

GROWING COUNTERFEIT IN MEDICINE WORLDWIDE AND ITS IMPACT ON HEALTH AND WORLD ECONOMY

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ABSTRACT

In today's era, the counterfeiting of currency and medicine are common problems that plague governments and manufacturers worldwide. However, of all the different counterfeit and falsified goods produced, none are more potentially damaging than those affecting public health and safety, such as the production, distribution, and consumption of counterfeit and falsified medicines. According to the World Health Organization (WHO), a significant fraction of the world's drug supply is counterfeit and falsified. Estimates of counterfeit drugs range from 10 to 15 % for the world drug supply, to more than 25% in developing countries.

Counterfeit drugs generated an estimated \$75 billion in revenue in 2010, according to the National Association of Boards of Pharmacy. Unlike fake sunglasses, fake drugs can kill their purchasers. Each year upwards of 100,000 people around the world may die from substandard and counterfeit medications, according to a recent estimate by Amir Attaran of the University of Ottawa and Roger Bate of the American Enterprise Institute. To date, governments of most of countries have struggled to safeguard the distribution of legitimate drugs and crack down on the fakes.

Lifesaving drugs are also not exempted from the trade in counterfeit medicines. The World Health Organization (WHO) is working with Interpol to dislodge the criminal networks raking in billions of dollars from this cynical trade.

Keyword: Counterfeit Medicine, Fake Medicine, Spurious Remedies, Falsified Medicine
Life Saving Drugs

INTRODUCTION

A counterfeit medication or a counterfeit drug is a medication or pharmaceutical product which is produced and sold with the intent to deceptively represent its origin, authenticity or effectiveness. A counterfeit drug may contain inappropriate quantities of active ingredients, or none, may be improperly processed within the body (e.g., absorption by the body), may contain ingredients that are not on the label (which may or may not be harmful), or may be supplied with inaccurate or fake packaging and labelling. Medicines which are deliberately mislabelled to deceive consumers—including mislabelled but otherwise genuine generic drugs—are counterfeit. Counterfeit drugs are related to Pharma fraud. Drug manufacturers

and distributors are increasingly investing in countermeasures, such as traceability and authentication technologies, to try to minimise the impact of counterfeit drugs.

Counterfeiting is difficult to detect, investigate and quantify. The threat from the rising number of counterfeited or falsified medicines is aggravated by two factors. Traditionally, the most common types of counterfeit drugs were those described as “lifestyle drugs” such as those used to treat erectile dysfunction or baldness. However, recently there has been an increase in the counterfeiting of “lifesaving” drugs meant to prevent or treat asthma, malaria, cancer, HIV/AIDS, tuberculosis, blood pressure and heart conditions, diabetes, and severe diarrhoea (Lyebecker, 2003).

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Internet sales

Use of internet is another threat & widely used tool to in business of counterfeit medicine. “Criminal gangs are increasingly using the internet to market life-threatening counterfeit medicines and some have even turned up in legitimate outlets such as pharmacies, according to a review led by Dr Graham Jackson, editor of *IJCP, the International Journal of Clinical Practice*

In industrialized countries and to some extent in poorer countries, Internet-based sales of pharmaceuticals are a major source of counterfeit medicines, threatening those who seek cheaper, stigmatized or unauthorized treatments. Some Internet pharmacies are completely legal operations, set up to offer clients convenience and savings. They require patient prescriptions and deliver medications from government licensed facilities. Illegal Internet pharmacies sell medications without prescriptions and use unapproved or counterfeit products. In some cases, Internet pharmacies are operated internationally and sell products that have an unknown or vague origin.

Counterfeit medicine threatens lives in Africa

Malaria is one of the diseases affected by unscrupulous traders in fake and substandard drugs

International health experts are warning of a mounting health crisis in parts of Africa because of an influx of counterfeit medicine from Asia that is playing havoc with the treatment of diseases such as malaria. Porous borders in Africa coupled with indifferent oversight in China are combining to turn the continent and its pressing health problems into a free-for-all for maverick manufacturers, some of whom are producing pills with no active ingredients at all.

Precise data is hard to track down because of the informal nature of African health systems. But several recent studies warn that as many as one-third of malaria drugs in Uganda and Tanzania are fake or substandard, with most believed to originate in China or India.

David Nahomya, chief drug inspector for the Ugandan national drug authority, said: "What we are told is this, if someone wants to counterfeit a drug, they just take the package to

China and they can make it in thousands. You have seen how they make it there. They can copy anything."

Counterfeit medicine & cancer

Counterfeiters are targeting cancer drugs because of the big profits to be made. While pills such as Viagra, long a favourite of the counterfeit trade, cost about \$15 to \$20 a tablet, a 400-milligram vial of the injectable drug Avastin costs about \$2,400.

Fake versions of costly cancer medicines have appeared in increasing numbers in Asia and the Middle East in recent years and occasionally in Europe and the U.S. In 2011, cancer drugs ranked eighth among the top 10 types of drugs targeted by counterfeiters, according to the Pharmaceutical Security Institute, an industry-funded group; five years ago, they weren't on the list at all.

The fake Avastin found in the U.S. is just a small part of the global trafficking in counterfeit cancer drugs. A police raid in the Chinese city of Guangzhou last year netted 23 million tablets of a variety of counterfeit drugs, including bogus copies of the generic breast-cancer drug tamoxifen, according to Chinese law-enforcement documents.

In March 2010, customs officers in Malta seized a cargo of counterfeit Gleevec, Novartis AG's NOVN.VX₁+2.06% leukaemia drug, according to Anthony Busuttill, director of enforcement for Maltese customs. He declined to comment on where the fakes came from or where they were being shipped.

The most serious case yet to hit Europe involved fakes of AstraZeneca AZN.LN₁+0.48% PLC's prostate-cancer drug Casodex, which reached U.K. pharmacies in 2007. The counterfeits were made in China, and sent through Hong Kong, Singapore and Belgium before reaching the U.K., where a little-known wholesaler called Consolidated Medical Supplies repackaged the tablets in French packaging and sold them to unsuspecting wholesalers and pharmacies, according to the U.K.'s Medicines and Healthcare products Regulatory Agency, or MHRA.

SIGNIFICANCE OF STUDY

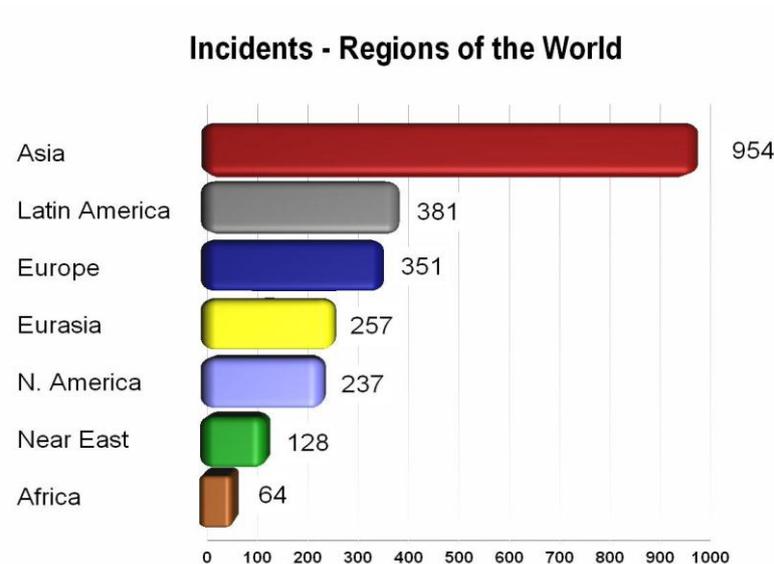
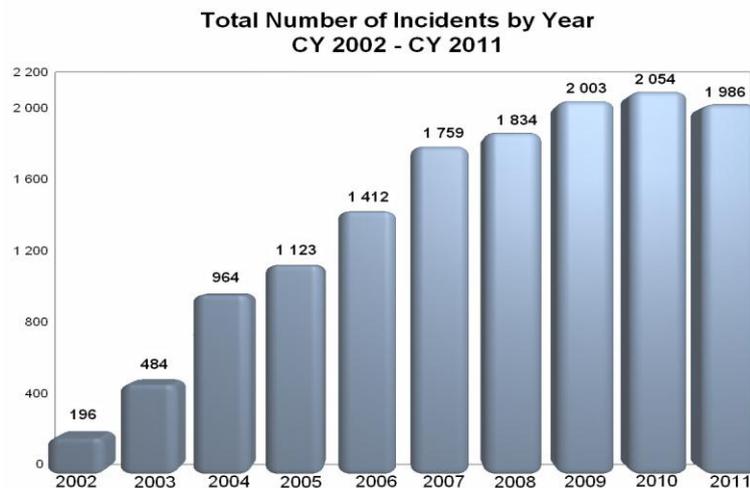
The deadly implications of counterfeit drugs are well understood to be a central challenge to the integrity of public health systems around the globe, as well as a direct threat to our individual health and welfare. What is less understood is that the profits from this sinister crime are increasingly being co-opted by an array of organized criminal groups and terrorist entities as a means by which to fund their nefarious operations around the world. As such, counterfeit pharmaceuticals pose a direct threat to national and international security.

It is necessary to understand main cause, implication & impact on health & economics of counterfeit medicines. It is essential to modus operandi of counterfeit medicine in order to prevent it.

RESEARCH METHODOLOGY

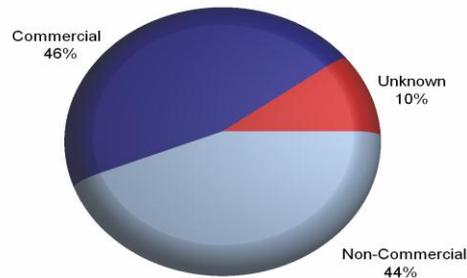
Research Approach

Qualitative as well as Quantitative approach has been used for this Paper with the focus on quantitative approach. Secondary data is used, which collected from authenticated website.

DATA ANALYSIS AND INTERPRETATION**Incident of Counterfeit Medicine Reported**

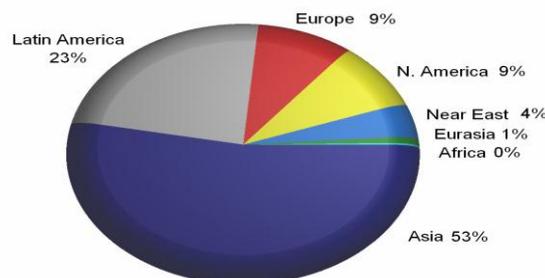
Source: www.psi-inc.org/index.cfm

In CY 2011, incident data was analyzed with respect to seven regions of the world. Every region experienced a pharmaceutical crime incident. While there was a decline in incidents in Asia, four of the seven regions recorded an increase in the total number of counterfeiting, theft and illegal diversion incidents. In CY 2011, Asia and Latin America were again the top two regions most frequently linked to pharmaceutical crime incidents.

Counterfeit Seizure**Counterfeit Seizures CY 2011**

SOURCE-www.psi-inc.org/index.cfm

In Year 2011, there were 908 counterfeiting incidents which involved either customs seizures or police/health inspector raids. Nearly half of the seizures made by law enforcement were confirmed as being of "commercial" size. As the adjacent pie-chart shows, commercial seizures accounted for forty-six percent (46%). This is a slight decline in commercial size seizures compared to CY 2010 totals.

ARREST BY Region**Arrests by Region
CY 2011**

SOURCE-www.psi-inc.org/index.cfm

Through member and open source reports, PSI documented the arrest of 1,311 persons involved in counterfeiting, diversion or theft of pharmaceutical drugs worldwide during CY 2011. This was a fourteen percent (14%) increase over the CY 2010 arrest total, and the second largest annual arrest total ever documented by the Institute.

According to Dr Jackson's review

- European Union seizures and detentions are increasing and medicines accounted for 10% of all detained materials in 2009.

- There is clear evidence that counterfeit drugs are being found in legitimate supply chains. For example, the UK has had nine product recalls in the last three years after counterfeit medicines reached pharmacy and patient levels and a further five were discovered at wholesale level.
- A UK study of 96 websites selling painkillers, found that 48% sold drugs that should be only supplied on prescription and 76% of those did so without a prescription. And a US study of 159 sites offering controlled drugs found that 85% did not require a prescription.
- 21% of the 14,000 plus people who took part in a 14-country European study had bought prescription only medicines without a prescription. The figure was 12% in the UK.
- Another study estimated that 9% of Europeans had bought online prescription only drugs, even though 69% agreed that it was a 'bad idea' or 'dangerous'. Cheaper costs (46%) and convenience (30%) were the most common reasons.
- The UK medical newspaper GP reported that 33% of the 423 doctors it surveyed said that they had treated, or suspect they had treated, a patient for the side-effects of substandard prescription only drugs purchased online.
- A study carried out by the European Alliance for Access to Safe Medicines found that 62% of medicines ordered on the internet were substandard or counterfeit. Of these, 68% were unlicensed imitations and the rest were counterfeit branded medicines. The study also found that 90% of sites did not require a prescription for prescription only drugs.
- Five 'Tamiflu' vaccines tested by the American Food and Drugs Administration contained no active ingredient at all and a further four contained varying levels unapproved for use in the USA.
- An analysis of 2,383 seized 'Viagra' samples carried out by Pfizer found that only 14% were authentic.
- Internet security experts estimate that 25% of all email is spam advertising counterfeit and/or unlicensed drugs.

According to a report released by the [[Organisation for Economic Co-operation and Development]] (OECD), 75% of fake drugs supplied world over have some origins in India, followed by 7% from Egypt and 6% from China.

A Pfizer-sponsored study, one of the largest investigations conducted in 14 European countries, estimated that western Europeans spend more than US\$ 14 billion a year on illicitly-sourced drugs, many of them counterfeit. A big share of the market constitutes the so-called “lifestyle” drugs. The study found that almost half the counterfeit drugs sold on the Internet were for weight loss, followed by influenza medicines. Another key market for counterfeits in Europe, as in Asia, is erectile dysfunction, nourished by the growth in online pharmacies that offer access to prescription-only medicines without the embarrassment of consulting a doctor. A Dutch study cited by the *International Journal of Clinical Practice* found that, of 370 seized Viagra samples, only 10 were genuine.

In Singapore, 150 people were admitted to hospital in the first five months of 2008 having severe hypoglycaemia – a sharp drop in blood-sugar levels. Four of them died and seven suffered severe brain damage. They had reportedly taken counterfeit copies of drugs purporting to treat erectile dysfunction but which contained a hefty dose of glyburide, used for treating diabetes.

FINDING & CONCLUSION

Health Impact of Counterfeit medicine

- It is difficult to quantify the continental morbidity and mortality toll of counterfeit or falsified medical products. There have been no comprehensive studies to quantify its damage. Most literature derives estimates put the total loss of life to counterfeit pharmaceuticals between 500 000 and 1 million people each year (Kafchinski, 2009).
- The impact of counterfeit or falsified medical products can be both direct and indirect. Patients who take disease prevention drugs may end up getting sick when they believed they were protected. Counterfeit or falsified medications can lead to varying degrees of effectiveness and danger. For some counterfeit life-style drugs, such as medications to treat erectile dysfunction, the health effects on patients can be described as „inconvenient“. But increasingly drugs counterfeited in Asia are not just „lifestyle“ drugs but widely used drugs such as those for cholesterol or high ticket items such as cancer drugs. Recently the Fides Agency reported that, according to the WHO, about 700, 000 people die each year due to counterfeit medicines for malaria or tuberculosis (Akunyili, 2011).

Economic Impact of Counterfeit medicine

- Estimates of the economic scale of counterfeiting are difficult to quantify. The economic burden of drug counterfeiting is continuously increasing. Current estimates state that 7 to 33% of the medicinal products in the world market are counterfeit medicines (Dittmer, 2008). Although counterfeit medicines have been distributed through every economy, Asia is reported to be the largest source of economy.
- Because counterfeiting is an illegal trade, counterfeiters do not pay any import duties when they bring drugs into the country and they do not pay any sales tax on the drugs that they sell so the local economy suffers. Unfortunately, the lower prices of the counterfeits encourage purchases by consumers.
- Counterfeit or falsified drugs can damage public trust, resulting in reduced investment in the pharmaceutical industry. It also can severely affect the business of the manufacturer whose products are being copied through loss of confidence as well as revenue. Counterfeiting wastes the enormous human effort and financial outlay made in development of medicines, optimizing dosage, carrying out clinical trials, discussing policy change, and manufacturing medicines.

Reasons for Counterfeit of drugs

- There are certain truths about medicines that cannot be denied. For many people they are too expensive forcing people to search for cheaper alternatives. For some they

are inconvenient prompting some to search for „doctor free“ alternatives. Counterfeiting impacts nations of every size and income levels and drugs of every description. No drug is invulnerable and no country is immune.

- Asia represents a lucrative market for counterfeiters of medicines and medical devices. Weak economies, increasing prices, a large market, increased internet connectivity, inconsistent regulatory oversight and a complex supply chain all conspire to encourage those engaged in the manufacture and supply of counterfeit medicines and devices to target this area. The increasing availability of the Internet has facilitated a global communication channel for counterfeiting that has no political or geographic boundaries.

Remedial Measures

- In order to prevent counterfeit of medicine Developing countries must be given all the scientific, technical and legal help they need to counter the growing trade in fake medicines. Health and law enforcement organisations must work together to stop the spread of counterfeit medicine.
- "If you want to be efficient in fighting it, you have to have a very strong regulatory authority, very strong collaborations, very good distribution networks and good co-operation between governments," said Sabine Kopp, who manages the anti-counterfeiting and medicines quality assurance programmes at the World Health Organisation
- Recommendations made by Brain D finlay (Counterfeit drug & National security) such as creating awareness, development of a transparent and verifiable chain of custody from point of production to point of sale:("e-pedigree" system),legal gap analysis by every country, enhanced early authentication procedure should be implicated & practiced seriously.

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