



THE KILLER COUNTERFEITS

Counterfeit consumables are a danger to both health and wealth, argues Vaughn Volpi.

The manufacturing of counterfeit goods or the deliberate act of compromising a product with inferior and dangerous materials are criminal acts, and they attract suitably alarming headlines across the world:

- “FDA says 86 US deaths due to Heparin”
- “More than 2 million counterfeit drugs seized in Belgium”
- “Toxic liquor death toll rises to 168 in India”
- “A third of the medicine in Africa is counterfeit”

While knock-offs of designer goods and luxury items typically grab the lion's share of public attention, of equal, if not more, concern are counterfeit consumables, which encompass an expansive definition of products.

The illicit trade in these goods has left a trail of death, injury and heartache across the globe. Counterfeit products do present intellectual property and trade problems, but according to the International Intellectual Property Institute, they are, worryingly, barely on the public's radar in terms of their serious health consequences.

In particular, counterfeit drugs, alcohol, cigarettes, food and personal care items are of great concern, says the institute. Many die from counterfeit consumables each year, while thousands are injured and hospitalised. Little has been done to define the scope of the problem, due, in part, to the difficulty in detecting, investigating and quantifying the extent of counterfeit manufacturing and sales.

The current global financial chaos will likely spur the production and circulation of even more counterfeit products. Historically, when the economy dips, product pirates flourish. Given its reach and relative anonymity, the Internet has become the counterfeiters' weapon of choice as a platform that opens an infinite number of channels for hawking illicit fakes. PICA, which monitors the Internet and secondary markets around the world for illicit products, has already seen a sizeable increase this year in counterfeit consumables, especially in the pharmaceutical and cosmetic industry.

Terrorists and organised crime profits

Globalisation presents many new business opportunities—for the legitimate businessman and criminal alike. Investigations have shown that illicit profits often fund both organised crime and terrorist activity. This lucrative boon for counterfeit consumables threatens not only human health, but the financial well-being of businesses and governments.

Counterfeit sales are now estimated to cost the world economy \$650 billion annually, and the economy of the United States \$200 to \$250 billion a year. Meanwhile, the sales of counterfeit cigarettes and alcohol rob world governments of more than \$50 billion in tax revenues, according to testimony before the US House Ways and Means Committee.

Just from pharmaceuticals alone, public interest health groups predict that counterfeit sales will top \$75 billion worldwide in less than two years, an increase of more than 90 percent from 2005. In the US, this year, commerce in counterfeit pharmaceuticals is expected to top \$39 billion.

Knock-off drugs can range from one percent of market sales in developed countries to a whopping 30 to 50 percent in developing nations, says the World Health Organization.

Meanwhile, an emerging but less visible trend of grave concern to consumer health is the misuse, reimportation and repackaging of single-use medical devices. These instruments are not usually thought of as ‘consumable’ goods in the traditional sense, but they do present a tremendous risk to a trusting public.

In the past five years, PICA investigators have turned up thousands of instances in which companies sold these products to unsuspecting hospitals

outside the scope of FDA regulations. The instruments were often illegally reimported, with no record of how they were shipped or whether they were stored under sanitary conditions.

In one instance, \$3,000 surgical staples were being smuggled out of a hospital, concealed within the contents of bagged-up, biohazard waste. Those same staples were then able to be sold on the Internet for half the price.

Separately, PICA supported the FDA on a case that resulted in a \$3 million seizure of illicit prescription medical devices and illustrated a typical scenario in secondary market investigations. The products were stored in a dirty Florida warehouse and garage with no temperature control, compromising the efficacy of the instruments. Those involved sold the products to Fortune 500 companies, which then sold them to hospitals around the world.

Supply chain awareness

The task for legitimate businesses to maintain control of merchandise is clearly a challenge, but supply chain integrity is critical to ensuring stability and public trust in a product.

First, companies must explore the background of all new customers to ensure that they don't represent a diversion front business that will sell a product outside of the approved chain. Taking this step would also help identify non-creditworthy customers prior to the shipping of merchandise.

Brand owners considering a client for the sell-off of surplus products should also conduct thorough background checks. Many surplus wholesalers will agree to sell product under strict client guidelines and then sell instead to the highest bidder. Flooding a secondary market with legitimate goods paves the way for the sale of illicit goods in the same space.

Routinely monitoring the scope and volume of merchandise on the secondary market is another positive step for brand owners. Such action allows for a quick response if problems surface. This work is best left to a professional investigative company that is familiar with these channels and that already has extensive cover operatives positioned around the world.

Monitoring and remaining proactive in the secondary market is the key to a successful brand protection programme. Businesses can significantly reduce risk through vigilance and will stand to gain financially by removing counterfeits from the marketplace. Just one highly publicised incident can seriously, or fatally, damage a consumable brand. Once customers lose confidence in a product, even for a short period, it may negate years of costly promotions and challenge a brand in ways from which it may never recover. Be smart, be proactive.

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Vaughn Volpi



Vaughn Volpi is a graduate of Miami University and has served as co-chairman of the International Anticounterfeiting Coalition's Investigators Committee. He joined PICA in 1989, becoming its president in 1996. Vaughn's areas of expertise include all aspects of intellectual property investigations, and he has personally developed, supervised and executed thousands of brand protection projects around the world.