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AN ARTICLE ON COUNTERFEIT MEDICINES ('PEOPLE ARE DYING EVERY DAY')

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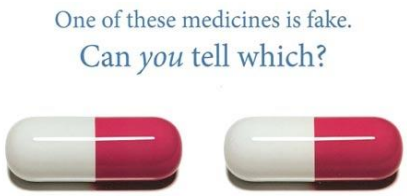
ABSTRACT

The proliferation of counterfeit and poor-quality medicines is a major public health problem, especially in developing countries lacking adequate resources to effectively monitor their prevalence. Industrialized countries are, for the moment, more affected by the phenomenon of adulteration of dietary supplements (DS) and herbal drugs. Counterfeit medicines (CM) in addition to the serious health risk they pose to populations, constitute a major challenge for analytical laboratories for their detection and characterization. The aim of this review is to present several examples for uncovering CM.

KEYWORDS: Counterfeit, Drug, Antibiotic, Absorption, Dietary supplements, RFID, FDA, NAFDAC, IMPACT and Anticounterfeiting.



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 labeling. Medicines which are deliberately mislabeled to deceive consumers—including mislabeled 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 minimize the impact of counterfeit drugs. Patients die after being given counterfeit drugs that do not cure their condition. Antibiotics with insufficient quantities of an active ingredient add to the problem of antibiotic resistance.

Legitimate, correctly labeled, low-cost generic drugs are not counterfeit or fake (although they can be counterfeited), but can be caught up in anticounterfeiting enforcement measures. In that respect, a debate is raging as to whether "counterfeit products [are] first and foremost a threat to human health and safety or [whether] provoking anxiety [is] just a clever way for wealthy nations to create sympathy for increased protection of their intellectual property rights". Generic drugs are subject to normal regulations in countries where they are manufactured and sold.

What risks are involved with taking counterfeit drugs?

An individual who receives a counterfeit drug may be at risk for a number of dangerous health consequences. Patients may experience unexpected side effects, allergic reactions, or a worsening of their medical condition. A number of counterfeit products do not contain any active ingredients, and instead contain inert substances, which do not provide the patient any treatment benefit. Counterfeit drugs may also contain incorrect ingredients, improper dosages of the correct ingredients, or they may contain hazardous ingredients.

What is the worldwide prevalence of counterfeit drugs?

The extent of the problem of counterfeit drugs is unknown. Counterfeiting is difficult to detect, investigate, and quantify. For these reasons, it is hard to know or even estimate the true extent of the problem.

What is known is that counterfeit drugs can be found worldwide and are more prevalent in developing countries. The World Health Organization (WHO) estimates that while the incidence of counterfeit drugs is less than 1% in developed countries, a much higher percentage of the medicines on sale in some developing countries may be counterfeit.

What is the prevalence of counterfeit drugs in the U.S.?

Drug counterfeiting occurs less frequently in the U.S. than in other countries due to the strict regulatory framework that governs the production of drug products and the distribution chain, and enforcement against violators. However, the U.S. has recently experienced three highly publicized examples of counterfeit drugs within the U.S. distribution system: (1) Lipitor tablets, a cholesterol-lowering medication, (2) Procrit, an injectable drug used to stimulate red blood cell growth, and (3) Alli, an over-the-counter weight-loss drug. FDA continues to believe, and works to ensure, that the overall quality of drug products that consumers purchase from U.S. pharmacies remains high. The American public can be confident that these medications are safe and effective.

Should consumers who currently purchase drugs over the Internet or import medications from other countries be concerned about counterfeits?

Consumers can be confident in the quality, safety, and efficacy of drugs purchased from a state-licensed pharmacy in the U.S. Websites that sell drugs over the internet are not necessarily legitimate licensed pharmacies and may be located anywhere around the world. Consumers need to be cautious when they buy drugs over the internet, because they may not receive the FDA-approved drug, which has been reviewed for safety and effectiveness. For those consumers who purchase drugs over the Internet, look for websites that have the Verified Internet Pharmacy Practice Sites (VIPPS) seal. These are licensed pharmacies where FDA-approved medications can be purchased. These sites are identified by the VIPPS hyperlink seal displayed on their Website. Unless medications have been purchased from a state-licensed pharmacy website in the U.S., the safety and efficacy of these medications cannot be guaranteed.

Why is FDA focusing on counterfeit drugs?

Although FDA does not believe that the number of counterfeits entering the U.S. drug supply has significantly escalated in recent years, the agency believes that it needs to be proactive to prevent counterfeit drugs from reaching consumers. Growth in counterfeiting may be spurred by the economic incentives provided by an increasing volume of high cost drugs, the development of technologies that make it easier to counterfeit drugs, and the ability to sell drugs directly to consumers without face-to-face contact through purchases over the internet.

How can pharmacists, physicians, and other healthcare professionals identify counterfeit medications?

Pharmacists, physicians, and other healthcare professionals should familiarize themselves with those drugs most likely to be counterfeited and how to identify these products. FDA periodically places updated information regarding counterfeiting on its website at www.fda.gov/counterfeit. Healthcare professionals should suspect that a patient may have received a counterfeit drug if the patient has experienced an unexplained worsening of their medical condition or an unexpected side effect. Also, if a patient reports that the drug tastes or looks different, if tablets are chipped or cracked, or if the patient experiences burning at the injection site for an injectable drug, they might have a counterfeit. Healthcare professionals who believe that a patient has received a counterfeit drug should contact the FDA immediately. In addition, any irregularity in packaging or labeling of a drug product should be reported to the FDA and to the manufacturer immediately.

What can consumers do to protect themselves from counterfeit drugs?

Consumers can protect themselves from the risks associated with counterfeit drugs by purchasing prescription medications from state-licensed pharmacies in the U.S. Consumers must be vigilant when examining their personal medications, paying attention to the presence of altered or unsealed containers or changes in the packaging of the product. Differences in the physical appearance of the product, taste, and unexpected side effects experienced should alert the patient to contact their physician, pharmacist, or other healthcare professional who is providing treatment.

What should consumers do if they suspect that they have a counterfeit drug?

If a consumer believes that they may have received a counterfeit drug, they should check with their pharmacist first. The pharmacist will know if the manufacturer recently changed the appearance, flavor, or packaging of a drug product. Also, if a pharmacy changes from one generic manufacturer to another generic manufacturer for dispensing the same drug, the color or shape of the drug product may be different. In this event, your pharmacist can verify that it is not a counterfeit and can explain the change.

How does FDA work with domestic and foreign government agencies to combat counterfeits?

FDA is currently working with various U.S. government agencies, such as the Department of Homeland Security (Customs and Border Protection) and the Department of Justice, to combat counterfeit drugs. FDA is also very active in WHO's International Medical Products Anti-counterfeiting Task Force (IMPACT) which is a public/private effort to develop regulatory, legislative, enforcement, communication, and technological tools to

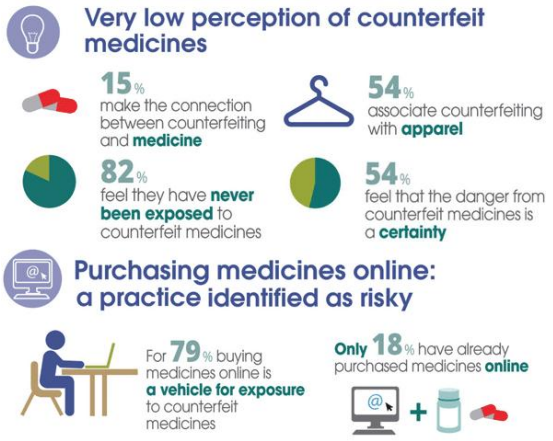
combat counterfeit drugs around the world. FDA also works bilaterally and multilaterally with individual countries and regions.

How does FDA work with the public and industry to combat counterfeits?
FDA works with pharmaceutical manufacturers, wholesale distributors, retailers, and other dispensers to identify and prevent counterfeit drugs. FDA's Action Plan outlined in the 2004 Counterfeit Drug Task Force Report is based on the efforts of the public and private sector to implement solutions to further secure our nation's drug supply. FDA continues to work with these entities on the solutions and measures outlined in this Report.

Are there any promising technologies that have the capability of preventing counterfeiting?
There are several technologies that may prove helpful, including radio frequency identification (RFID) chips and taggants. For example, radio waves are used to automatically read RFID tags that are contained on items, such as pharmaceutical products. These tags could have individual serial numbers on each product, thus allowing the product to be tracked and traced through the supply chain. Appropriate implementation and use of this technology can help decrease the opportunities for diversion and counterfeiting by allowing wholesale distributors and pharmacies to authenticate that the product was handled by legitimate, licensed entities in the drug supply chain.

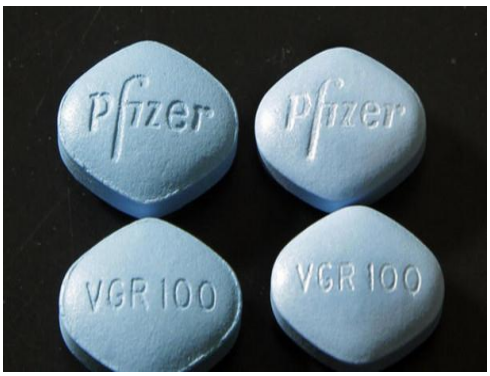
Is expressing a concern for counterfeit drugs an excuse to crack down on cheap drugs that Americans import from Canada?
No, the FDA is concerned about unsafe counterfeit drugs from any country. Counterfeits are not equivalent in quality, safety, and efficacy to the authentic drug. Counterfeits may enter the U.S. distribution system from within the U.S. or from other countries, including Canada. FDA is not attempting to single out any individual country in its efforts to protect Americans from counterfeit drugs. FDA can only ensure that FDA-approved products that have undergone the extensive review process are safe and effective; many products from other countries have not undergone this process and therefore present potential safety risks.

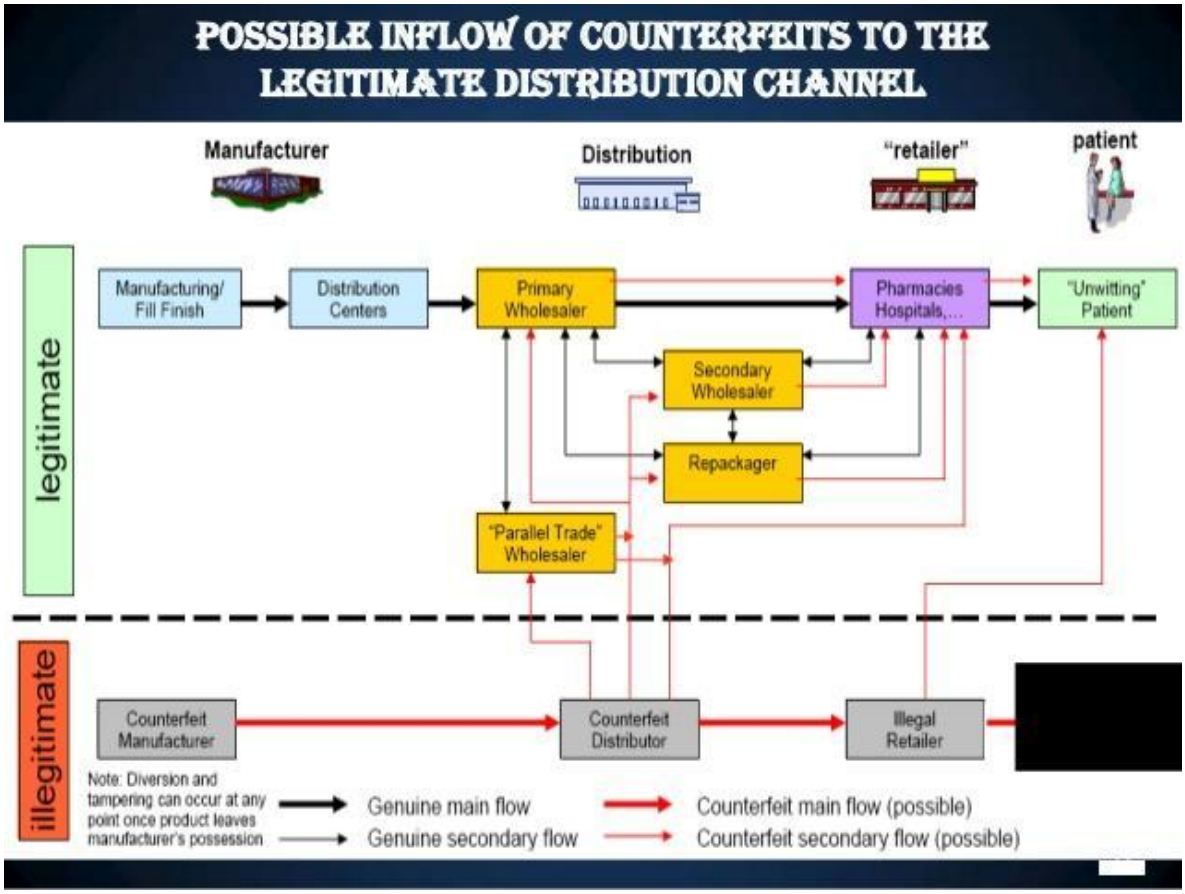
How do counterfeits relate to current bioterrorism issues?
Although counterfeit drugs and bioterrorism may potentially be related, FDA has no reason to believe that counterfeit drugs are being manufactured or introduced for any reason other than making a profit. The FDA is not currently aware of activity where use of counterfeit drugs is connected with terrorism. However, FDA is working with appropriate agencies within the Department of Health and Human Services and the Department of Homeland Security to ensure that if any such threat appears, it will be immediately identified and addressed.



According to Outsourcing Pharma citing the European Commission, 75% of counterfeit drugs supplied world over have some origins in India, followed by 7% from Egypt and 6% from China.

The Central Drug Standards Control Organization (CDSCO), the drug regulatory authority of India conducted a nationwide survey in 2009 and announced that of "24,000 samples [that] were collected from all over India and tested. It was found that only 11 samples or 0.046% were spurious."





ANTICOUNTERFEIT PLATFORM

In 2007, the world's first free-to-access anticounterfeit platform was established in the West African country of Ghana. The platform, dubbed mPedigree, relies on existing GSM networks in that country to provide pharmaceutical consumers and patients with the means to verify whether their purchased medicines are from the original source through a free two-way SMS message, provided the manufacturer of the relevant medication has subscribed to a special scheme. Still in trial stages, the implementers of the platform announced in 2009 that they are in partnership with Ghana's Ministry of Health and the country's specialized agency responsible for drug safety, the Food and Drugs Board, to move the platform from pilot to full-deployment stage. A similar service is being rolled out in India.

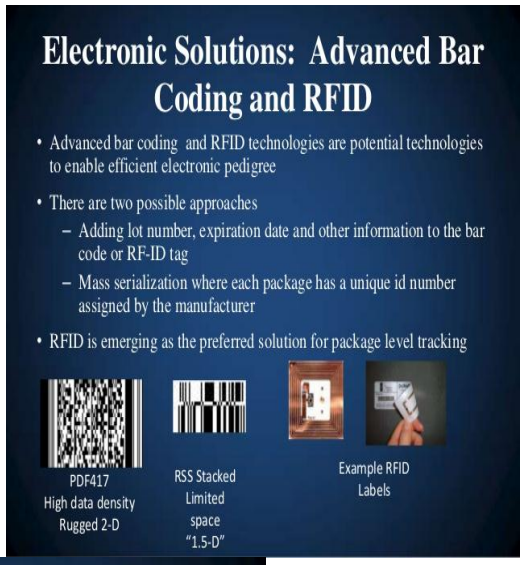
In 2010, NAFDAC in Nigeria launched an SMS-based anticounterfeiting platform using technology from Sproxil. That system was also adopted by GlaxoSmithKline (GSK) in February 2011. In April 2011, CNN published a video highlighting Sproxil's solution in the fight against counterfeit drugs in Nigeria. In July 2011, Kenya's Pharmacy and Poisons Board also

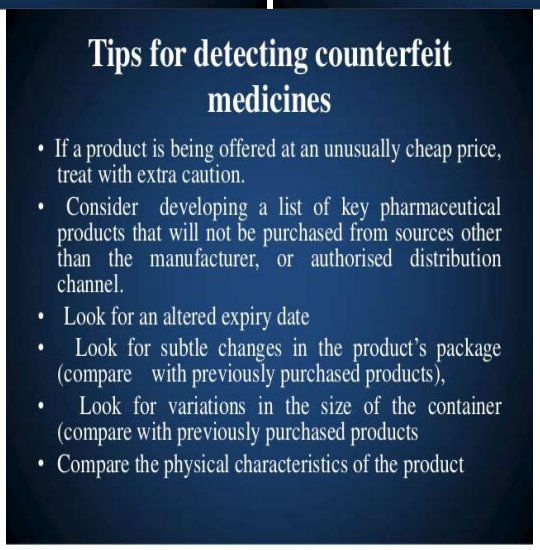
adopted text message-based anticounterfeiting systems and endorsed the Sproxil solution. In early 2012 it was announced that more than one million people in Africa had checked their medicines using the text-message based verification service developed by Sproxil.

An ePedigree is another important system for the automatic detection of counterfeit drugs. States such as California are increasingly requiring pharmaceutical companies to generate and store ePedigrees for each product they handle.

Chemical and physical counterfeit pharmaceutical investigations

- Determine presence of active pharmaceutical ingredients (APIs) present by NMR, GC-MS, LC-MS
- Determination of the levels of APIs present
- Dissolution testing according to Eur.Ph. or USP for tablets
- Screening for excipients and other ingredients present, such as coating materials
- Impurity profiling and impurity identification
- Screen for organic volatiles / residual solvents by GC-MS
- Solid state characterisation such as XRD analysis for API morphology
- Microscopy investigation (FTIR, RAMAN, optical and Electron Microscopy (SEM))
  - Particulate shape and morphology
  - Thickness of coatings
- Metals analysis and metals screening
- LC-MS analysis to identify intermediates for patent litigation support
- Packaging investigations:
  - Printed and Security ink analysis by gas chromatography
  - Paper and card testing
  - Surface chemistry investigations e.g. Time-of-Flight Secondary Ion Mass Spectrometry (ToF-SIMS), X-ray photoelectron spectroscopy (XPS), FTIR Microscopy.





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