

Pharmaceutical Counterfeiting a Global Healthcare Menace: A New Technology Tool

By: Alan Clock, Senior Vice President, Sales and Marketing, XStream Systems, Inc.

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The Issue

Counterfeit and adulterated medications are by any measure or definition a very dangerous and serious threat to all consumers globally.

In the pharmaceutical industry, the global market share of counterfeit drugs is estimated worldwide at nearly 10%¹. In developed countries the percentage is estimated at 1% while in specific regions of the world, for example in Asia and Africa, the overall percentage is considered by most experts to be significantly higher than the global market average.

The four basic categories of counterfeits are:

- Completely fraudulent counterfeit medications with no active ingredients or clinical benefit. In some cases the ingredients may actually be toxic or pose a significant risk to the person taking the counterfeit medication. It is estimated that 40% of the counterfeit drugs currently in circulation do not even contain an active ingredient from the counterfeited medication.
- Counterfeit medications which contain poor-quality ingredients or a diluted active ingredient. These medicines pose a significant health risk because even though there may be some clinically beneficial ingredients in the counterfeit medication, their medicinal value is unknown or extremely limited. Use of these counterfeit medications will cause harm to the person taking the medication because they are realizing unknown or only a partial benefit of the medicinal therapy.
- Expired medications that are re-packaged and resold. These medicines pose a significant health risk because it is unknown if the active ingredients are still viable and useful to the patient. Some ingredients may have degraded while other ingredient's molecular structure may be altered due to a variety of causes.
- Medications that mimic the pharmaceutical formula using unknown raw materials/ingredients and manufacturing processes. The benefit of these medications is completely unknown and should be considered extremely hazardous given their lack of regulation, quality control or processes. These medications are primarily produced to infringe on a pharmaceutical manufacturers patent with the quality and efficacy of the medication is completely unknown.

Also of significant concern, while not considered counterfeit goods, is the rise of global outsourcing of raw materials, manufacturing and finished goods by pharmaceutical companies worldwide. As seen in other industries and products recently, the lack of oversight, regulation and enforcement of the raw materials and finished goods of industry where this products are produced, has led to a variety of public safety and health concerns internationally (e.g. pet food recalls, lead paint in toys, etc.).

Wide spread use of toxic or unsafe materials in the manufacturing process and lack of regulation and quality control are causing concern in the pharmaceutical industry regarding the efficacy of products globally outsourced.

Many of the countries in Asia and elsewhere where these products are rapidly being outsourced have a very poor track record of government control and product safety and in fact are where most of the suspected counterfeit products are being produced for international distribution.

While there is a major concern, it is anticipated that nearly all pharmaceutical manufacturers will be expanding, some doubling, their outsourced manufacturing in 2008.

The primary reasons for the rapid increase of counterfeit and adulterated medications include:

- **The high price of pharmaceuticals worldwide.** Medications have become a global currency. Pharmaceuticals increase in value over time, are relatively easy to re-produce, relatively easy to transport and relatively easy to distribute.
- **The technology to re-produce reasonable near identical or reasonable forgeries of all the components of a medication including labels, containers, form and ingredients is now widely available worldwide.**
- **The ease of even relatively unsophisticated counterfeiters to take legitimate or expired medications, dilute and/or alter and repackage and re-introduce into the supply chain.**
- **The Globalization of the world's economy specifically as it relates to the pharmaceutical industry as a whole, including the access to raw materials, manufacturing, supply chain and dispensing.**
- **The ease of use of the Internet which provides individuals and sophisticated organizations a relative anonymous access to direct consumers worldwide.**
- **Insufficient, weak or inconsistent laws, regulations and standards which govern the pharmaceutical supply chain globally.** From manufacturing to dispensing, current regulations do not provide an effective prevention, in terms of enforcement and penalties, to deter counterfeiters. Internationally, nationally and locally the regulations and law enforcement efforts are not focused on catching and properly punishing this type of criminal activity. The reward versus the risk is very high.
- **Sophisticated, global organized crime networks have realized the high return of this crime and have become increasingly involved in counterfeiting medications.** Given the penalties and enforcement it is now a higher return to counterfeit legitimate medications than to manufacture and distribute illicit drugs.

The Scope of the Issue

Even in countries that are generally considered to have a more regulated pharmaceutical supply chain the United States, Canada and most of the European Union nations, counterfeit medicines have entered the

legitimate supply chain. The U.S. Food and Drug Administration (FDA) reports that counterfeiting investigations have increased dramatically over the past several years:

- In 2000 the FDA opened six counterfeit drug cases and in 2004 they opened 58 cases a 960% increase in investigations in four years².
- In the United Kingdom in 2004, seventeen incidents were reported and in 2005, forty-six; a 270% increase in counterfeiting incidents in one year³.
- In June 2005, following the discovery that an accredited pharmacy in Canada had dispensed counterfeit Norvasc, eleven reported deaths were examined for a link to the fakes. The regional coroner reported that of the eleven deaths, the counterfeit medicine could not be ruled out as a cause for four of them⁴.
- In 2005, the United Kingdom saw the recall of medicines from the legitimate supply chain when a counterfeit version Lipitor was found. The resulting nationwide recall of 120,000 packs of the 20 mg Lipitor involved 240 pharmacists. After analysis it was found that approximately 60% of all packs returned were counterfeit⁵.
- In 2003, 18 million repackaged Lipitor tablets – a mix of counterfeit tablets and authentic tablets intended for non-US markets – were recalled from the legitimate supply chain. According to authorities, it was the largest recall of a prescription medicine in the U.S.⁶.
- Counterfeiters have soaked the labels off vials of a low-strength version of Johnson & Johnson's anemia drug Procrit, used for treating cancer patients and replaced them with forged labels for the highest strength⁷.
- In 2006, Pfizer reported more than 8.1 million counterfeit doses of their branded medicines were found and seized within these nations pharmaceutical supply chain. Unfortunately, most experts agree that those 8.1 million doses seized represent only a small fraction of those introduced into the entire global supply chain⁸.
- Counterfeit vials of the human growth hormone Serostim used to treat severe symptoms of AIDS, have been discovered in New Jersey, Texas and Hawaii⁹.
- In Ecuador, after an investigation of counterfeit Dayamineral being sold in the marketplace, nine raids took place, resulting in the seizure of 626 bottles of product and 5,000 counterfeit labels¹⁰.
- Working in concert, U.S., U.K. and Hong Kong law enforcement authorities arrested a Shanghai-based wholesaler of counterfeit Reductil and other products¹¹.
- With Americans purchasing 44% of all pharmaceuticals sold worldwide last year, if only 1% of the US drug supply was tainted it would equal 34.2 million prescriptions that are potentially life threatening. This equates to approximately one counterfeit prescription for every nine American citizens in 2006 alone¹².

Current Measures to Fight Global Pharmaceutical Counterfeiting

Currently there are a variety of measures used globally by Pharmaceutical Manufacturers to fight counterfeiting globally. These include watermarks, barcodes, RFID tags, holograms or patterns applied by special printing inks on the bottle or packaging of the pharmaceutical product itself.

Domestically within the United States, individual states have enacted laws that require a Pedigree program that tracks the trail of each pharmaceutical throughout the supply chain from manufacturer to dispenser.

Each of these are measures are important tools in the fight against counterfeit medications and they all have some success in dealing with the overall issue of counterfeiting in specific markets.

Unfortunately watermarks, barcodes, holograms and patterns applied by special printing inks have the ability to be forged much like the pharmaceuticals inside the package and are very limited in their ability to defeat sophisticated counterfeiters.

RFID tags are more effective but are extremely expensive, add significant cost to the product itself and require special equipment to read and write data that is being communicated to the various places in the supply chain. RFID tags also can be forged by sophisticated counterfeiters.

Pedigree programs are also an effective anti-counterfeiting process but it is not a fool proof solution. The Pedigree process and paperwork can easily be forged and like the counterfeit products can lead to a false sense of security for the person dispensing the medicines. Additionally the process is very labor intensive, requires significant documentation and adds significant costs to the supply chain.

Ultimately all of these tools are effective but limited solutions in fighting counterfeit medications. The one common element to all of these solutions is that they rely entirely on the fact that the product that is in bottle that they are attached to or documenting is the actual product and has not been forged, diluted or adulterated somewhere within the supply chain when these tools were attached to the specific product.

Technology as a Solution

Given the limitations of the current measures of tags, barcodes and pedigrees, the only effective way to authenticate and verify the contents of the unit of sale of medication is the introduction of a technology that can penetrate sealed bottles and read the molecular finger print of the medication inside the container.

XStream Systems' XT250™ System can help mitigate many risks businesses and consumers face in the global pharmaceutical supply chain. With this cost-effective and non-destructive technology, medications can now be authenticated and verified while still in the manufacturer's sealed bottles. The unit accurately scans through opaque plastic, cardboard, even metal packaging to ensure consumer safety.

This type of technology does not destroy or alter the product that it is analyzing and is the only current technology that can verify the product without breaking the seal or destroying the product that it is analyzing.

The XT250 System is adaptable and can be customized for optimal results from the pharmaceutical manufacturing plant to the consumer; by using EDXRD, the various members of the pharmaceutical supply chain can look beyond the packaging and into the actual drug itself by creating an individual molecular finger print.

This solution can provide verification of raw ingredients and quality control for manufacturers. It allows pharmaceutical distributors and wholesalers conclusive authentication of incoming merchandise and proof of due

diligence. Finally, it assures the consumer that their medication has been verified as authentic, fortifying their trust in the industry.

One of the most important value propositions of this technology and the XT250 is that it is primarily designed to be used in a warehouse or non-laboratory setting allowing for use within the actual supply chain process by non-technical labor. This eliminates added costs and delays associated with traditional testing methods.

Implementing this type of technology safeguards the public's well being by thwarting counterfeiting and in authenticating the clinical viability pharmaceuticals that are globally outsourced.

How Do You Protect Yourself as a Consumer?

The best way to avoid counterfeit drugs is to purchase prescription medicines at a well respected chain or local pharmacy that is staffed by well established, experienced pharmacists and pharmacy technicians.

A consumer should only use online pharmacies that are associated with reputable national chains and/or those that are certified by the National Association of Boards of Pharmacy (NABP). The NABP helps ensure the quality and safety of every online prescription. The NABP's Verified Internet Pharmacy Practice Sites (VIPPS) program certifies pharmacies that the online pharmacy meets state licensing and inspection requirements.

Consumers should never buy medications from online pharmacies that aren't licensed in their home country or with pharmacies that offer to write prescriptions or sell medications without prescriptions.

Consumers should always, avoid drugs in foreign language packaging. Recent evidence suggests that up to 50% of products shipped from internet pharmacies located in foreign countries are counterfeit, fraudulent or adulterated.

It is also critical that consumers examine all of their prescription medications and its packaging. If there is anything unusual, as it relates to its packaging, look, taste or if they have a different reaction to their medicine they should contact the pharmacy that dispensed the medication and/or local authorities as soon as possible.

Ultimately consumers should always heed the advice of the age old saying, if the price of a product seems too good to be true; it most likely is¹³.

Conclusions

There are sophisticated networks, organizations and individuals that are taking advantage of the technology, lax regulations and the high cost of pharmaceuticals worldwide to produce counterfeit medications that pose a significant health risk to millions of people worldwide.

Many factors play into this criminal phenomenon but ultimately the high reward versus risk faced by counterfeiters have made this a global menace to healthcare.

The proliferation of the outsourcing of pharmaceutical manufacturing to non-industrialized nations also poses a significant threat to the safety and security of the supply chain as a whole. With manufacturing globally outsourced. It is imperative that the raw materials, finished products and distribution of these medicines are monitored as a public safety initiative worldwide.

Current methods to fight this menace are limited in their ability to truly authenticate the actual contents of the medicine inside the bottles within the pharmaceutical supply chain. Once a fraudulent medication has defeated these measures the only certain way that the fraudulent material will be detected is by using a technology that actually verifies and authenticates the product itself.

The inclusion of a technology like XStream Systems' XT250 into the pharmaceutical supply chain that actually penetrates inside the sealed container and verifies the molecular fingerprint of the medication seems to be the most effective way to protect against this very dangerous and serious threat to all consumers globally.

¹ (Relative to sales) Source: Pharmaceutical Anti-Counterfeiting Strategies, Business Insights Ltd., 2005.

² FDA. Combating Counterfeit Drugs: A Report of the Food and Drug Administration Annual Update. May 18, 2005.

³ "Counterfeit Medicines, A Clear and Present Danger: One Company's Experience Around the World." Pfizer Inc.

⁴ Nelson, Marissa. "Bitter Pill." *The Hamilton Spectator*. October 7, 2005.

⁵ "Safeguarding the integrity of the medicines supply chain in Europe." Pfizer Inc., February 2006.

⁶ <http://www.pfizer.com/files/products/LipitorUSRecall.pdf>. Pfizer Inc. December 2007.

⁷ http://www.pfizer.com/products/counterfeit_and_importation/counterfeit_qa.jsp. Pfizer Inc., December 2007.

⁸ Ibid

⁹ "Pharmacy Fakes" *Self Magazine*. March 2003.

¹⁰ http://abbott.com/global/url/content/en_US/40.30.15:15/general_content/General_Content_00323.htm, December 2007.

¹¹ Ibid

¹² http://www.xstreamsystems.net/news.html#November_30th, December 2007.

¹³ "Counterfeit Medicines, A Clear and Present Danger: One Company's Experience Around the World." Pfizer Inc.

Additional sources

Bayer Technology Services Brochure; Protexxion, The new dimension in anti-counterfeiting, 2007