive approach is needed to ensure consumer safety.

The internet has exploded into a global platform where finished drugs and APIs are sourced and sold, and pharmaceutical companies are waging an unceasing battle against the sale of counterfeit drugs. The sheer volume and dynamic nature of these sales can be seen in the growth of the 'gray market', which involves the shifting of products into unauthorized sales channels, parallel imports where products move from one market to another and, of course, the ongoing threat of counterfeit products, which is the greatest threat to consumer safety and a company's reputation.

On the go...

- Analyze the online landscape and assess your exposure to fraud in trade boards, online pharmacies and other e-commerce platforms.
- Understand the online environment of buyers and sellers in internet drug sales.
- Deploy a comprehensive brand protection strategy that leverages internet expertise and the latest technological tools.
- Use technology to identify and link suspicious online activities.
- Educate all constituents in the supply chain as pharmaceuticals travel through many hands before reaching the consumer.

Perhaps the biggest obstacle is the absence of comprehensive regulations for internet drug sales, coupled with the issue of enforcement responsibility, a murky legal area that involves the competing interests of manufacturers, distributors, e-commerce sites and governments. Additionally, the global nature of online sales blurs geographic boundaries and complicates enforcement, responsibility and applicable laws.

The US-based Center for Medicine in the Public Interest (CMPI) believes that counterfeit drug sales will rocket to US \$75 billion by 2010, a 92% increase above 2005 activity.¹ "Counterfeit sales are increasing at nearly twice the rate of

legitimate pharmaceutical sales and they are a money machine," said Peter Pitts, President of CMPI.¹ The pharmaceutical industry needs effective strategies to combat a colossus that seemingly has no growth limits. The strategy exists and its principal weapons are technology and internet expertise.

The complexity of counterfeiting

As the internet is highly anonymous, counterfeiters can easily source and sell counterfeit pharmaceutical products on business-to-business online trade boards and business-to-consumer online pharmacies. Trade boards provide a platform to source large quantities of finished goods or APIs. Counterfeiters can operate under the guise of legitimacy within the unregulated trade board environment. Often, online pharmacy operators source products from these boards.

The thousands of online pharmacies offer even more opportunities for fraud. Some are reputable, but many operate in countries other than the location purported on their websites and do not even require a prescription for purchase both of which are common indicators of counterfeit or substandard product sales. The National Association of Boards of Pharmacy (IL, USA) offers its Verified Internet Pharmacy Practice Sites (VIPPS) seal only to online pharmacies that meet stringent criteria. Of the thousands of internet pharmacies, only 15 were VIPPS certified as of June 2008.² Unfortunately, many online consumers are unaware of the VIPPS programme and do not know what criteria to look for when purchasing pharmaceutical products online.

The source of counterfeit drugs can be tracked through a series of twisted channels in the pharmaceutical supply chain. The complexity of tracking to the source was graphically revealed in a *New York Times* investigative series that traced unlicensed, uninspected and unregulated facilities in China as the source of

heparin contaminants, which are believed to be responsible for 19 US deaths, and counterfeit glycerine in cough syrup, which killed 120 in Panama.³ The series highlighted the relative ease for tainted ingredients to infiltrate supply chains. "The importation of counterfeit, infringing, misbranded and unapproved pharmaceutical products in the United States is increasing exponentially," the *New York Times* reported.⁴ Compounding the problem for investigators is that counterfeit sellers can easily hide their true addresses and are difficult to trace to a professional entity.

Some pharmaceutical companies have tried to tackle the problem head-on by searching the internet with internal resources. However, the lack of proper tools, resources and expertise often results in a frustratingly ineffective and time-consuming effort. Fortunately, new strategies for online brand protection and new developments in technology offer hope.

What can be done?

Companies need to assess their exposure to fraud, unauthorized sales or possibly tainted APIs; for example, they must determine how much activity involving the company's product is occurring in online pharmacies, trade boards or auctions. Next, companies have to understand the environment of internet drug sales, such as how they are offered, at what price and by what 'business'. An assessment of the landscape is a baseline for measuring the impact of any brand protection activities deployed in the future. Companies should then develop a brand protection strategy that addresses the key risks of patient health and protection strategy that addresses the key risks of patient health and safety, noncompliance (e.g. order fulfillment and cold chain requirements), gray market activity, and legal and intellectual property infringements. The strategy should contain specific, attainable goals that can be adapted to changing market forces and enforcement strategies.

Many pharmaceutical companies overlook the importance of educating all of the important constituents of the supply chain, such as pharmacists and hospital administrators searching for cheaper products. As the supply chain is complex and involves ingredients traveling through many hands before reaching the consumer, all of those 'hands' must be educated.

The key is to be proactive and to take advantage of available domain expertise through suitable partners.

New technology

One successful anticounterfeiting technological tool employs search engines that filter and categorize information while also detecting areas of concern; this includes investigation of online pharmacies and trade boards that are identified as posing a threat to the health and safety of consumers.

Technology can also map and link relationships to sites that on the surface, may appear unconnected. This is especially effective in determining where to apply resources because activity can be prioritized based on the scope and extent of the illegal distribution. By continuous monitoring of online entities, the software can map traffic from the network back to the ultimate source.

The driving forces behind the technology include search and filter capabilities that capture product data, order fulfillment requirements and other key aspects of the online environment. The technology also creates a link analysis based on various site characteristics to determine storefront (e.g. marketing affiliate) and hub (source of order fulfillment) relationships, which could be vital information should there be an investigative or legal response. In addition to capturing suspicious postings on trade boards and online pharmacies, a database stores information for future litigation including the web posting, product image and description, pricing and seller data.

Companies that authenticate and track their pharmaceutical drugs through the database can purchase products from online entities to determine their authenticity and product origin. Combining intelligence from the internet with information from product purchasing activities and investigative data is often the key to maintaining a successful programme. The use of internet monitoring technology is an effective tool in developing an accurate understanding of the online risks impacting a brand. It can also be viewed as a cornerstone in implementing an online brand protection strategy.

Companies should not wait for the first reports of tainted or fraudulent products bearing their brand before they take action. The size and worldwide scope of the counterfeit drug business should prompt companies to act now.

Alina Halloran is Vice President of OpSec Security Inc.

1. P. Pitts, "False Profits, Center for Medicine in the Public Interest" (2008). www.drugwonks.com

2. National Association of Boards of Pharmacy, "Verified Internet Pharmacy Practice Sites," June 2008. <http://vipps.nabp.net/verify.asp>

3. W. Bogdanich, "Heparin Find may Point to Chinese Counterfeiting," *The New York Times* (12 March 2008).

4. W. Bogdanich, J. Hooker and A.W. Lehren, "Chinese Chemicals Flow Unchecked onto World Drug Market," *The New York Times* (31 October 2007).



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3 Copley Place, Suite 201

Boston, MA 02116

Phone: 617.226.3000

Fax: 617.226.3001

Website: www.opsecsecurity.com