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Counterfeit medicines: Threat to patient health and safety

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Counterfeit medicines are, first and foremost, a matter of patient health and safety. Counterfeit medicines pose a threat to patients because of the conditions under which they are manufactured, in unlicensed, unregulated, uninspected and often unsanitary sites.

The "medicines" themselves pose a threat to patient health and safety because their contents are not regulated and they may not contain the correct active pharmaceutical ingredient (API) to deliver the therapeutic benefit for which they were prescribed, or even ingredients that are themselves harmful such as heavy metals or pesticides.

To mitigate that threat, and ensure that their patients receive safe and effective medicines, pharmaceutical companies have incorporated anti-counterfeiting technologies into their packaging and implemented campaigns to detect and disrupt those counterfeiters who place greed above patient safety.

Although counterfeiting presents a global threat from which no company, therapeutic area, region or country is immune; gauging the true scope of the problem has remained a challenge. There are hopeful signs, however, as we have seen improved reporting and greater transparency by enforcement and regulatory agencies.

Keywords: Counterfeit, spurious, falsified, fake medicines, pharmaceutical crime, legitimate supply chain, patient health

1. What's in a name?

They may be known by many names – counterfeit, spurious, falsified, fake – but the common element to medicines, whether branded or generic, that have been deliberately and fraudulently produced and/or mislabeled so as to appear as a genuine product, is that they pose a threat to patient health and safety. For purposes of this article, we use the term "counterfeit" to refer to those products.[1]

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[1]In an attempt to reach consensus among its member states, in 2012 the WHO adopted the category of SSFFC (substandard, spurious, falsely labelled, falsified or counterfeit). While all medicines within that category are inherently unsafe, we think it is important to distinguish between counterfeit medicines, as defined above, and those of poor quality (substandard,) if we are to understand the criminal nature and extent of the counterfeiting phenomenon.

Pharmaceutical counterfeiting is a crime of trick and deceit. Counterfeit medicines, and the threat they pose to patient health and safety, are a growing problem from which no country, therapeutic category, or pharmaceutical company is immune.

2. Serious threat to patient health and safety and the healthcare system

Counterfeit medicines are, first and foremost, a matter of patient health and safety. Counterfeit medicines pose a threat to patients because of the conditions under which they are manufactured, in unlicensed, unregulated, uninspected and often unsanitary sites. We have seen "life-saving" medicines being manufactured in rodent and pest infested laboratories, with mold growing on the walls, peeling paint and dirty equipment.

The "medicines" themselves pose a threat to patient health and safety because their contents are not regulated and they may contain none of the active pharmaceutical ingredient (API) to deliver the therapeutic benefit for which they were prescribed, the incorrect dosage or the wrong API. Patients are also placed at risk by the ingredients that counterfeiters use to produce their products: pesticides (boric acid); rat poison; leaded highway paint; commercial grade paint; cartridge ink; crayons; chalk, floor polish; brick dust; plaster and wallboard. There have also been reports of heavy metals, arsenic and even anti-freeze.

Counterfeiters, motivated by profit, are more concerned with the appearance of their products than the effect they might have on a patient. Due to advances in modern technology, the copies they are able to produce have become virtually indistinguishable from authentic tablets, and many can only be identified through detailed laboratory analysis.

Patients who unknowingly receive and ingest counterfeit medicines are denied the therapeutic benefit of the medicines prescribed by their physicians. When counterfeit medicines do not deliver the anticipated therapeutic benefit, not only are patients' lives placed at risk, but they lose "confidence in medicines, healthcare providers and health systems" [1].

3. Industry efforts to mitigate the risk

It is precisely because of the threat that counterfeit medicines pose to patients that pharmaceutical companies have implemented campaigns to detect, disrupt and deter major manufacturers and distributors of counterfeit medicines. In addition to our investigative efforts, we must:

- Incorporate anti-counterfeiting technologies into our products and packaging, making it more difficult for counterfeiters to copy our medicines, and easier for patients and healthcare providers to distinguish counterfeit from authentic medicines.

- Advocate for stronger penalties for individuals and/or organizations involved in the manufacture, distribution and sale of counterfeit medicines.
- Educate the public, healthcare professionals and policy-makers to the prevalence and dangers of counterfeit medicines.
- Forge partnerships with enforcement and regulatory authorities in which information on suspicious medicines is shared.
- Educate patients and healthcare professionals to the need to report suspicious medicines to the manufacturer.

To successfully stem the flow of counterfeit medicines, we must attack both supply and demand.

On the supply side, pharma companies should actively monitor their supply chains, including the pharmacies that dispense their medicines, to detect the presence of counterfeits. Concerns about the presence of counterfeit medicines should be pro-actively and thoroughly investigated, and the results referred to enforcement authorities for their action. Forging strong partnerships with enforcement authorities in each region and country is the keystone to a successful anti-counterfeiting program. Training those authorities not only raises their awareness to the counterfeiting problem, but also facilitates their ability to distinguish between counterfeit and authentic medicines.

On the demand side, we must continue efforts to educate patients by raising awareness to the threat that counterfeit medicines pose to their health and safety, supporting efforts by law enforcement and regulatory authorities, as well as NGOs and trade associations to raise awareness among patients to the threat that counterfeit medicines do pose to their health and safety.

3.1. Pfizer's anti-counterfeiting program

While the programs may vary from company to company, they have many common elements.

At Pfizer, for example, we conduct and manage pro-active investigations and refer the cases we develop to enforcement authorities for their action. Those investigations are initiated in response to "leads" from a variety of sources, including complaints from patients and healthcare professionals, observations by members of our sales force, information concerning changes in sales volume and patterns, from confidential informants, and from enforcement authorities. "Market surveys", in which we make test purchases from pharmacies, are also undertaken as part of our program to monitor the integrity of our medicines sold in the legitimate supply chain.

Because we work our way up the hierarchy of the criminal enterprises we investigate, our referrals to authorities often identify the manufacturer or major distributor. Enforcement actions taken based on our referrals have a domino effect, protecting patients in the global market.

The success of our program can be attributed to our talent – colleagues placed strategically around the world with extensive law enforcement experience who know

how to initiate and develop cases – and the effective partnerships we have forged with enforcement authorities around the world.

Through these efforts, authorities around the world have taken significant enforcement actions, including the disruption of manufacturing and packaging operations, and counterfeiting networks distributing counterfeits to hospitals, pharmacies and other retail outlets

Pfizer's efforts to ensure the integrity of its medicines, is not limited to its robust anti-counterfeiting program, but extends to the incorporation of various security features into its packaging to make it more difficult for counterfeiters to make convincing copies of our medicines. These features vary from product to product and may include holograms, special paper and inks and tamper-resistant labels and closures to alert patients that a package has previously been opened.

3.2. Public-private collaboration mitigates threat to patient health and safety

To mitigate the threat that counterfeit medicines pose to patients, Pfizer initiates pro-active investigations, the results of which are then referred to authorities for their action. These case studies are examples of the results that such collaborative efforts yield in our war against counterfeit medicines.

3.2.1. Criminal enterprise targeting gulf states and the united states disrupted

Based on referrals by Pfizer Global Security (GS), enforcement authorities in China and the United Arab Emirates (UAE) disrupted a major network, in the southern provinces of China, responsible for distributing large quantities of counterfeit medicines, manufactured in China, throughout the Gulf States and the United States (US).

Strands of this network were first discovered by GS in 2005. Through a well-coordinated effort by our three regional teams and GS Intelligence – including careful analysis of lab results, physical surveillance and shipping methodologies – we linked together what appeared on the surface to be separate investigations in China, Jordan, Romania, the UAE and the US.

The first blow to the criminal network was struck by authorities in the UAE in May 2010. Based on a referral from Global Security, authorities raided a hotel basement in which the counterfeits were stored and arrested an active police officer in Sharjah, described as the kingpin's right hand man. Although only counterfeit Viagra® was seized in those raids, our investigation linked the network to sales of counterfeit Dostinex® and Lipitor®, and the manufacture of Viagra®, Lipitor®, Xanax® and Aricept® in China.

Shortly after those raids, Global Security met with Chinese authorities, who accepted the case for criminal investigation. In May 2011, as a result of that referral, more than 300 Chinese law enforcement officers, from both the Public Service Bureau (PSB) and State Food and Drug Administration (SFDA), initiated enforcement

actions that dismantled one of the most prolific counterfeiting organizations ever uncovered in China. In two separate, but related enforcement operations on May 19 and May 21, PSB and SFDA raided two manufacturing sites and 26 storage facilities from which was seized as many as 200 million doses of counterfeit and unapproved generic medicines from at least five pharma companies. Also seized were large quantities of API, which may be beyond the capability of the authorities to accurately weigh. The seizures included equipment – 54 machines and 1,230 molds, tools and dies – with which to manufacture the counterfeits. Chinese authorities made 26 arrests, but a key member of the criminal enterprise, not present during the raids, evaded capture.

After the 2011 raids, we continued to monitor the target's travels and activities. We linked the target to the 2013 seizure of 1.2 million counterfeit Viagra® and Cialis® tablets in Saudi Arabia. When we located the target in Dubai, we launched an investigation that confirmed he was still distributing counterfeit Viagra®, and identified key locations of his ongoing operation. That information was shared with authorities, leading to his arrest, raids on three locations, and the seizure of 588,000 counterfeit Viagra® tablets (July 2014).

3.2.2. Criminal enterprise toppled, pharmacies and national lab shuttered

Rafael Brito, National Prosecutor for health-related matters, called it the biggest case ever developed in the Dominican Republic.

Simultaneous raids by Dominican authorities on 11 sites – including four pharmacies, where enforcement efforts were not a moment too soon. The counterfeit medicines had not only flooded the Dominican market, but posed a serious threat to US patients, as the network sought to introduce them into what they perceived as a very lucrative North American market. To evade detection by Customs and Border Protection Inspectors, they packaged counterfeit versions of Viagra® disguised as bottles of multi-vitamins. Among the premises raided was the clandestine laboratory where the counterfeits were packaged.

The raids, which culminated an investigation initiated by GS in early 2014 into the presence of counterfeit Ponstan® in the Dominican market, were made possible by the cooperation of the HSI (Homeland Security Investigations) Attaché, who provided access to the vetted National Police Unit.

3.2.3. Polish police pursue fleeing purveyor of counterfeit Viagra®

The arrest of a resident of Gorzow Wielkopolski culminated an investigation into a criminal network, based in Warsaw, for the distribution of counterfeit Viagra®. An investigator retained by Global Security first made contact in late 2015 and placed a small order, advising he wished to sample the quality of his product prior to placing a much larger order. The parcel arrived in early January, permitting GS to use payment collection from the Post Office to identify the seller's true name and bank account.

The investigator then placed an order for 1,200 Viagra®, which the suspect agreed to deliver in person on February 6. Shortly before the scheduled meeting, however,

he called the investigator and cancelled the meeting, stating he was too nervous for a face-to-face meeting as he had previously been convicted of and imprisoned for drug dealing.

Rather than meeting in person, he advised the investigator that he would mail the order in several packages between February 8 and 9. Police, who had been alerted to the scheduled face-to-face meeting were advised and established surveillance at the Post Office from which he had sent the first package. On February 9, police observed the suspect nearing the front door of the post office. They approached and identified themselves, but he evaded their grasp. Police gave chase and, after a brief struggle, apprehended him. The bag, which he had discarded during his escape attempt, was recovered. Inside the bag were three envelopes, one of which contained 200 Viagra® tablets intended for the investigator.

According to police, the suspect has been involved in the sale of counterfeit erectile dysfunction products for a long time. During the last four months alone, he had mailed several thousand counterfeit Viagra® tablets to customers. Nor was the sale of counterfeit medicines his only involvement in the trafficking of illegal substances. Police confirmed that he was previously convicted of illegal sale of various illegal drugs. A post-arrest search of his apartment revealed that he was illegally cultivating marijuana.

3.3. The online threat

Despite increased reports of breaches in legitimate supply chains, the Internet and the many professional looking websites that promise safe, approved, branded medicines from countries such as Canada or the United Kingdom (UK) also pose a major threat to patients.

Unsuspecting patients are easily lured by the ease with which they can order their medicines online, often without the need to consult a doctor or provide a valid prescription. While buying online, patients face a complete lack of transparency as to the true location of the "pharmacy" and the source and authenticity of the medicines it dispenses. Based on the "virtual" nature of the online sales of counterfeit medicines, it is difficult to determine the true physical location of any particular site. Many sites do not list a physical address; those that do frequently provide a false address, selecting a "trusted" market such as Canada.

Patients are at the greatest risk when they purchase their medicines from online pharmacies (OLPs) that are not licensed by, or registered with, their local regulatory authorities, many of which disguise their true location and mislead patients as to the source of the medicines they dispense.

It is possible for US patients to buy their medicines safely online through pharmacies that have been accredited by the National Association of Boards of Pharmacies (NABP) as complying with licensing and inspection requirements. Those pharmacies, designated as verified internet pharmacy practice sites (VIPPS), represent only a small percentage of online pharmacies. In a report issued in April 2016, the NABP found that, of the more than 10,000 websites it analyzed:

- 6,576 (61.5%) had no location posted on website
- 9,453 (88.5%) did not require a valid prescription
- 5,370 (50.3%) offered foreign or non-FDA approved medicines
- 1,318 (12.3%) dispensed controlled substances

9,605 (89.9%) appear to have affiliations with rogue networks of Internet drug outlets [2]. In addition to OLPs, counterfeit medicines are also readily available through Business to Business (B2B) platforms, social networking sitesand bulletin boards.

Social networking sites are an attractive marketing platform, permitting distributors to market their products directly to consumers, providing anonymity and global reach to potentially billions of users with limited monitoring of user activity. For example, although the sale of medicine via Facebook is a violation of its terms and conditions, advertisements increasingly involve illicit products, including illegal, counterfeit or unauthorized medicines for the treatment of cancer, cardiovascular disease, panic and anxiety disorders, erectile dysfunction, and pain and inflammation. Intentional misspellings of product names or keywords, such as pharmacist or supplier, and the posting of images rather than text make it more difficult to search and locate sellers.

Bulletin boards also expose unsuspecting patients to the threat of counterfeit medicines. In many instances those bulletin boards who offer small quantities direct to patients also serve as drop shippers, fulfilling orders placed with OLPs or B2Bs. And in developing markets such as Latin America and Southeast Asia, sellers use popular microblogging sites to facilitate in-person transactions. Unlike the profiles found on some social networking sites, these microblogs appear to offer fewer choices and only target a specific therapeutic area.

3.4. Mitigating the online threat

To protect unsuspecting patients from the risk of obtaining counterfeit medicines online, many pharma companies have internet monitoring programs that include OLPs, social media sites and bulletin boards. These programs:

- Monitor OLPs and social media platforms to identify advertisements offering suspect medicines for sale
- Confirm, through test purchase and testing, whether counterfeits are being dispensed
- Identify the sellers
- Refer to law enforcement

Illegal OLPs that dispense counterfeit and generic medicines use call centers to contact patients on their behalf. While a call center may be located in any country, those selling medicines frequently misrepresent to patients that they are based in Canada, creating a false sense of confidence that the medicines they order, although cheaper than available from their brick and mortar pharmacies, are safe and effective. Disrupting such call centers is an effective way to disrupt the flow of counterfeit medicines to unsuspecting patients.

4. A global threat

Many patients, particularly those in more developed countries with strong regulatory systems, would like to view counterfeiting as a myth, or a problem limited to less developed nations. Unfortunately, this is not the case. Counterfeit medicines are a problem from which no country, pharmaceutical company or therapeutic area is immune.

As noted by the WHO, "they can be found in illegal street markets, via unregulated websites through to pharmacies, clinics and hospitals" [3].

We have seen the spread of counterfeit medicines from developing countries with poor regulatory systems to countries such as Canada, the United States and the UK.

Counterfeit medicines are frequently smuggled into a country by those who either conceal them in electronic equipment, stuffed animals, or in false compartments constructed in shipping containers or even gas tanks of their vehicles.

We have noted that those involved in the distribution of counterfeits use complex transport routes in order to evade customs controls by disguising the true source of their product. In many instances, attempts are made to create an aura of legitimacy by passing shipments through countries such as the UK, Belgium, France, Canada and the US. Frequently, shipments are routed through Free Trade Zones, such as those found in the Middle East and Latin America, where they receive little if any scrutiny.

4.1. Avastin® case: A clear example of the circulatory routing of counterfeit medicines

On February 12, 2012, the US Food and Drug administration (FDA) issued a public warning that counterfeit versions of the injectable cancer medication Avastin®, had been found in the US drug supply chain. On analysis, the fake contained cornstarch, acetone and other chemicals but no API originally detected in the clinical setting. Since that time, a second warning was issued on counterfeits that appear to be diverted, namely Turkish versions of Avastin®, Altuzan®. More than 130 doctors in 28 US states have been sent FDA warning letters concerning their dealings with the foreign supplier that was the source of the counterfeit Avastin®. Counterfeit Avastin® traveled to the US via Turkey, Switzerland, Denmark, the UK before reaching the US where it was purchased from a little-known drug wholesaler, Montana Healthcare Solution connected to online pharmacy Canadadrugs.com.

4.2. The scope of the threat

The exact size of the counterfeiting problem is not known. Due to the criminal nature of their activities, counterfeiters seek to avoid detection, concealing the extent of the crimes committed, which makes data collection and reporting extremely difficult. One measure we have – the number of seizures reported by enforcement authorities around the world – represents only the tip of the iceberg.

In an article published in April 2015, in the American Journal of Tropical Medicines and Hygiene, authors assessed "counterfeit reports involving the legitimate supply chain using 2009–2011 data from the Pharmaceutical Security Institute Counterfeit Incident System (PSI CIS) database that uses both open and nonpublic data sources. Of the 1,510 identified CIS reports involving counterfeits, 27.6% reported China as the source country of the incident/detection. Further, 51.3% of the reports were counterfeit but the specific counterfeit subcategory was not known or verifiable. The most prevalent therapeutic category was anti-infectives (21.1%) with most reports originating from health-related government agencies. Geographically, Asian and Latin American regions and, economically, middle-income markets were most represented. A total of 127 (64.8%) of a total of 196 countries had no legitimate supply chain CIS counterfeit reports. Improvements in surveillance, including detection of security breaches, data collection, analysis, and dissemination are urgently needed to address public health needs to combat the global counterfeit medicines trade" [4]. Key findings of this review are depicted below.

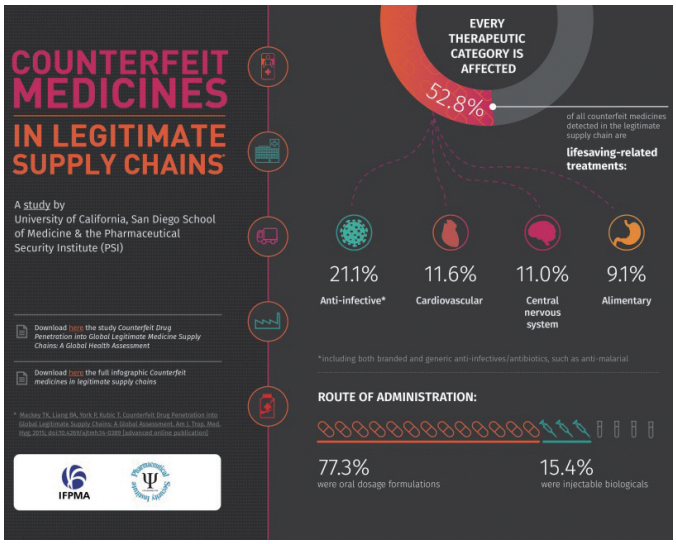
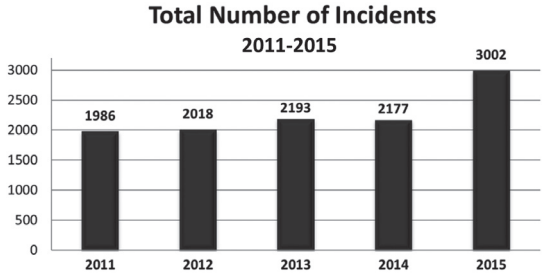


Fig. 1. Counterfeit medicines in legitimate supply chain.

5. The pharmaceutical security institute incident trends

Despite those limitations, the industry has continued to strive for improved data regarding counterfeit medicines. The Pharmaceutical Security Institute (PSI)[2] is a

[2]The Pharmaceutical Security Institute, founded in 2002, is a not-for-profit, membership organization dedicated to: Protecting the Public Health; Sharing Information on the Counterfeiting of Pharmaceuticals; and Initiating Enforcement Actions through the Appropriate Authorities. See www.psi-inc.org.



non-profit organization composed of the security departments of thirty-three major pharmaceutical companies.[3] These companies share information on illegal manufacture and trade in pharmaceuticals. Because criminals who make and traffic illegal drugs target a wide range of companies' products, cooperation and data sharing among companies adds depth to their collective understanding of the problem [5].

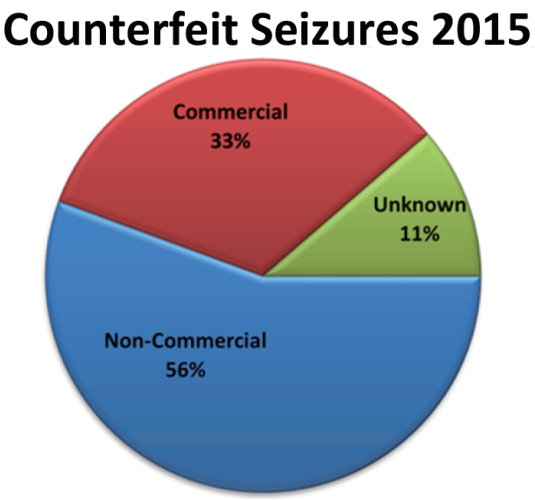
While most of its efforts are in support of law enforcement and drug regulators, the PSI updates the public section of its website based on its annual report on the global pharmaceutical crime situation. The institute maintains a secure database, the Counterfeit Incident System (CIS) to which members report cases of fraudulent manufacture and mislabel of drugs, as well as cases of fraudulent packaging. The database is organized into incidents, discrete event[s] triggered by the discovery of counterfeit, illegally diverted or stolen pharmaceuticals. A unique tracking number links every incident to a distinct date, time, place, and product. Incidents can vary in size: sometimes small amounts of a single product are affected, other times large quantities of many products. Some incidents last for years, others are resolved in one year [5]. In the May 2016 report, *Illicit Trade – Converging Criminal Networks*, the OECD found that the PSI data is "perhaps the best counterfeiting data in the world".

PSI defines a counterfeit incident as "the discovery of a medicine (whether branded or generic), which was deliberately and fraudulently produced and/or mislabeled with respect to identity and/or source to make it appear to be a genuine product." [6] For reporting purposes, an authentic medicine that has been repackaged in counterfeit packaging is deemed a counterfeit incident [6].

This section and the ensuing materials are derived from PSI's recently updated website. PSI has collected data on counterfeiting, illegal diversion and theft incidents for the past fourteen years. The yearly totals for the last five years are shown in the below bar chart.

The Institute documented 3,002 incidents of pharmaceutical crime during 2015. This represented a significant increase from 2014 and an all-time annual high. From 2011 to 2015, total incidents increased by fifty-one percent (+51%).

[3]Abbott, Abbvie, Actavis, Amgen, Astellas, Astra Zeneca, Biogen, Boehringer Ingelheim, BMS, Chugai Pharmaceutical, Celgene, Eisai, Eli Lilly, Genentech, Gilead, GSK, Lundbeck, Roche, Horizon Pharma, Johnson and Johnson, Merck & Co, Merck KGaA, Mylan, Novartis, Novo Nordisk, Otsuka Pharmaceutical, Pfizer, Purdue Pharma, Sanofi, Servier, Sumitomo Dainippon, Takeda, Teva.



To better understand the magnitude of the counterfeiting incidents in 2015, PSI continued to track the quantity of drugs seized in each law enforcement action. Any incident which involved the seizure of more than 1,000 dosage units was classified as a commercial incident. Those incidents involving less than 1,000 dosage units were classified as non-commercial. In 2015 there were 971 counterfeiting incidents which involved either customs seizures or police/health inspector raids. This represents a thirty-four percent (34%) increase over the prior year.

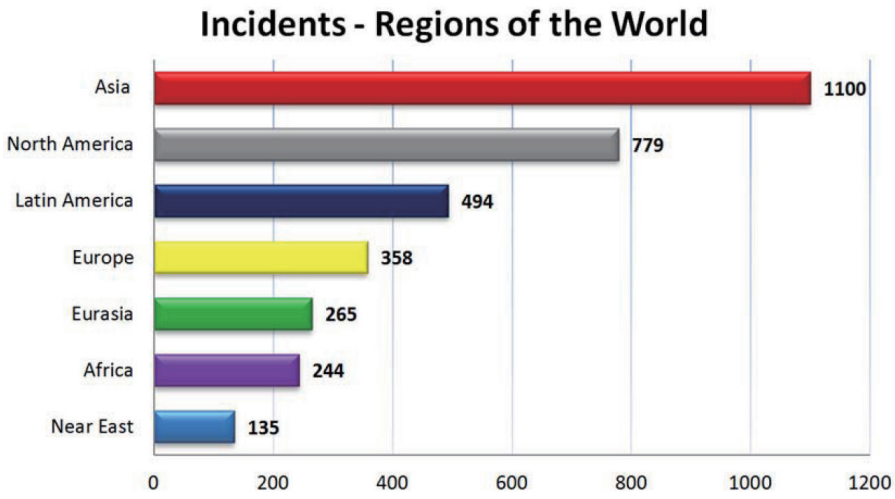
As the adjacent pie-chart shows, thirty-three percent (33%) of counterfeit medicines seizures made by law enforcement were of "commercial" size. Also, the number of non-commercial seizures increased significantly in 2015. The seizure of one thousand dosage units or less represented fifty-six percent (56%) of the total.

5.1. Geographic distribution

In 2015, incident data was analyzed with respect to seven regions of the world. As mentioned above, the PSI recorded a total of 3,002 pharmaceutical crime incidents. Every region experienced a pharmaceutical crime incident. In total, there were 128 countries found to have been impacted by pharmaceutical crime. A country is viewed as being impacted if the suspect medicines originated in that country, transited that country or were found in that country.

PSI documented a thirty-eight percent increase (+38%) in the worldwide incident total compared to the previous year. Incidents impacting the Asia Pacific region surpassed one thousand incidents annually for the first time in 2015. Also, incidents in North America increased over 100% from the previous year.

In the below chart, the regions are ranked in order from those experiencing the highest number of incidents to those with the lowest number of incidents.



Totals exceed 3,002 incidents because a region is included if it is the "origin, point of seizure or transit, or destination" of illegal pharmaceuticals.

It is important to note that the regions that are more frequently linked to incidents are not necessarily those with weak enforcement and inspection programs. Rather, countries in these regions are effectively identifying pharmaceutical crime through law enforcement activity and inspections by drug regulatory agencies. Many countries in regions with high incident totals are quite transparent in government operations and their activities are known to the media and public.

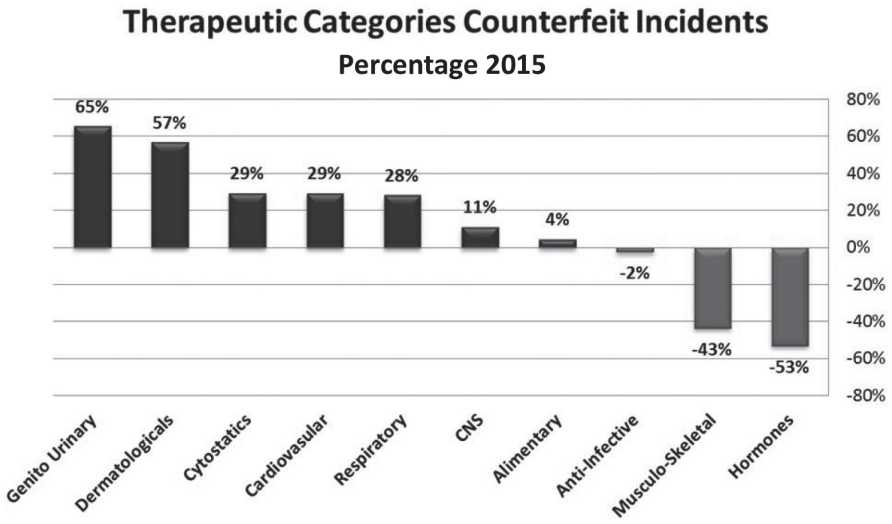
Those regions with seemingly low incident totals are not necessarily unaffected by or at a lower risk of pharmaceutical crime. Due to competing law enforcement priorities, lack of funding or inadequate regulatory structures, in certain regions of the world, counterfeit medicines often go undetected. It is important to recognize these facts, since they complicate region to region comparisons.

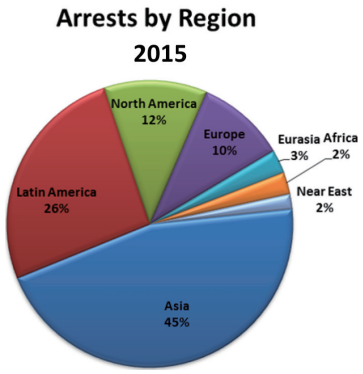
5.2. Therapeutic categories

The 3,002 incidents occurring in 2015 involved 1,095 different pharmaceutical products. The number of products found in a single incident ranged from one drug to thirty-seven different drugs. Once again, pharmaceuticals in every therapeutic category were copied by criminal organizations.

CIS data revealed that medicines in the genito-urinary, anti-infectives and central nervous system (CNS) therapeutic categories contained the largest number of counterfeit incidents. These three categories were seen as having drugs which were the most frequently targeted by individuals engaged in pharmaceutical counterfeiting.

While the ranking of the top therapeutic categories were relatively unchanged, the Institute has noted seven therapeutic categories that have had a percentage increase on a year-to-year basis.





Specifically, the genito-urinary therapeutic category led with the largest percentage increase at sixty-five percent (+65%). Categories with percentage increases also included dermatologicals (+57%), cytostatics (+29%), cardiovascular (+29%), respiratory (+28%), CNS (+11%), and alimentary (+4%).

5.3. Enforcement efforts – Arrests

Arrests are often viewed as a key measure of law enforcement's effectiveness in addressing crime. However, law enforcement practices with regard to arrests can differ significantly from country to country. In addition to identifying law enforcement's involvement in a particular incident, PSI has been collecting information concerning arrests as an indicator of governments' commitment to address pharmaceutical crime.

Through member and open source reports, PSI documented the arrest of 1,375 persons involved in counterfeiting, diversion or theft of pharmaceutical drugs worldwide during 2015. This represented a decrease of eight percent (−8%) from the global arrests in 2014.

Not totally unexpected, the arrests in 2015 tracked fairly well with the incident data. So, the Asia region, with the highest number of incidents, also had the largest percentage of arrests.

6. Conclusion: What more can we do?

We have seen progress in the fight against counterfeit medicines, but much more needs to be done. Pharmaceutical counterfeiting is a high profit criminal activity that carries a low risk to the criminal which is why it has attracted drug traffickers, firearm smugglers and even terrorists. Those who counterfeit medicines seem confident that even if they get caught, they will get a mere "slap on the wrist".

We must create a more favorable **enforcement environment through several steps**:

- Encourage policy-makers to recognize pharmaceutical counterfeiting as a serious crime with penalties commensurate with the threat that such conduct poses to patients around the world as well as the potential profits to be realized.
- Encourage authorities to make more resources available to enforce existing laws against pharmaceutical counterfeiting.
- Address the serious threat posed by rogue online pharmacies, seeking expedited procedures to shut them down, working in cooperation with internet service providers to block the flow of traffic to those sites and with credit card companies to prevent the processing of payments.
- Encourage collaboration within and between countries.
- Engage all key stakeholders in the fight against counterfeit medicines.

We must **educate and empower** patients to avoid counterfeit medicines in several ways:

- Raise awareness of the threat that counterfeit medicines pose.
- Buy from reliable sources.
- Notify healthcare professionals if they notice any difference in the appearance of the packaging, or the appearance and taste of, or responses or reactions to, their medicines.

Effective communications remain central to dispelling the myths surrounding counterfeit medicines, such as "counterfeiters only target lifestyle products", or, "if a counterfeit contains some API it must be doing the patient some good". As this article illustrates, it is impossible to know which medicines and patients will be targeted by counterfeiters. All counterfeit medicines can pose a risk, not only for what ingredients they do contain, but for what they don't contain, and how they have been manufactured.

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