Counterfeit Medicines: A Regulatory Perspective to Global Threat

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Counterfeit Medicines: A Regulatory Perspective to Global Threat

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Abstract

Counterfeiting is generally perceived by society as a victimless crime, with ‘Fakes’ simply constituting a cheap alternative option, and seen by criminals as having a low risk of prosecution with light penalties relative to the large profits to be made. The reality is that the international trade in counterfeit a product is estimated to exceed six percent of global trade. The range of counterfeit products is extremely broad and the trends indicate that counterfeits no longer confine their activities to luxury goods but increasingly are exploiting consumer goods, including everyday items such as baby food, medicines, cosmetics, aircrafts and vehicle parts.

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. [1] 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 in order to deceive consumers—including mislabeled but otherwise genuine generic drugs—are counterfeit. Illegal drugs of abuse are often produced and sold with the intent to deceptively represent their origin, authenticity or effectiveness. An example of this would be a marijuana sample with a false claim that it came from a particular area, or has special strength. The nature of fraudulent drugs ranges from those which contain no active ingredients (e.g., when a bag of powdered lactose is claimed to be cocaine), to cases in which the active ingredients are "cut" with a less expensive diluant (e.g., baking soda or lactose) or "spiked" with a chemical "enhancer" (e.g., strychnine or PCP), to cases in which the actual active ingredients present differ from those claimed (e.g., when methamphetamine is sold as cocaine). Legitimate, correctly labeled, low-cost generic drugs are not counterfeit or fake (although they can be counterfeited), but can be caught up in anti-counterfeiting enforcement measures.[1] 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".[1] Generic drugs are subject to normal regulations in countries where they are manufactured and sold.

Prescription and over-the-counter drugs:

Counterfeit medicinal drugs include those with less or none of the stated active ingredients, with added, sometimes hazardous, adulterants, substituted ingredients, completely misrepresented, or sold with a false brand name. Otherwise legitimate drugs that have passed their date of expiry are sometimes remarked with false dates.[1] Low-quality counterfeit medication may cause any of several dangerous health consequences including side effects, allergic reactions, in addition to their obvious lack of efficacy due to having less or none of their active ingredients. Since counterfeiting is difficult to detect, investigate, quantify, or stop, the quantity of counterfeit medication is difficult to determine. Counterfeiting occurs throughout the world, although there are claimsthat it is more common in some developing countries with weak regulatory or enforcement regimes. It is estimatedthat more than 10% of drugs worldwide are counterfeit, and in some countries more than 50% of the drug supply is counterfeit. In 2003, the World Health Organization cited estimates that the annual earnings of counterfeit drugs were over US$32 billion. [2]

The considerable difference between the cost of manufacturing counterfeit medication and price that counterfeiters charge is a lucrative incentive. Fake antibiotics with a low concentration of the active ingredients can do damage world wide by stimulating the development of drug resistance in surviving bacteria. [2] Courses of antibiotic treatment which are not completed can be dangerous or even life threatening. If a low potency counterfeit drug is involved, completion of a course of treatment cannot be fully effective. Counterfeit drugs have even been known to have been involved in clinical drug trials. There are several technologies that may prove helpful
in combating the counterfeit drug problem. An example is radio frequency identification which uses electronic devices to track and identify items, such as pharmaceutical products, by assigning individual serial numbers to the containers holding each product. The U.S. Food and Drug Administration (FDA) are working towards an Electronic pedigree (ePedigree) system to track drugs from factory to pharmacy. This technology may prevent the diversion or counterfeiting of drugs by allowing wholesalers and pharmacists to determine the identity and dosage of individual products. Some techniques, such as Raman spectroscopy and Energy Dispersive X-Ray Diffraction (EDXRD) can be used to discover counterfeit drugs while still inside their packaging. Some of the proposed anti-counterfeiting measures provoke privacy concerns, or the possibility that drug manufacturers will seek to use anti-counterfeiting technologies to undermine legitimate parallel trade in medicines. According to these reports, many of the fake drugs came from the same countries that make normal drugs, in particular China and India. [3] In the case of India, while it is against the law to sell fake drugs for domestic use, there is no prohibition on export of counterfeit drugs. Anti-counterfeit platforms: In 2007 the world's first free-to-access anti-counterfeit 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 FDB (Food & Drugs Board), to move the platform from pilot to full-deployment stage. In 2010 NAFDAC in Nigeria launched an SMS-based anti-counterfeiting platform using technology from Sproxil, that system was also adopted by GlaxoSmithKline (GSK) in Feb. 2011. In April 2011, CNN published a video highlighting Sproxil's solution in the fight against counterfeit drugs in Nigeria. 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. [3] On January 5, 2007 EPCglobal ratified the Pedigree Standard as an international standard that specifies an XML description of the life history of a product across an arbitrarily complex supply chain. [3] Illegal drugs of abuse: Illegal drugs can be counterfeited easily because there are no standards or regulations governing them or their packaging. While there are some isolated examples of illegal drugs being sold under "brand names" that indicated that certain standards or dosage levels were being adhered to, as in the case of 1960s-era LSD which was sold with patterns or logos printed on blotter paper, this is the exception[4] Even with these rare examples of "branding", the illegal "brands" can also be counterfeited by drug dealers who want to be able to sell their product at a higher price. Counterfeit illegal and recreational drugs range from products which do not contain any active ingredients, as in cases where lactose powder is sold as heroin, or dried herbs such as oregano are sold as cannabis, to cases where the active ingredients are "cut" with a diluent (as in cases where cocaine is mixed with lactose powder); [4] and cases where the claimed active ingredients are substituted by something cheaper (e.g., when methamphetamine is sold as cocaine). A common strategy is to claim that a domestic or lower-grade drug is in fact a higher-priced import. The use of diluents in illegal drugs reduces the potency of the drugs and makes it hard for users to determine the appropriate dosage level. Diluents include "foodstuffs (flour and baby milk formula), sugars (glucose, lactose, maltose, and mannitol), and inorganic materials such as powder." The diluents used often depend on the way that drug purchasers consume particular drugs. [4] Drug dealers selling heroin to users who inject the drug with different products than dealers selling to users who smoke or insufflate the drug; diluents which can easily form a solution with water for injecting heroin can be problematic for users who are sniffing the powder. When cocaine is mixed with diluents for the purpose of injection, the "...diluents can produce serious abscesses and pain if the user misses the vein and injects into muscle tissue." "Diluents and adulterants are often added to No. 3 heroin", including sugar, quinine, barbital and caffeine, some of which "can cause serious side effects." In some cases, if a dealer does not take the time to dilute the drug with lactose or other fillers, a "very potent blend of heroin" is sold, which can lead to overdoses. The most dangerous types of counterfeiting for recreational drug users are the use of chemical "enhancers" and the misrepresenting of drugs. When poor-quality cannabis is "spiked" with a disassociate
drug such as PCP, the user may experience extreme reactions. "The popularity of PCP and marijuana mixtures in some areas is highlighted by the report from Delaware that many teens who report they only use marijuana are surprised when they also test positive for PCP on urinalysis", because without their knowledge, the drug dealer had sprinkled PCP on the cannabis that they were purchasing to enhance its psychoactive effects. Claims that illegal drugs are routinely cut with substances such as rat poison and crushed glass, often cited in anti-drug pamphlets, are largely unsubstantiated. [5]

**Key facts**

Counterfeit medicines are medicines that are deliberately and fraudulently mislabeled with respect to identity and/or source. Use of counterfeit medicines can result in treatment failure or even death. Public confidence in health-delivery systems may be eroded following use and/or detection of counterfeit medicines. Both branded and generic products are subject to counterfeiting. All kinds of medicines have been counterfeited, from medicines for the treatment of life-threatening conditions to inexpensive generic versions of painkillers and antihistamines. Counterfeit medicines may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient or too much active ingredient, or with fake packaging. Counterfeit medicines are found everywhere in the world. They range from random mixtures of harmful toxic substances to inactive, ineffective preparations. Some contain a declared, active ingredient and look so similar to the genuine product that they deceive health professionals as well as patients. But in every case, the source of a counterfeit medicine is unknown and its content unreliable. Counterfeit medicines are always illegal. They can result in treatment failure or even death. Eliminating them is a considerable public health challenge. [6]

**Extent of the problem**

Defining the extent of counterfeiting is difficult for a number of reasons. The variety of information sources makes compiling statistics a difficult task. Sources of information include reports from national medicines regulatory authorities, enforcement agencies, pharmaceutical companies and nongovernmental organizations, as well as ad hoc studies on specific geographical areas or therapeutic groups. [7]

The different methods used to produce reports and studies also make compiling and comparing statistics difficult. Studies can only give snapshots of the immediate situation. Counterfeiters are extremely flexible in the methods they use to mimic products and prevent their detection. They can change these methods from day to day, so when the results of a study are released, they may already be outdated. Finally, information about a case under legal investigation is sometimes only made public after the investigation has been concluded. Counterfeiting is greatest in regions where regulatory and enforcement systems for medicines are weakest. In most industrialized countries with effective regulatory systems and market control (i.e. Australia, Canada, Japan, New Zealand, most of the European Union and the United States of America), incidence of counterfeit medicines is extremely low – less than 1% of market value according to the estimates of the countries concerned. But in many African countries, and in parts of Asia, Latin America, and countries in transition, a much higher percentage of the medicines on sale may be counterfeit. [7]

Not only is there a huge variation between geographic regions in terms of incidence of counterfeit medicines, variation can also be significant within countries: for example, between urban and rural areas, and between cities. All kinds of medicines have been counterfeited – branded and generic – ranging from medicines for the treatment of life-threatening conditions to inexpensive generic versions of painkillers and antihistamines.

**Public health risks**

Counterfeit medicines pose a public health risk because their content can be dangerous or they can lack active ingredients. Their use can result in treatment failure (and contribute to increased resistance in the case of antimalarial that contain insufficient active ingredient) or even death. Unlike substandard medicines where there are problems with the manufacturing process by a known manufacturer, counterfeit medicines are made by people with the intent to mislead. The extreme difficulty in tracing the manufacturing and distribution channels of counterfeit medicines makes their circulation on markets difficult to stop. Even a single case of a counterfeit medicine is unacceptable since it indicates that the pharmaceutical supply system in which it was detected is vulnerable. Worse, it undermines the credibility of national health and enforcement authorities. [9]

**Contributory factors**

Several factors contribute to the counterfeit medicine problem. Paying for medicines can consume a significant
proportion of individual or family income. Some people seek medicines that are sold more cheaply. These are often available from non-regulated outlets, where the incidence of counterfeit medicines is likely to be higher. People might also purchase medicines from non-regulated outlets if, as is often the case in the rural areas of developing countries, medicines supplies at regular health facilities do not meet demand.

Counterfeiting medicines can be very lucrative. Since many countries have not yet enacted deterrent legislation, counterfeiters often do not fear prosecution. The growth in international trade of pharmaceutical ingredients and medicines adds a further dimension of complexity to this issue. For example, trade through brokers and free trade zones where regulation is lax or absent (and medicines repackaged and relabeled to conceal country of origin) is increasing. [9]

WHO response

Stringent regulatory control of medicines and enforcement by national medicines regulatory authorities contributes significantly to prevention and detection of counterfeit medicines. WHO provides direct country and regional support for strengthening medicines regulation [10]

To fight counterfeit medicines effectively, a range of stakeholders – not just health professionals – is needed. In 2006, WHO helped to create the International Medical Products Anti-Counterfeiting Taskforce, or IMPACT [10] the aim is to involve a range of stakeholders in collaborative efforts to protect people from buying and taking counterfeit medicines. To prevent the manufacture and distribution of counterfeit medicines, IMPACT’s areas of focus are:

- Legislative and regulatory infrastructure
- Regulatory implementation
- Enforcement
- Technology
- Communication

General considerations

Counterfeiting of drugs is often undertaken by people and organizations involved in other types of crime, frequently on a large national or even international scale. Measures are needed to prevent the manufacture, supply and distribution of counterfeit drugs. Close cooperation between the various drug control and law enforcement agencies within countries and at the international level is required to ensure that these measures are implemented effectively.

Governments and national DRAs are the organizations with the collective prime responsibility to develop such measures. Legitimate pharmaceutical manufacturers also have a responsibility in the fight against counterfeiting. However, counter-measures are often most effective when they are instituted collaboratively by government and industry. [11]

Experience gained so far has shown that the nature and extent of counterfeiting and the factors facilitating it vary from country to country, and that there is no single or simple way to eliminate the problem. Thus each country has to develop a strategy based on its own situation, taking into account the magnitude of the problem and the available infrastructure, and human and other resources. Even countries with a highly evolved drug regulatory system may not find it easy to design and implement appropriate strategies. Countries with less developed drug regulatory systems and accompanying shortages of trained human resources and funds may have difficulties. It is hoped such countries can be given support and guidance from international organizations, such as WHO, and from selected developed countries with experience in this area.

In the first instance, measures should be directed towards the effective detection of counterfeit drugs in national drug distribution channels, and to preventing them entering these channels. While this may not totally eradicate counterfeit drugs, it should substantially reduce the exposure of the population to the risks associated with these products. Although counterfeit drugs are known to exist in the national drug distribution channels of many countries, their extent and nature are not fully known. An assessment of the current situation is therefore the first step, ensuring that a clear distinction is made between substandard and counterfeit products. [12] Measures should also include procedures to improve drug control systems and cooperation in enforcing existing legislation.

A global public health crisis

Counterfeit medicines represent an enormous public health challenge. Anyone, anywhere in the world, can come across medicines seemingly packaged in the right way, in the form of tablets or capsules that look right, but which do not contain the correct ingredients and, in the worst case scenario, may be filled with highly toxic substances. In some countries, this is a rare occurrence, in others, it is an everyday reality. [13]

Counterfeit medicines range from random mixtures of harmful toxic substances to inactive, useless preparations. [13] Occasionally, there can be “high quality” fakes that do contain the declared active ingredient. In all cases, contents of counterfeits are unreliable because their source is unknown or vague and always illegal. Fake drugs can cause harm to patients and sometimes lead to death.
Any kind of product can be and has been counterfeited: expensive lifestyle and anti-cancer medicines, antibiotics, medicines for hypertension and cholesterol lowering drugs, hormones, steroids and inexpensive generic versions of simple pain killers and antihistamines. In developing countries the most disturbing issue is the common availability of counterfeit medicines for the treatment of life-threatening conditions such as malaria, tuberculosis and HIV/AIDS. [14]

Estimates
The US based Centre for Medicines in the Public Interest predicts that counterfeit drug sales will reach US$ 75 billion globally in 2010, an increase of more than 90% from 2005. Although precise and detailed data on counterfeit medicines is difficult to obtain, estimates range from around 1% of sales in developed countries to over 10% in developing countries, depending on the geographical area. That range takes into consideration both regional disparities in the presence of counterfeits, and specific global market value shares. Apart from the huge differences between regions, variations can also be dramatic within countries, i.e. city versus rural areas, city versus city. [15]

Currently, the sources of information available include reports from non-governmental organizations, pharmaceutical companies, national drug regulatory and enforcement authorities, ad hoc studies conducted on specific geographical areas, and occasional surveys. Counterfeiting is greatest in those regions where the regulatory and legal oversight is weakest. Most industrialized countries with effective regulatory systems and market control (e.g. USA, most of EU, Australia, Canada, Japan, New Zealand) have a low proportion, i.e. less than 1% of market value. Many countries in Africa and parts of Asia and Latin America have areas where more that 30% of the medicines on sale can be counterfeit, while other developing markets have less than 10%; overall, a reasonable range is between 10% and 30%. [15]

Many of the former Soviet republics have a proportion of counterfeit medicines which is above 20% of market value — this falls into the developing country range. Medicines purchased over the Internet from sites that conceal their physical address are counterfeit in over 50% of cases.

Internet sales
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. [16] 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. [16]

Counterfeiting grows more sophisticated
Trade in fake medicines is more prevalent in countries with weak drug regulation and enforcement, scarcity or erratic supply of basic medicines, unregulated markets and unaffordable prices. But as counterfeiting becomes more sophisticated, these products are increasingly present even in better controlled markets. [17]

In January 2006, the United States Food and Drug Administration (FDA) issued an alert about fraudulent flu remedies, including counterfeit prescription oseltamivir (Tamiflu) medication. The Dutch Healthcare Inspectorate warned consumers in early 2006 not to buy Tamiflu through the Internet, after counterfeit capsules were found in the Netherlands containing lactose and vitamin C, and no active substance. In the United Kingdom, officials seized 5 000 packets of counterfeit Tamiflu in early 2006, estimated to be worth £500 000. [17]

A recent study in The Lancet concluded that up to 40% of products labeled as containing artesunate (anti-malarial) contain no active ingredients and therefore have no therapeutic benefits. That study showed that counterfeiters’ ability to reproduce holograms and other sophisticated printing techniques had dramatically improved between 2001 and 2005, making detection even more difficult.

Around the world: reports of counterfeit medicines
In Peru the sale of counterfeit drugs has risen from an estimated US$ 40 million in 2002 to a current US$ 66 million, according to Peru’s Association of Pharmaceutical Laboratories (ALAFARPE). These figures include medicines that entered the country as contraband, expired, counterfeit, and adulterated, with altered or missing labels and those stolen from the warehouses of the Ministry of Health, the armed forces, and the police. In Lima alone the number of illegal pharmacies devoted to counterfeit medicines has increased from an estimated 200 in 2002 to a current number of 1 800 stores. The General Directorate of Medicines, Supplies and Drugs (DIGEMID) of the Department of Health (MINSA) seized around 460 000 adulterated and expired medicines in 2005 alone. In 2006, Russia’s Federal Service for Health Sphere Supervision (FSHSS) reported that 10% of all drugs sold in Russia were counterfeit.
on the Russian market were counterfeit. However, other sources estimate that the real figure could be much higher. [17]

**Key challenges to halting counterfeit medicines**

Because of inadequate regulation and enforcement, the quality, safety and efficacy of both imported and locally manufactured medicines in many developing countries cannot be guaranteed. Smuggling and illegal importation of drugs are rife. [18] Counterfeit drugs are not only sold in countries with ineffective drug regulation but they are also exported or re-exported. Counterfeiters and their allies aggressively seek to avoid detection. They engage in elaborate conspiracies to disguise their activities. They establish fictitious businesses and front companies. They exploit weaknesses in border control whenever governments try to promote world commerce by reducing border inspections. [18] They use false documents to obtain essential active pharmaceutical ingredients, as well as manufacturing equipment to replicate genuine products.

Some policy-makers have argued that drug regulation represents an unnecessary barrier to trade and should be reduced to a minimum. Pharmaceuticals, however, are not a standard commodity, since consumers and prescribers are unable independently to assess their quality, safety and efficacy and the consequences of ineffective regulatory oversight can be deadly to patients. [18]

**Counterfeiting medicines is a lucrative business**

The production of counterfeit drugs need not occur in large infrastructures or facilities. The majority of the counterfeiters apprehended so far carried out their activities in ordinary households, small cottage industries, or in backyards. Counterfeiting of medicines is a hugely lucrative business due to the continued high demand for medicines and low production costs. The absence of deterrent legislation in many countries also encourages counterfeiters since there is no fear of being apprehended and prosecuted.

When prices of medicines are high and price differentials between identical products exist there is a greater incentive for the consumer to seek medicines outside the normal supply system. [19] In many countries the official supply chain fails to reach many communities, especially in rural areas. Poverty, and the lack of an official supply chain, is major factors in creating markets for counterfeit products.

**WHO leads the global effort to combat counterfeit medicines**

In order to mobilize awareness and action in the fight against fake drugs, in February 2006, WHO created the first global partnership known as the International Medicinal Products Anti-Counterfeiting Taskforce (IMPACT). IMPACT is comprised of all 193 WHO Member States on a voluntary basis and includes international organizations, enforcement agencies, national drug regulatory authorities, customs and police organizations [20], non-governmental organizations, associations representing pharmaceutical manufacturers and wholesalers, health professionals and patients’ groups. These groups have joined to improve coordination and harmonization across and between countries so that eventually the production, trading and selling of fake medicines will cease. To accomplish this mandate, IMPACT will focus on the following five key areas:

**Legislative and regulatory infrastructure**

Legal systems are often not equipped to deal with the extremely serious consequences of counterfeit medicines and penalties for counterfeiters are too light to act as deterrents. Stronger legislation will help empower those who have to deal with counterfeiters and counterfeiters in the course of their work; namely, the police, customs officials and the judiciary. Regulatory (IMPACT) will look at existing laws in countries; present effective models countries can replicate and adapt to meet their own needs. [20] Regulatory (IMPACT) will focus on developing a set of principles for the establishment of appropriate legislation and penal sanctions including a clear legal definition of counterfeit medicines. [21]

**Regulatory implementation**

IMPACT will identify the means by which regulators may take action and implement legislative measures taken on counterfeit medicines, including revised approaches to ensure that standards for quality, safety and efficacy are implemented and distribution chains effectively controlled. [21] In many countries regulatory oversight of pharmaceuticals is ineffective, especially of distribution channels. Coordinated action at the local level is essential between health authorities, police, customs, and judiciary institutions to ensure proper regulation, control, investigation and prosecution. Regulatory will help countries with weak regulatory systems to strengthen them by improving collaboration and drawing from the experience, capacity and resources of all stakeholders. [21]

**Enforcement**

Regulatory (IMPACT) will help to identify and coordinate action between customs, police and the judiciary of different countries to monitor borders, track counterfeit goods and apprehend counterfeiters. [22] By working with the World Customs Agency, Interpol, and informal networks of enforcement officers and will facilitate communication between enforcement and health authorities improve international collaboration.
and develop appropriate mechanisms that will enable importing countries, especially in the developing world, to trigger investigation and identification of the actual source of counterfeit medicines plaguing their markets. [23]

Methods

By utilizing the broad partnership from health agencies to pharmaceutical manufacturers and distributors, Regulatory (IMPACT) aims to help develop innovative solutions. Given disparities between the level of technological access in industrialized and developing countries, this will help facilitate the transfer of technology across both developed and developing countries. [22] [23] Technology can contribute creative tools and in some cases leapfrog lengthy legal and administrative processes to provide faster solutions. For under-resourced countries, means to technology transfer and adapt it to the local situation should be explored.

Risk communication

This will identify and create the most coordinated and effective mechanisms required to both respond and alert key audiences, stakeholders and the general public about counterfeits in communities and across countries. [22] International information networks will be created or strengthened to monitor the traffic of goods, exchange information, issue alerts from country to country and region to region. Increased public information is essential for patients, dispensers, and doctors who have a right to know if there are suspect goods on the market but must also contribute to detecting counterfeits by reporting and helping to investigate suspicious cases. Special initiatives will be launched to make internet users aware of the risks they run when purchasing medicines from unknown sources and to address consumers in extremely poor and rural areas where patients may be unable to make informed choices and may not be aware of their rights. [24]

Conclusion

Counterfeit drugs are a global and persistent problem. They can only be combat by international collaboration. This includes securing the actual drug product and its packaging, securing the movement of the product through drug distribution chain, enhancing regulatory oversight and enforcement, increasing penalties for counterfeiters, heightening vigilance and awareness of counterfeit drugs and increasing international collaboration.

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Illustrations

Illustration 1

Table: Examples of counterfeit medicines [8]

<table>
<thead>
<tr>
<th>Counterfeit medicine</th>
<th>Country/Year</th>
<th>Report</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-diabetic traditional medicine (used to lower blood sugar)</td>
<td>China, 2009</td>
<td>Contained six times the normal dose of glibenclamide (two people died, nine people hospitalized)¹</td>
</tr>
<tr>
<td>Metakelfin (antimalarial)</td>
<td>United Republic of Tanzania, 2009</td>
<td>Discovered in 40 pharmacies: lacked sufficient active ingredient²</td>
</tr>
<tr>
<td>Viagra &amp; Cialis (for erectile dysfunction)</td>
<td>Thailand, 2008</td>
<td>Smuggled into Thailand from an unknown source in an unknown country³</td>
</tr>
<tr>
<td>Xenical (for fighting obesity)</td>
<td>United States of America, 2007</td>
<td>Contained no active ingredient and sold via Internet sites operated outside the USA⁴</td>
</tr>
<tr>
<td>Zyprexa (for treating bipolar disorder and schizophrenia)</td>
<td>United Kingdom, 2007</td>
<td>Detected in the legal supply chain: lacked sufficient active ingredient⁵</td>
</tr>
<tr>
<td>Lipitor (for lowering cholesterol)</td>
<td>United Kingdom, 2006</td>
<td>Detected in the legal supply chain: lacked sufficient active ingredient⁶</td>
</tr>
</tbody>
</table>
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