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## Issue Brief

### Counterfeit Medicines: A Global Public Health Risk

#### Overview

In December 2004, a 22-year-old woman died in Argentina after being injected with a counterfeit iron supplement at a public hospital. Two other women also died after receiving the counterfeit product and another dozen women were less severely harmed. These cases illustrated the extent of the penetration of counterfeit products as people died from medicines administered in hospitals.

Five years later, the authorities in Argentina are just now exposing the extensive reach of these well-entrenched criminal organizations. Arrests have been reported in a pharmaceutical counterfeiting scheme involving at least seven health plans which provide services and medicines to over three million people. Most of the counterfeit medicines were used to treat deadly diseases such as cancer, HIV/AIDS, genetic disorders, and hemophilia. These criminals diluted the drugs, recycled expired products and filled used vials with water. Argentina's Superintendent of Health Services estimated that a minimum of 20,000 patients received the illegal pharmaceuticals.

Counterfeit medicines are regularly sold on the internet, sometimes with dire consequences. In December 2006, a 56-year-old woman in Canada was found dead in her bed. There was no evidence of foul play, suicide or trauma. Among her possessions, though, were unmarked packages and bags of pills. A toxicology report showed a mix of prescription drugs in her system, but also dangerously high levels of metals, including aluminum, phosphorus, titanium, tin, strontium and arsenic, in her liver. The aluminum level alone was 15 times higher than normal.

Officials found that the pills she had been taking were from unlicensed pharmacies on the Internet. The medicines were counterfeit – poorly manufactured replicas containing impure “filler” materials. The woman's cause of death was listed as cardiac arrhythmia caused by metal toxicity.

While many would like to believe that the examples above are isolated events, they are not. Encounters with counterfeit medical treatments are reported month after month, year after year, in countries around the world. And the counterfeiters do not discriminate. Fake versions of both approved branded and generic medicines have entered the supply chain in rich and poor countries.

Counterfeit drugs pose a global public health risk. They cause illness, disability and even death, in a growing global epidemic that must be fought both locally and internationally. For many years now, the IFPMA has been an active global partner in the fight against counterfeiting of medicines.

#### Background

Criminals act deliberately and fraudulently as they seek to pass their fake versions off as approved and properly labeled medicines. All kinds of medicines are counterfeited, including many for life-threatening conditions such as cardiovascular disease, bacterial and viral infections and other serious infectious diseases like malaria. Notwithstanding that many legitimate medicines are already relatively inexpensive to buy, counterfeiters still can make a large profit by producing their copies at almost no cost - often because they do not contain the active pharmaceutical ingredient and are not made to regulatory standards – and selling them at the legitimate branded or generic medicine's market price.

## **Extent of the Problem**

Despite vigilance, the extent of counterfeiting is extremely hard to measure. Statistics are often unreliable because the evidence of counterfeit medicines is consumed and deaths are usually attributed to the disease, rather than the medicine utilized. Numbers from law enforcement agencies also underestimate the full extent of the problem because they report data from raids and seizures, which represent only a small percentage of the overall problem.

The WHO has warned against using a single, average figure for the global pervasiveness of counterfeit medicines because it misrepresents the extent of the problem. International comparisons and country rankings are also misleading because they usually demonstrate more the activity and ability of regional law enforcement authorities in catching counterfeiters, rather than showing the countries with the greatest counterfeiting problem.

The most reliable data, based on incident reporting, currently comes from the R&D-based pharmaceutical companies and is collected, analyzed and disseminated by the Pharmaceutical Security Institute (PSI), a not-for-profit organization established in 1997. Through independent research and reports from its 27 member companies, the Institute identified 1,585 incidents of counterfeiting in 2008, many of which involved millions of dosages of counterfeit medicines. The recorded incidents covered 651 different pharmaceutical products, from every therapeutic category, in 115 countries on five continents.

Incidences occurred in both developed and developing countries, but research has shown that counterfeiting is more prevalent in countries facing such problems as scarce or erratic supply of medicines, and, more importantly, weak regulatory controls and enforcement.

## **Combating Counterfeits**

Both the WHO and the IFPMA are committed to combating counterfeit medicines throughout the world. The WHO first started collecting data on the global threat posed by fake drugs in 1982. The first international forum to address counterfeits was a 1985 Conference of Experts on the Rational Use of Drugs. In 1988, the World Health Assembly adopted a resolution that requested the Director-General of the WHO to initiate programs for the prevention and detection of falsely labeled, counterfeit and substandard pharmaceuticals. In 1994, the Assembly adopted a resolution to request the Director-General to assist Member States in their efforts to ensure that available medicines are of good quality and to combat the use of counterfeit drugs. The WHO published guidelines to combat counterfeit medicines in 1999. Since then, numerous workshops, trainings and country studies have been conducted all around the world.

The reasons for the proliferation of counterfeit medicines are numerous and interrelated. Criminals are attracted to this activity because it offers a low-cost, low-risk way of making money, and the potential market is growing because consumption of medicines is increasing. This is compounded by poverty, which makes many people desperate enough to overcome their normal suspicion of unnaturally cheap medicines. The lack of risk is due in large part to the absence of adequate regulatory and enforcement capacity in many countries, especially developing ones, plus the practical difficulties of distinguishing fake medicines from genuine ones. Finally, the internet provides counterfeiters with direct access to potential buyers worldwide and helps them to circumvent national regulatory controls.

The complexity of the counterfeiting problem led regulators around the world to agree on the need for a global initiative. The International Medical Products Anti-Counterfeiting Taskforce (IMPACT) was launched in 2006. A wide range of stakeholders have been invited to participate, including WHO Member States, representatives of the health-related professions and industries, patient groups and international organizations. IMPACT builds coordinated networks of multi-disciplinary stakeholders to help halt the international production, trade and sale of fake medicines around the globe, and to assist developing countries in improving their capabilities in this area.

The IFPMA, which works with the WHO to improve medicine quality and to fight the global scourge of counterfeiting, endorsed the formation of IMPACT. The IFPMA contributes the technical expertise of its members to IMPACT's efforts, particularly targeting the needs of developing countries. The IFPMA is also affiliated with PSI, as the IFPMA Director General is a member of the PSI board.

There is broad consensus among representatives from public and private sector groups dealing with the counterfeit medicines issue that continued international cooperation (especially among trade partners) and the timely and appropriate exchange of information are needed to prevent the spread of counterfeit medicines in an increasingly interconnected world. The PSI, with the support of the IFPMA, has helped develop and implement incident reporting, enhance analytical assessments and improve the dissemination of information about counterfeiting. In addition, the PSI is helping to train and to liaise with international law enforcement, customs officers and drug regulatory authorities to improve the detection of counterfeit medicines.

Although counterfeiting is an international issue, especially with the rise of the Internet, prevention also requires a concerted effort at the national level. Unfortunately, too many countries treat counterfeiting of medicines in the same manner as counterfeiting of branded consumer goods, such as handbags or jewelry, or pirating of music or movies. But unlike counterfeit purses and music, counterfeit medicines can kill. It is also important for people to understand that there is no such thing as a “good” counterfeit; even apparently “perfect” copies can be achieved with imperfect or alternative ingredients and unsafe manufacturing practices. Indeed, this is what makes counterfeit medicines so dangerous.

Furthermore, some mistakenly and dangerously portray anti-counterfeiting efforts as a way for makers of branded medicines to curb the sale of legitimate generic drugs. Nothing could be further from the truth. Approved generic drug manufacturers have nothing to fear from efforts to stop counterfeiting medicines. Indeed, counterfeits threaten the full spectrum of legitimate medicines, including generics. Because counterfeiters do not differentiate between R&D-based pharmaceuticals and generic drugs, both R&D and generic drug manufacturers are actively involved in IMPACT and its activities. Experts from the R&D-based companies, working through the IFPMA, work closely with representatives of the generic and over-the-counter medicine industries, regulatory officials, health professionals and patient groups in pursuit of the common goal of combating counterfeit medicines of all kinds.

To effectively deter counterfeiters, the IMPACT partners recommend that the penalties be proportional to the severity of the crime – in particular, that they reflect the fact that fake medicines can endanger human life. In addition, it is important to find ways to help every country understand that, without national vigilance, guidelines and penalties, plus participation in international collaborative efforts, counterfeiting activities will hurt their own people as well as patients in other parts of the globe. The damage done by fake drugs goes beyond national borders.

## **Conclusion**

The counterfeiting of medicines poses a serious, global health risk that will continue to grow unless a concerted, national - and international - response is mounted. The IFPMA will continue to build awareness around the issue with all stakeholders, including medicines regulators, policymakers, law enforcement officials and the general public around the world.

Only by increasing awareness and changing how these crimes are perceived and dealt with will we be able to prevent further deaths and harm from counterfeit medicines.

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**About the IFPMA:**

The International Federation of Pharmaceutical Manufacturers & Associations is the global non-profit NGO representing the research-based pharmaceutical, biotech and vaccine sectors. Its members comprise 27 leading international companies and 44 national and regional industry associations covering developed and developing countries. The industry's R&D pipeline contains hundreds of new medicines and vaccines being developed to address global disease threats, including cancer, heart disease, HIV/AIDS and malaria. The IFPMA Clinical Trials Portal ([www.ifpma.org/ClinicalTrials](http://www.ifpma.org/ClinicalTrials)), the IFPMA's Ethical Promotion online resource ([www.ifpma.org/EthicalPromotion/](http://www.ifpma.org/EthicalPromotion/)) and its Health Partnerships information ([www.ifpma.org/HealthPartnerships/](http://www.ifpma.org/HealthPartnerships/)) – Developing World) help make the industry's activities more transparent. The IFPMA strengthens patient safety by improving risk assessment of medicines and combating their counterfeiting. It also provides the secretariat for the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). For more information, please go to [www.ifpma.org](http://www.ifpma.org).