A RISK-BASED REMEDY FOR PHARMA SUPPLY CHAIN SECURITY CONCERNS

An Analysis by Dan Purtell, Senior Vice President, BSI Supply Chain Solutions

No business is immune from costly supply chain disruptions, particularly at a time when globalization and increased operational complexities continue to magnify our shared exposure to risk. High-value, tightly regulated products such as pharmaceuticals are especially vulnerable and attractive targets, and the need for end-to-end risk mitigation strategies in the industry has never been greater.

Despite recent advances in security practices throughout the industry, pharmaceutical supply chains across the globe continue to be subject to alarmingly high levels of theft and product counterfeiting. Manufacturers and distributors are investing in counter-measures such as improved product tracking technologies, but fail to account for the full breadth of potential risk within the supply chain. One critical step remains lacking: stakeholders within the pharmaceutical sector need a comprehensive, risk-based approach to security that fortifies the entire supply chain and tracks the changing risk profiles of every country in which they operate.

The estimated annual value of exports from countries with severe or high terrorism risk exposure is in excess of 1 trillion USD.
Multiple Threats

Pharmaceutical products are prone to a number of supply chain disruptions, and these exposures increase costs and undermine competitiveness as well as create potential health hazards and expose stakeholders to brand damage.

As is the case with any commercial product, when pharmaceuticals fail to reach the point of sale and immediate buyer demand remains unfulfilled, companies across the supply chain lose out on forecasted revenue and, potentially, market share. There is a far greater consequence at stake: when drugs are stolen, there is the likelihood that these temperature-sensitive and perishable items will not be handled properly, and if they enter the market, could pose serious health risks to consumers.

Similar health concerns are raised when fake or adulterated medications infiltrate the supply chain and are peddled to unwitting distributors or buyers. In addition, counterfeit product decreases market share for pharmaceutical manufacturers, distributors and retailers because it displaces sales of legitimate products.

Less obvious costs incurred by the trade in stolen and fake pharmaceuticals include an increase in transportation costs due to carrier liability. Shippers often hold carriers liable for a portion of a loss due to theft. Not surprisingly, if these costs are not fully covered by insurance policies (or are covered, but result in a subsequent increase in premiums), it is likely that freight rates and insurance premiums will rise to compensate for theft-related losses. Compounding the problem, insurance companies often subrogate costs associated with claims against the carrier and in the end, the transportation provided is on the hook to both the manufacturer and the shipper’s insurance company.

Disruptions also carry serious risk to brand integrity and company reputation. When pharmaceuticals are stolen, manufacturers and distributors are legally required to notify the authorities and provide as much information as possible about the incident. While these measures are an essential part of the recovery effort, the negative publicity can be extremely damaging to the companies involved and can result in a costly recall of entire production lot or batch which could magnify the loss four to six times the original retail loss.

A more recent threat is the connection between cargo theft and terrorism. For example, law enforcement agencies in the United States discovered that criminal gangs were targeting shipments of baby formula in Texas. The stolen product was sold in the border areas of Texas and Arizona, and the proceeds were used to fund a well-known terrorist organization. In global terms, the estimated annual value of exports from countries with severe or high anti-Western terrorism risk exposure exceeds US $1 trillion. Companies that fall victim to these types of crimes have to cooperate with counter-terrorist government agencies as well as law enforcement offices that deal with regular theft incidents.
Another government intervention that affects supply chain security comes in the form of new transportation regulations. One example is the recently mandated TSA Certified Cargo Screening Program 100% inspection rule that requires security screening of all cargo loaded on passenger planes flying within the domestic United States. High-value pharmaceutical products are often shipped by air.

Concerns over such mandates were evident in the 2010 annual healthcare supply chain survey carried out by UPS Healthcare Logistics and Harris Interactive. Senior decision-makers in approximately 150 companies in the pharmaceutical, medical device, medical supplies, and biotech industries were surveyed in March and April 2010. The third-highest issue rated by the executives polled was product security, and two-thirds of respondents planned to increase their supply chain security spending over the subsequent 18 months.

Harsh Reality

These various threats to the integrity of pharmaceutical supply chains are not theoretical; incidents of theft and counterfeiting have reached alarming levels worldwide.

As a global independent business services organization that operates in more than 140 countries, BSI is uniquely positioned to assess the vulnerabilities of international distribution networks. BSI Supply Chain Solutions provides supply chain security products and services that enable companies to identify and mitigate supply chain threats.

BSI’s worldwide annual cargo theft loss forecast for 2010 is $20.5 billion. This amount is up fractionally from the firm’s 2009 loss estimate of $19.4 billion. BSI’s 2010 loss forecast in the United States alone is $4.5 billion. BSI consistently rates pharmaceutical theft as the top targeted commodity in the U.S. and in many other countries.

A single heist can net big profits for criminals. In March 2010, thieves stole drugs including painkillers and antidepressants worth an estimated $75 million from an Eli Lily and Company’s distribution center in Enfield, Connecticut. The cost of a loss such as this is substantial, both in terms of lost revenues and, in the case of pharmaceuticals, having to replace product that is no longer saleable. An incident in Milwaukee in November 2009 involved the theft of a truckload of goods that was later recovered. The load included more than 900 doses of the H1N1 flu vaccine that had to be returned to the manufacturer and destroyed.

As supply chains become more complex and diverse, companies can no longer confine their risk mitigation resources to domestic or primary markets.
The U.S. Food and Drug Administration (FDA) is so concerned about the high incidence of thefts that the Acting Assistant Commissioner for Regulatory Affairs, Michael A. Chappell, sent a letter to industry stakeholders about the problem in April 2010. “FDA is very concerned about the increase in cargo and warehouse thefts of FDA-regulated products, including prescription and over-the-counter medicines, vaccines, medical devices, and infant formula,” Chappell wrote.

Firms that supply these products “have a fundamental responsibility to continuously review their warehouse physical security and security practices and procedures for transporting products to ensure that measures are in place to minimize the risk of warehouse and cargo theft,” Chappell continued. Such measures should span the entire supply chain from manufacturing to point of sale, and enterprises “should ensure that their business partners and carriers review and have strengthened their storage and in-transit security practices as well,” the Commissioner advised.

Drug counterfeiting is also on the rise. A survey released in 2010 by the Pharmaceutical Security Institute, a non-profit that represents pharmaceutical manufacturers, estimated that drug counterfeiting has increased worldwide by more than 9% from the previous year. The survey identified 808 types of counterfeit pharmaceutical products in 2009, up more than 36% from 2008, and counterfeit product was detected in 118 countries in 2008. According to the survey, in 531 incidents, counterfeit products reached licensed wholesale distributors and/or pharmacies in 48 different countries. Selling counterfeit pharmaceuticals is lucrative. “Bloomberg Business Week” recently reported that according to Interpol’s Aline Plancon, pharmaceutical counterfeiters can invest seed money worth just $1,000 and make $450,000 from counterfeit drug sales, compared to $20,000 in the heroin trade. 1

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Steps to Security

How can the industry combat such large-scale threats to pharmaceutical supply chains? By developing a risk-based, methodical approach to security that provides end-to-end protection against cargo theft and counterfeiting.

1. Initial Assessment

An initial risk assessment of the entire supply chain and areas of operation reveals where the weaknesses lie.

It is imperative that this assessment is all-inclusive. A common pitfall is to focus on primary facilities such as plants, even though thefts are most likely to occur while pharmaceuticals are in transit. Across all industries worldwide, over 80% of cargo theft occurs in transit.

2. Deep-Dive Analysis

A more detailed analysis of operational areas that require attention follows the broad evaluation of the company’s supply chain security risk.

For example, BSI’s Quantitative Risk Solutions℠ (QRS) analyzes cargo theft exposure and countermeasures on a lane-by-lane or country-by-country basis using data on billions of dollars worth of losses from 200+ countries. QRS applies sophisticated statistical and financial analysis and proprietary risk algorithms to quantify a company’s cargo exposure. Suppliers can be the weak link in a supply chain’s security armor, particularly in the global pharmaceutical business.

BSI works with companies to create a customized global supplier risk map. BSI applies real-time intelligence, including proprietary data related to global cargo disruption and tampering rates and anti-Western terrorism activity. BSI also incorporate country risk variables, such as the rule of law and the effectiveness of local law enforcement. This intelligence is the basis of a patented risk algorithm, and the resulting analysis assists BSI’s clients to identify and mitigate their risk exposure.

BSI’s web-based application for managing supplier security compliance, Supplier Compliance Manager℠ (SCM), distributes, collects, analyzes, and scores supplier security self-assessment questionnaires. SCM administers questionnaires in multiple languages and by business type. Companies may add up to 250 questions of their own in order to customize the questionnaire. SCM enables companies to implement an automated monitoring system for tracking and improving compliance with internal and government-sponsored security programs.

SCM backend analysis includes terrorist-related threats to international supply chains. It employs proprietary risk indexes that contain information on over 800 terrorist groups located in more than 200 countries, a level of detail surpassed only by
some government databases. This depth of information is necessary given the expanding reach of terrorist groups; targets of anti-Western terrorism threat include Australia, Canada, New Zealand, the United States, and Western Europe.

Membership in initiatives such as C-TPAT has become an important component of international supply chain security programs. The FDA’s PREDICT risk targeting program also aims to expedite the clearance of low-risk cargo at the border, enabling the agency to focus attention and resources on higher risk shipments. PREDICT has the potential to significantly speed up cross-border movements, but there will be enormous pressure on importers to file accurately and consistently to avoid being red-flagged for administrative (even keystroke) mistakes. Consistent with the public-private partnership approach of both of these programs, the onus is on pharmaceutical companies to identify where improvements need to be made in order to comply. BSI’s Supply Chain Solution Group’s Gap Analysis service involves an in-depth review of current security policies and practices to determine the affect of programs such as C-TPAT on an organization.

3. Recommendations

Drawing from the findings of the security evaluation, BSI recommends and prioritizes actions to secure the supply chain. BSI evaluates exposures facing manufacturing and operational facilities in the form of financial-based recommendations and provides two types of reports: a detailed document that lists security deficiencies alongside recommended corrective actions and a high-level report on the company’s supply chain security risk based on the company’s operating environments and oversight practices.

4. Action Plans

Applying these recommended actions, BSI works with the client to develop an action plan for minimizing domestic and international shipment risk. The actions are framed in a customized supply chain security program, which takes into account country, threat, economic stability, cargo type, transportation mode, and numerous other factors that need to be addressed when securing a pharmaceutical supply chain.
Tailored Treatment

BSI’s experts have decades of experience analyzing and developing successful global supply chain security programs for companies of all sizes, from small import-export firms to FORTUNE® 100 companies, which help to ensure that risk is effectively mitigated and operations run smoothly. A typical program includes policies and procedures review and development, facility audits by one of BSI’s 2,500 resident experts, and security countermeasure analyses. The end result is a program tailored to the needs and operational environment of the client which effectively reduces security risk and ensures supply chain integrity.

There is no single cure-all for the security concerns that disrupt pharmaceutical supply chains and drive up industry costs. Steeling supply chains against these threats requires a systematic and comprehensive approach.

About the Author

Dan Purtell leads BSI’s Supply Chain Security Solutions division which assists some of the world’s largest organizations to reduce cargo tampering and disruption. Considered one of the top supply chain security experts, Dan Purtell has conducted transportation infrastructure risk analysis in more than 57 countries. With over 25 years of experience, Dan is frequently consulted to educate corporations, government and insurance underwriters on supply chain security threats and strategies to fortify cargo security.

BSI’s Supply Chain Security portfolio includes state-of-the-art supply chain security tools coupled with BSI’s extensive field-based network of supply chain security assessment professionals. As a leading global provider of risk-based solutions, assessments, and training programs, BSI’s solutions are geared toward improving corporate efficiencies and protecting corporate brand. By incorporating proprietary global cargo tampering data and terrorism risk modeling to evaluate overall supply chain risk as well as the potential risk exposure of specific suppliers, BSI is able to provide maximum visibility and business intelligence to emerging markets and supplier practices worldwide.

About BSI Group

BSI Group is a global independent business services organization which enables businesses, governments and other organizations to increase profits and market access, and to enhance reputation with its standards-based solutions and assurance services. From its origins as the world’s first National Standards Body, BSI Group draws upon over 100 years’ experience to partner with 66,000 organizations in 147 countries from its 50 offices. Today, through its independence, innovation and integrity, BSI continues to improve the lives of millions by raising standards worldwide.