About OMICS Group

OMICS Group is an amalgamation of Open Access Publications and worldwide international science conferences and events. Established in the year 2007 with the sole aim of making the information on Sciences and technology 'Open Access', OMICS Group publishes 500 online open access scholarly journals in all aspects of Science, Engineering, Management and Technology journals. OMICS Group has been instrumental in taking the knowledge on Science & technology to the doorsteps of ordinary men and women. Research Scholars, Students, Libraries, Educational Institutions, Research centers and the industry are main stakeholders that benefitted greatly from this knowledge dissemination. OMICS Group also nternational conferences annually across the globe, organizes 500 where knowledge transfer takes place through debates, round table discussions, poster presentations, workshops, symposia and exhibitions.

OMICS International Conferences

OMICS International is a pioneer and leading science event organizer, which publishes around 500 open access journals and conducts over 500 Medical, Clinical, Engineering, Life Sciences, Pharma scientific conferences all over the globe annually with the support of more than 1000 scientific associations and 30,000 editorial board members and 3.5 million followers to its credit.

OMICS Group has organized 500 conferences, workshops and national symposiums across the major cities including San Francisco, Las Vegas, San Antonio, Omaha, Orlando, Raleigh, Santa Clara, Chicago, Philadelphia, Baltimore, United Kingdom, Valencia, Dubai, Beijing, Hyderabad, Bengaluru and Mumbai.





Dr. Tarek Kilani

World Health Organization Definition of a Counterfeit Medicine



A Product that is deliberately and fraudulently mislabelled with respect to source and/or identity.

World Health Organization Definition of a Counterfeit Medicine



Counterfeiting can apply to both generic and branded products.

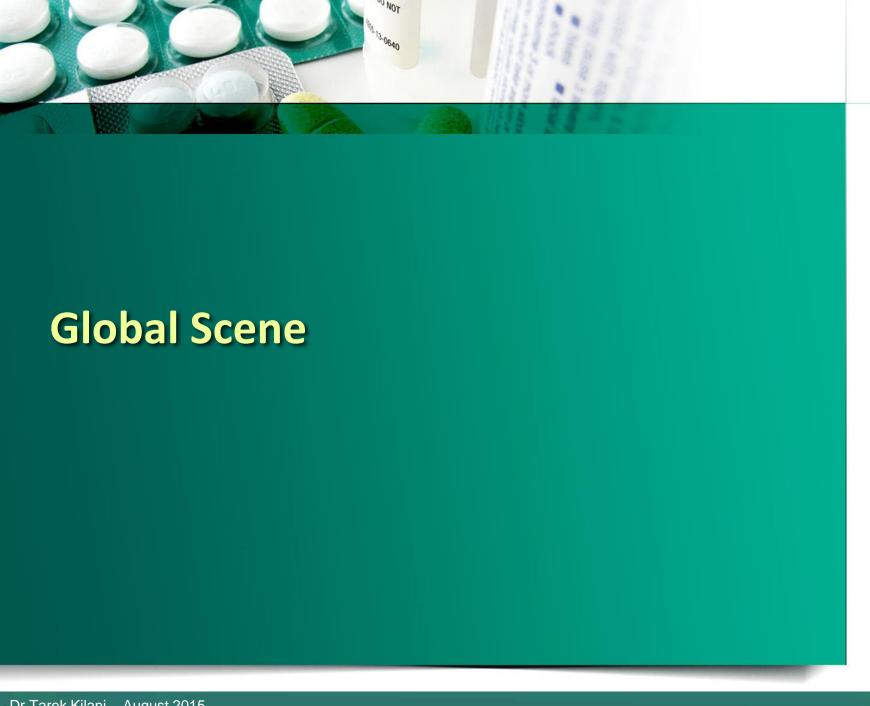
World Health Organization Definition of a Counterfeit Medicine

Counterfeit Medicine may include products:

- with the correct ingredients,
- with the wrong ingredients,
- without ingredients,
- with incorrect quantities of active ingredients,
- with fake packaging.

Types of Medicinal Product Affected by Counterfeiting

- High volume (high level of prescribing)
- High price
- Known brand
- "Lifestyle"/non-reimbursed
- Blockbusters
- Parenterals (in developing world)
- All generics
- Off-label use drugs
- Drugs in short supply



 The problem of counterfeit drugs is known to exist in both developed and developing countries. However, the true extent of the problem is not really known since no global study has been carried out.

 The appearance of counterfeit medicines in international commerce was first mentioned as a problem at the WHO Conference of Experts on Rational Drug Use in Nairobi, Kenya, in 1985.

 Since then, public awareness of the problem of counterfeit drugs has grown. Both government authorities and manufacturers have been concerned with efforts aimed at preventing the problem, and WHO has received reports related to counterfeit drugs from some of its member states on a voluntary basis. According to this information, the problem is known to involve both developed and developing countries.

- The impact of counterfeit medications on the legitimate global pharmaceutical market has been estimated to reach \$75 billion
- Annual value of counterfeited consumer goods is US\$200 billion equivalent to 6% of world trade
- In 2005 market was US\$32 billion
- In 2006 it was US\$ 40 billion

- Estimates indicate that less than 1% of prescription medications sold in the United States and Europe and 30% sold in developing nations are counterfeit
- Africa, Asia and Latin America have > 30% of counterfeit medicines
- Other developing markets have < 10%; overall range is 10% to 30% (WHO)

Products without active ingredients, 32.1%;

Products with incorrect quantities of active ingredients, 20.2%;

Products with wrong ingredients, 21.4%,

 Products with correct quantities of active ingredients but with fake packaging, 15.6%;

Copies of an original product, 1%; and

Products with high levels of impurities and contaminants, 8.5%

Estimates of Counterfeit Medicines

WHO estimates counterfeit medicines account for 6% of the world market

EU 2 – 10%

Europe (non EU) 2 – 25%

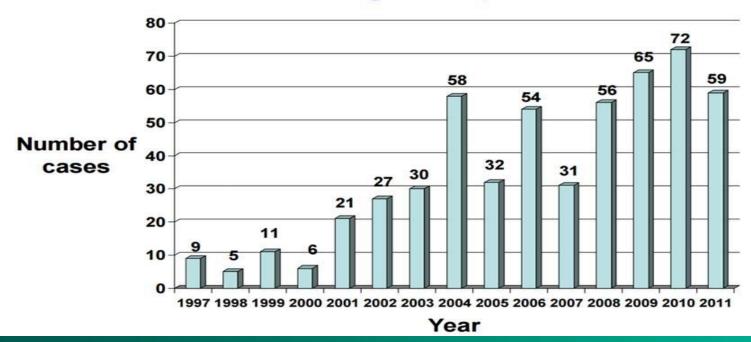
Asia 10 – 80%

Africa 10 – 40%

Latin America 5 – 60%

Counterfeit Drugs Cases Opened By FDA Per Year

Counterfeit Drug Cases Opened by FDA's Office of Criminal Investigations per Fiscal Year



Counterfeit Drugs Cases Opened By FDA Per Year



Some of the Largest Seizures of Counterfeit Drugs

October 2008

More than 2 million units Painkillers, antimalaria treatments

BRUSSELS, BELGIUM

2011 - seizure of 10 containers each holding hundreds of thousands of counterfeit medicines Egyptian customs in the Suez

DUBAI, U.A.E.

September 2007 More than 5 million units Treatments for erectile dysfunction, sleeping pills **HENAN PROVINCE, CHINA**

September 2005 440,000 units Treatments for erectile dysfunction, cholesterol SHANGHAI, CHINA

November 2011 840,000 units Treatments for erectile dysfunction

UNITED KINGDOM

2007 1.12 million units Treatments for psychosis, blood clots, prostate cancer

Canal

HARYANA, INDIA

May 2011 250,000 units Cough tablets **GUANGZHOU, CHINA**

May 2011 6.9 million units Treatments for erectile dysfunction

ANGOLA June 2012 33.2 million dosage units Antimalaria treatments

Sources: Pharmaceutical Security Institute; U.K.'s Medicines and Healthcare Products Regulatory Agency; U.S. Food and Drug Administration; The United States Pharmacopeial Convention Inc.: Chinese state media

Details of the Angola Seizure Fake malaria drugs were hidden in

loudspeakers in Guangzhou, China, then loaded onto a freight ship to Angola. The drugs were seized at the Port of Luanda.

> Luanda ... ANGOLA

CHINA Guangzhou

Note: Route is approximate

Counterfeit Drugs Cases



- Counterfeit drugs sold online have been made from everything from <u>highway paint</u>, <u>rat</u> <u>poison</u>, <u>arsenic</u> and <u>floor wax</u>.
- Unsuspecting consumers can be exposed to counterfeit drugs by buying from illicit, unlicensed drug sellers on the internet.

Hazardous items, such as rat poison, boric acid, antifreeze,:

- These poisons can cause kidney damage and failure, cancer, developmental defects, and death.
- Interpol reported that "In Ecuador, boric acid was found as an ingredient in fake medication while sheet rock and rat poison were included in Columbia.

- Methamphetamine was also found in fake medication in Hungary,
- commercial-grade wall paint was used to color fake pills in Montreal.
- Antifreeze was found in cough syrups and other common drugs, resulting in the deaths of hundreds of adults and children in Panama, Haiti, Nigeria and Guanzhou."

Household items, such as *floor wax, brick dust, house* paint, road paint, paint thinner:

- These can cause vomiting, abdominal pain, dizziness, blurred vision, respiratory difficulty, nervous system disruption, coma, death.
- Investigators have found household items in counterfeit medications. Floor wax gives a nice sheen to mimic an enteric coating; brick dust and paints fake the proper color of pills, and sheet rock can be made into pills."

Drugs you didn't ask for:

 According to FDA orders over the Internet for Ambien, Xanax, Lexapro and Ativan received products containing what was identified as "foreign versions of Haldol (haloperidol), a powerful anti-psychotic drug. As a result, these customers needed emergency medical treatment for symptoms such as difficulty in breathing, muscle spasms, and muscle stiffness—all problems that can occur with haloperidol."

No Drugs at All:

- Even if a medication contains no poisons or wrong medications, a potentially life-saving medication without an active ingredient will cause harm, and potentially death.
- Medications with no active ingredients, or insufficient quantities, can harm you by not correcting your illness. In recent cases, fake medicines with no drugs at all in them have had an impact on cancer patients and asthmatics with dire consequences.

Correct Drug, Correct Ingredients

Viagra (not made by Pfizer)

Cialis (not made by Lilly)



Wrong Ingredients, but Therapeutically Active

Cialis (sildenafil instead of tadalafil)



Levitra (sildenafil instead of vardenafil)

Lipitor (lovastatin instead of atorvastatin)

No Active Ingredients

1995 - Fake meningitis vaccine lead to 3,000 Deaths in Niger

1998 - 60% of all malaria deaths attributed to fake quinine sulphate in Uganda.

2000 - 30 people died after taking fake malaria drugs being sold as mefloquine or artesunate in Cambodia.

Toxic-ingredients

- 1990 109 children die after taking a fake preparation contain di-ethylene glycol in Nigeria
- 1992 Paracetamol preparation containing di-ethylene glycol believed to have killed hundreds of children in Banglade
- 1995 30 children die after taking medicines containing di-ethylene glycol in Haiti
- 1998 30 infant deaths (di-ethylene glycol) in India
- 2006 11 people died from an antibiotic which was not proper sterilised in China

Cases of Counterfeit Reported

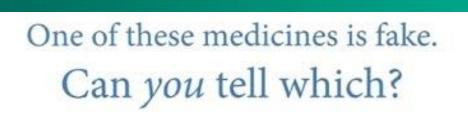
Medicine	Country/Year	Report
Avastin (for cancer treatment)	United States of America, 2012	Affected 19 medical practices in the USA. The drug lacked active ingredient ¹
Viagra and Cialis	United Kingdom, 2012	Smuggled into the UK. Contained undeclared active ingredients with possible serious health risks to the consumer ²
Truvada and Viread (for HIV/AIDS)	United Kingdom, 2011	Seized before reaching patients. Diverted authentic product in falsified packaging ³

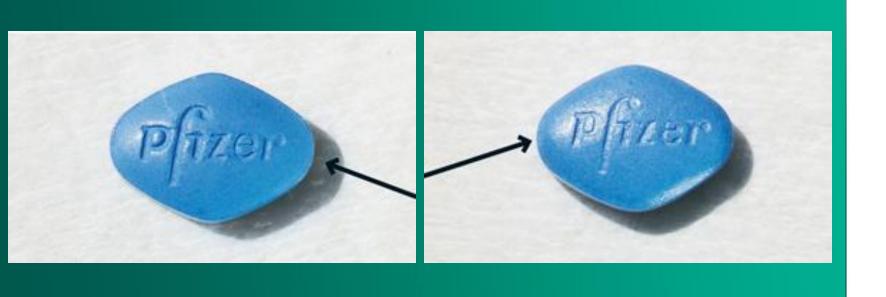
Cases of Counterfeit Reported

Zidolam-N (for HIV/AIDS)	Kenya, 2011	Nearly 3 000 patients affected by falsified batch of their antiretroviral therapy ⁴
Alli (weight-loss medicines)	United States of America, 2010	Smuggled into the USA. Contained undeclared active ingredients with possible serious health risks to the consumer ⁵
Anti-diabetic traditional medicine (used to lower blood sugar)	China, 2009	Contained six times the normal dose of glibenclamide. Two people died, nine people were hospitalized ⁶
Metakelfin (antimalarial)	United Republic of Tanzania, 2009	Discovered in 40 pharmacies. The drug lacked sufficient active ingredient ⁷

Identifying Counterfeit Medicines

- Evidence of tampering with packaging
- Switched or altered labels
- Altered expiry dates
- Compare packaging read labels, font size, colour orientation of label
- Compare containers size, shape, colour
- Compare products shape, colour, weight







This Viagra pill costs \$15.

To get it, you
have to go to a
doctor and talk about
your erectile issues.





This knockoff costs \$1.

You can order it over the Internet without a prescription or potential embarrassment.

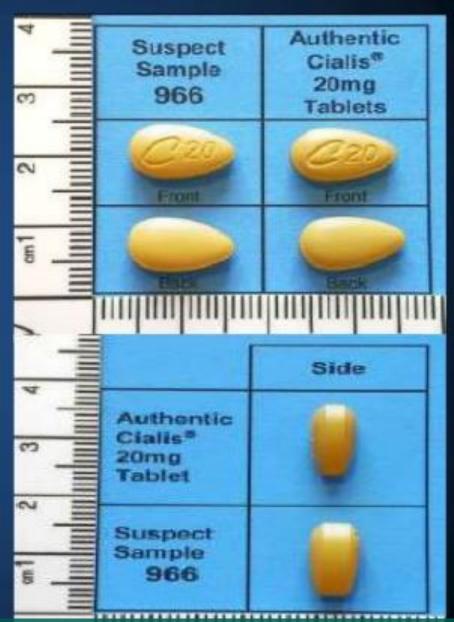
It might work.

It might also contain brick dust—or worse.

Counterfeit Cialis®







Counterfeit Product



Counterfeit

tablets

Counterfeit Viagra found in two **California pharmacies**



Genuine Viagra tablet

Counterfeit tablet containing blue speckles



Genuine white core Viagra tablet



- The counterfeit Lipitor tablets on the right are nearly identical from the authentic tablets on the left. Only distinguishable to the consumer by their bitter taste.
- More than 18 million counterfeit Lipitor tablets were removed from the U.S. supply chain in 2003

Counterfeit ZANTAC



Manufactured in Taiwan, discovered in United Kingdom. Excellent packaging of counterfeit.







Ponstan is an anti-inflammatory product. This counterfeit was found in Columbia contain yellow powder; it consist of boric acid, floor wax, yellow highway paint.

Dr. Tarek Kilani – August 2015



Counterfeit Viagra founded in Thailand 2012



Genuine Viagra

Clear and easy to see expiry date on the pack

Genuine: Lighter blue color

Counterfeit Viagra

Over printing of Product Name on the blister pack

Counterfeit: Darker blue color





Causes of Counterfeiting

- There is a lot of money to be made
- Lifestyle medicines are wanted
- Equipment is widely available
- Distribution is now easy, e.g. Internet and postal delivery
- Patients are self-prescribing
- Weak legislation and enforcement
- Organised crime has moved in

Whose problem is it?

- Police
- Regional Drug Squad
- Customs
- Trading Standards Office
- Regulatory Agency
- Pharmaceutical company
- Pharmacy organisations
- Pharmacists

International Collaboration and efforts

- World Health Organization
 - International working group
 - WHO/FDA cooperative agreement
 - To support building global capacity for the surveillance and monitoring of counterfeit medicines and supply chain threats
- INTERPOL led global operation targeting internet websites supplying illegal and dangerous drugs; 81 countries participated

The World Health Organization (WHO) has established an International Medical Products Anti-Counterfeiting Task Force (IMPACT) in order to bring together all stakeholders on the global level to fight counterfeit medical products.







U.S. Department of Health and Human Services



U.S. Food and Drug Administration

Protecting and Promoting Your Health

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Resources for You

Information for Consumers (Drugs)

Buying & Using Medicine Safely

Buying Medicines Over the Internet

Be SafeRx: Know Your Online Pharmacy

Resources for You

- About BeSafeRx
- · Frequently Asked Questions
- · For Campaign Supporters
- For Health Professionals
- Campaign Materials

BeSafeRx: Know Your Online Pharmacy



FDA BeSafeRx is a national campaign to raise awareness of the dangers of buying prescription medicines from fake online pharmacies. This campaign provides the resources to help consumers:









Information for Consumers (Drugs)

Buying & Using Medicine Safely

Buying Medicines Over the Internet

BeSafeRx: Know Your Online Pharmacy

Resources for You

Internet

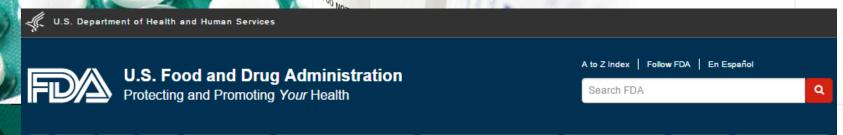
Quick Tips for Buying Online

- Make sure the site requires a prescription and has a pharmacist available for questions.
- Buy only from licensed pharmacies located in the United States. BeSafeRx: Know Your Online Pharmacy has more information about finding safe and legal online pharmacies.
- · Don't provide personal information such as credit card numbers unless you are sure the site will protect them.

- BeSafeRx: Know Your Online Pharmacy
- · Buying Prescription Medicine Online: A Consumer Safety Guide

Report Problem Sites

· Reporting Unlawful Sales of Medical Products on the Internet



Food

Drugs Medical Devices Radiation-Emitting Products

Vaccines, Blood & Biologics

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Home



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Resources for You Information for Consumers (Drugs) Buying & Using Medicine Safely Buying Medicines Over the Internet BeSafeRx: Know Your Online Pharmacy

Know the Signs



WARNING! Beware of online pharmacies that:

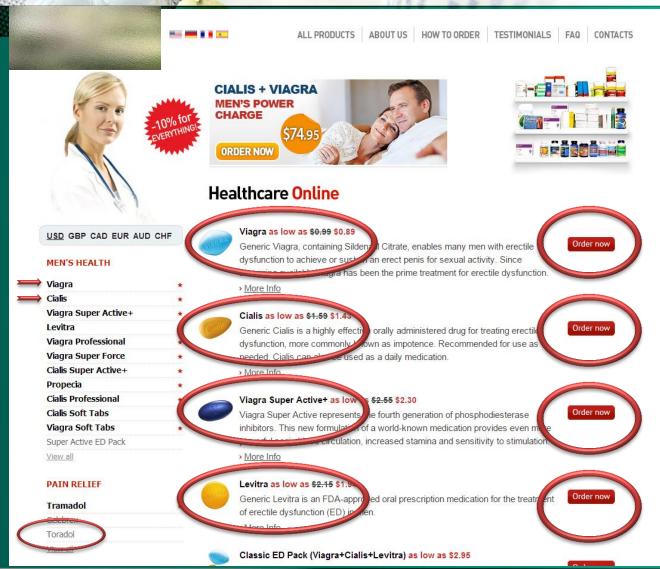
- Allow you to buy drugs without a prescription from your doctor
- · Offer deep discounts or cheap prices that seem too good to be true
- · Send spam or unsolicited email offering cheap drugs
- Are located outside of the United States
- Are not licensed in the United States

These are signs of a fake online pharmacy.

Tips for identifying safe online pharmacies:

- Always require a doctor's prescription
- Provide a physical address and telephone number in the United States
- Offer a pharmacist to answer your questions
- Have a license with your state board of pharmacy. Find your state's pharmacy licensing database.

Example of an Online Pharmacy





Measures to Combat Counterfeit Medicines

- Enacting new drug laws or updating existing drug laws for prohibiting counterfeit medicines;
- Establishing institutions for the regulation of medicines and clearly setting out in the drug laws, the power, duties and responsibilities of the institution(s);

Measures to Combat Counterfeit Medicines

- Training of personnel, including enforcement officers, for national drug control;
- Making available necessary financial and other resources;
- Ensuring that the drug laws are enforced;

Measures to Combat Counterfeit Medicines

 Fostering international cooperation in the control of pharmaceuticals and entering into bilateral and multilateral agreements with other governments and with international organizations such as WHO, Interpol and the World Customs Organization (WCO).

Steps to avoid Counterfeiting

Manufacturers' Secure Packaging

Steps to avoid Counterfeiting

Manufacturers' Secure Packaging

Manufacturers' Secure Packaging

- Tamper-proof outer packaging
- Covert markers eg Cryptoglyph encryption
- Radiofrequency identification (RFID)
- Holograms
- Security Inks
- 2-D Bar Coding
- Medicines Passports (Pedigrees)

Electronic Solutions: Advanced Bar Coding and RFID

- Advanced bar coding and RFID technologies are potential technologies to enable efficient electronic pedigree
- There are two possible approaches
 - Adding lot number, expiration date and other information to the barcode or RF-ID tag
 - Mass serialization where each package has a unique id number assigned by the manufacturer

Electronic Solutions:

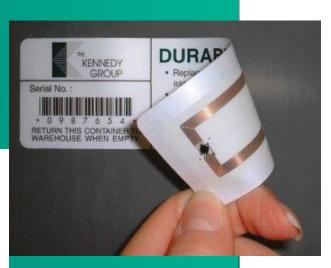
Advanced Bar Coding and RFID

 RFID is emerging as the preferred solution for package level tracking











AstraZeneca

Packs of Nexium (esomeprazole) are to be sealed with new tamper-proof seals and marked with unique carton numbers using a two-dimensional matrix code.

Is one of the first pharmaceutical companies to make all individual packs of a medicine traceable throughout the supply chain.



Steps to avoid Counterfeiting

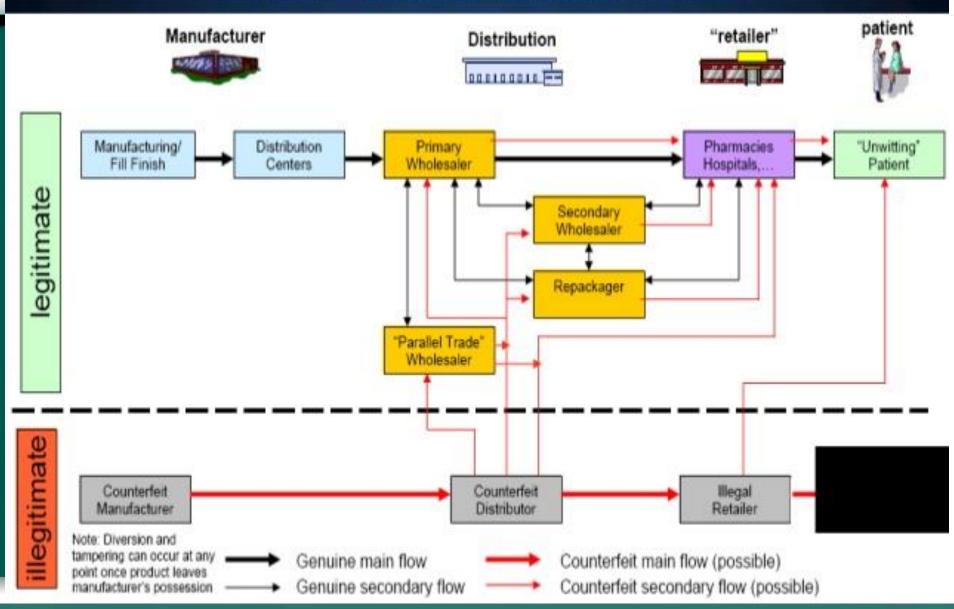
Manufacturers' Secure Packaging

Steps to avoid Counterfeiting

Manufacturers' Secure Packaging

- Buy from known sources
- Make a list of approved suppliers
- If using an alternative source obtain the pedigree of the product or a form of certification it is an authentic product
- Be wary of cheap deals
- Check with professional colleagues and the local Pharmaceutical Society if in doubt

POSSIBLE INFLOW OF COUNTERFEITS TO THE LEGITIMATE DISTRIBUTION CHANNEL



Effect of Counterfeit

- Ethics Increased corruption
- Government Loss of Reputation & Revenue
- Consumer
 - Health Hazard
 - Loss of confidence in the healthcare system
- Industry
 - Loss of Reputation & Brand Equity
 - Mistrust of Authorities, Health
 Practitioners and Consumers

Pharmacist's Role

- Minimize the risk of and exposure to counterfeit medical products
 - Know who you are doing business with
 - Stay informed
 - Safeguard products
 - Destroy empty packages/containers

Pharmacist's Role

- Be vigilant
 - Inspect the product and packaging
 - Know high risk products
 - Consider counterfeits if:
 - New/unusual side effects
 - Lack of therapeutic effect
 - Products tastes/smells abnormal
 - Patient experiences pain, burning, redness at injection site

Pharmacist's Role

- Counseling patients about counterfeit medical products
 - Encourage patients to shop online only at licensed pharmacies.
 - Tell you patient if you dispense a drug that may look different from their previously dispensed drug.
 - If paying for meds is a problem, counsel on assistance program and generics, rather than buying online.



Dr. Tarek Kilani
Head of Pharmacy & Continuing Medical Education Coordinator
Emirates French Hospital

Abu Dhabi - United Arab Emirates

