

Counterfeit medicines

Counterfeit medicines are part of the broader phenomenon of substandard pharmaceuticals – medicines manufactured below established standards of quality and therefore dangerous to patients' health and ineffective for the treatment of diseases. The difference is that counterfeits are deliberately and fraudulently mislabeled with respect to identity or source. Counterfeiting occurs both with branded and generic products and counterfeit medicines may include products with the correct ingredients but fake packaging, with the wrong ingredients, without active ingredients or with insufficient active ingredients.

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.

Counterfeit medicines range from random mixtures of harmful toxic substances to inactive, useless preparations. 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 counterfeited medicines for the treatment of life-threatening conditions such as malaria, tuberculosis and HIV/AIDS.

Counterfeit medicines can harm and kill

The regular use of substandard or counterfeit medicines can lead to therapeutic failure or drug resistance. In some cases, it can lead to death.

- During a **meningitis epidemic in Niger in 1995**, more than 50,000 people were inoculated with **fake vaccines resulting in 2500 deaths**. The vaccines were received as a gift from a country which thought they were safe.
- **89 children died in Haiti in 1995 and 30 infants died in India in 1998** due to the consumption of paracetamol cough syrup prepared with diethylene glycol (a toxic chemical used in antifreeze).

- In 2001, in **South-East Asia**, a WHO study revealed that 38% of 104 anti-malarial drugs on sale in pharmacies did not contain any active ingredients.
- **In Cambodia**, in 1999, at least 30 people died after taking counterfeit anti-malarials prepared with sulphadoxine-pyrimethamine (an older, less effective anti-malarial) which were sold as Artesunate.

A case in Argentina: In 2004, fake medicine led to a trail of death in Argentina. Veronica Diaz was a healthy 22 year old woman, living in Viedma, Argentina, who had mild anaemia caused by insufficient iron in her blood and required her to receive iron injections. In December of 2004, she became very sick and died of liver failure after receiving the 7th of a 10 injection treatment. The medicines authority of Argentina, ANMAT, determined that she had been given a highly toxic counterfeit. Authorities were unable to determine the source of the counterfeit product due to falsified paper work.

While most of the counterfeit production throughout Argentina was recovered and four persons were prosecuted, the highly fragmented distribution system prevented the recall from being 100% successful. In May of 2005 another woman died and a 22 year old pregnant woman was injected with the same counterfeit. She survived but gave birth to a 26 week premature baby. To date, Argentinean law does not consider counterfeiting medicines a crime.

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.

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 than 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%
- 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. 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.

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.

- 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 5000 packets of counterfeit Tamiflu in early 2006, estimated to be worth £500 000.
- A recent study in The Lancet concluded that up to 40% of products labeled as containing artusenate (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, 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 on the Russian market were counterfeit. However, other sources estimate that the real figure could be much higher.

In 2005

- The **Dominican Republic's** Public Health Department reported that 50% of the countries pharmacies operated illegally and 10% of the medicines that arrived in the country were fake. For example, some of the medicines found had expired over 10 years before.

- **El Salvador's** Association of Pharmaceutical Companies (INQUIFAR) reports that there is a widespread availability of counterfeit drugs on the domestic market. According to the local manufacturer Gamma Laboratorios, the commercialization of counterfeit medicines generated economic losses of around \$40 million to the country's pharmaceutical industry that year.
- **Indonesia's** International Pharmaceutical Manufacturers Group (IPMG) estimated that pirated drugs constituted 25% of Indonesia's \$2 billion pharmaceutical market. According to IPMG, the fake drugs hit foreign pharmaceutical companies' bottom lines and posed a potential serious public health threat.
- **In Kenya**, a random survey by the National Quality Control Laboratories (NQCL) and the Pharmacy and Poisons Board found that almost 30% of the drugs in Kenya were counterfeit. Some of the drugs were no more than just chalk or water marketed as legitimate pharmaceutical products. According to figures from the Kenyan Association of Pharmaceutical Industry, counterfeit pharmaceutical products account for approximately \$130 million annually in sales in the country.

In 2004

- **In Angola**, according to the National Department of Intellectual Copyright Crime of the Economic Police, approximately 70% of medicines used by the Angolan population were forgeries.
- **In Colombia**, the Association of Colombian Pharmaceutical Industries (ASINFAR) estimated that US\$ 60 million or 5% of the total annual market of medicines sold were contraband, counterfeit or adulterated.
- **Lebanon's** National Health Commission (NHC) reported in 2004 that 35% of pharmaceuticals available in the Lebanese market were counterfeit.
- **In Mexico**, federal agents seized approximately 60 tons of stolen, expired and counterfeit pharmaceuticals in Sahuayo, Michoacán, and Guadalajara, Jalisco. Reports indicated that in Mexico alone, illegal products represented about 10% of the pharmaceutical market.
- **In Nigeria**, the Ebonyi State Task Force on Counterfeit and Fake Drugs reported that approximately 48% of goods and drugs imported into the country were substandard or counterfeit.

In 2003

- **The Philippine's** Bureau of Food and Drug (BFAD) reported that 30% of drug store outlets visited by food and drug deregulation officers carry and sell counterfeit drugs.

In 2002

- **In Cambodia**, a Health Ministry survey conducted in 2002 revealed that 13% of drugs on the domestic market were counterfeit or substandard, including anti-malaria drugs and antibiotics.
- **China's** Research and Development-based Pharmaceutical Association estimated that about 8% of over-the-counter drugs sold in China are counterfeit.
- **India's** pharmaceutical companies suggested that in India's major cities, one in five medicines sold was a fake. They claimed a loss in revenue of between 4% and 5% annually. The industry also estimated that illegal drugs had grown from 10% to 20% of the total market.

- **Nigerian** health officials estimated that 70% of drugs in circulation in the country are either fake or adulterated.

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. 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. 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.

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. 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, are 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, 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 counterfeits and counterfeiters in the course of their work; namely, the police, customs officials and the judiciary. IMPACT will look at existing laws in countries; present effective models countries can replicate and adapt to meet their own needs. 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.

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. 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. IMPACT will help countries with weak regulatory systems to strengthen them by improving collaboration and drawing from the experience, capacity and resources of all IMPACT stakeholders.

Enforcement

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. By working with both the World Customs Agency, INTERPOL, and informal networks of enforcement officers IMPACT 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.

Technology

By utilizing the broad partnership from health agencies to pharmaceutical manufacturers and distributors, IMPACT aims to help develop innovative solutions. Given disparities between the level of technological access in industrialized and developing countries, IMPACT will help facilitate the transfer of technology across both developed and developing countries. 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

IMPACT 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. 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.

For more information contact: