

Growing threat from counterfeit medicines

Lifesaving drugs are not exempt from the trade in counterfeit medicines. The World Health Organization (WHO) is working with Interpol to dislodge the criminal networks raking in billions of dollars from this cynical trade.

In 2009, 20 million pills, bottles and sachets of counterfeit and illegal medicines were seized in a five-month operation coordinated by the International Criminal Police Organization (Interpol) across China and seven of its south-east Asian neighbours; 33 people were arrested and 100 retail outlets closed.

Also last year, a series of raids in Egypt found counterfeit medicines worth hundreds of millions of dollars and exposed a criminal network feeding consumers across the Middle East. And in Europe, customs officers seized 34 million counterfeit pills in just two months in 2009, a haul that the European Union's industry commissioner Guenter Verheugen said "exceeded our worst fears".

Results from this string of law enforcement operations around the world are slowly building a profile of the trade that shocks even regulators familiar with the issue. Health experts believe such operations have only scratched the surface of a flourishing industry in counterfeit medicines that poses a growing threat to public health around the world.

Asia accounts for the biggest share of the trade in counterfeit medicines, according to the industry-funded organization, the Pharmaceutical Security Institute. But, according to Interpol officer Aline Plançon, there are counterfeit medicine cases in every part of the world. "There is a flow of products coming from everywhere and going to everywhere, there are so many hubs," she says.

The threat from counterfeit pharmaceutical products is hardly new; many national authorities have long waged their own struggle against counterfeit medicines. Although WHO has been working actively on this complex, politically sensitive issue since it was first discussed in May 1998 at the World Health Assembly, enforcement efforts stepped up a notch in 2006 when it launched the International Medical Products Anti-Counterfeiting Task Force (IMPACT), drawing members from international organizations, enforcement agencies, industry and nongovernmental organizations.

Since then, IMPACT members have been collaborating closely on international criminal investigations, assisting

countries in strengthening their own detection and enforcement systems, and working with industry to develop such measures as secure, high-tech pharmaceuticals packaging.

Worldwide sales of counterfeit medicines could top US\$ 75 billion this year, a 90% rise in five years, according to an estimate published by the Center for Medicine in the Public Interest in the United States of America (USA). It is difficult to measure the extent of the problem when there are so many sources of information and different definitions of "counterfeit". Sabine Kopp, IMPACT's interim executive secretary and manager of WHO's anti-counterfeiting programme, says that WHO is currently conducting a survey to compare legislation and terminology used to combat counterfeiting of medical products in different countries.

"Studies really only give a snapshot of the situation as counterfeiters are extremely flexible in the way they mimic products and avoid detection," says Kopp.

There are no accurate data that accurately measure the scale of this vast, sophisticated and lucrative business, but "we're talking about big quantities seized and sophisticated criminal networks," says Interpol's Plançon, who co-chairs IMPACT's working group on enforcement.

The range of counterfeit products reaching markets has also broadened with the increased commercial use of the Internet to provide a dizzying array of both branded and generic drugs. In more than 50% of cases, medicines purchased over the Internet from illegal sites that conceal their physical address have been found to be counterfeit, according to WHO.

"In a shocking development, it was discovered relatively recently that counterfeit versions of lifesaving prescription medicines for cancer and serious cardiovascular diseases are also being sold to consumers online," the European Alliance for Access to Safe Medicines reports.

Developing countries are an obvious target for counterfeiters, because the cost of legitimate drugs may be beyond the reach of much of the population and legal controls are often weak, analysts say.

In "Operation Storm 2", the IMPACT-coordinated operation in Asia in 2009, the counterfeits seized ranged from antibiotics to birth-control medicines, anti-tetanus serums, antimalarials and drugs treating erectile dysfunction. In Egypt, investigators found everything from organ transplant drugs to medicines for illnesses such as heart diseases, schizophrenia and diabetes along with thousands of boxes of cancer drugs, Plançon says.



More than 260 premises were visited during IMPACT's Operation Zambezi in November 2009.

Even though higher-income countries have stringent regulations and better law enforcement, they also offer great rewards. According to the Medicines and Health care products Regulatory Agency in the United Kingdom, counterfeiters now also target the most lucrative markets, copying high-value, high-turnover, high-demand drugs. “Counterfeiting is primarily motivated by its potentially huge profits,” says Kopp. “Criminals are adept at quickly adjusting to where the most money can be made.”

A Pfizer-sponsored study, one of the largest investigations conducted in 14 European countries, estimated that western Europeans spend more than US\$ 14 billion a year on illicitly-sourced drugs, many of them counterfeit. A big share of the market constitutes the so-called “lifestyle” drugs. The study found that almost half the counterfeit drugs sold on the Internet were for weight loss, followed by influenza medicines. Another key market for counterfeits in Europe, as in Asia, is erectile dysfunction, nourished by the growth in online pharmacies that offer access to prescription-only medicines without the embarrassment of consulting a doctor. A Dutch study cited by the *International Journal of Clinical Practice* found that, of 370 seized Viagra samples, only 10 were genuine.

In Singapore, 150 people were admitted to hospital in the first five months of 2008 having severe hypoglycaemia – a sharp drop in blood-sugar levels. Four of them died and seven suffered severe brain damage. They had reportedly taken counterfeit copies of drugs purporting to treat erectile dysfunction but which contained a hefty dose of glyburide, used for treating diabetes.

The overall death toll attributable to counterfeit medicines, like the scale of the business, is unknown but the costs to public health are huge. Quite apart from the direct impact on individuals, counterfeits can cause resistance to medicines for tackling diseases that are leading causes of mortality. Malaria, which kills around a million people a year, is a prime example.

An unprecedented international collaboration and investigation of counterfeit antimalarials found that half of the 391 samples collected contained no active ingredient (artesunate) or too little to have any benefit. Manufacturers’ holograms provided no guarantee of protection as investigators found the

counterfeiters had developed their own sophisticated fake holograms. The results of the investigation, published in *PLoS Medicine* in 2008, concluded that the “epidemic” of counterfeits in south-east Asia had led to “deaths from untreated malaria, reduced confidence in this vital drug, large economic losses for the legitimate manufacturers and concerns that artemisinin resistance might be engendered.”

“People don’t necessarily find out that the drugs they were taking were counterfeit. Even a single case of a counterfeit medicine is unacceptable since it indicates a weakness in the pharmaceutical supply system and undermines the credibility of health systems,” says Kopp.

The scale and ingenuity of the trade in counterfeits poses a formidable challenge to enforcement. Moreover, international trade presents easy opportunities for counterfeiters to insert their products into the supply chain of legitimate pharmaceuticals and to disguise the source. “Even in hospitals, we have seen deliveries where counterfeit medicines have been added to genuine batches of medicines,” says Kopp. “The counterfeiters simply falsify the delivery papers by adding an extra zero to the quantity supplied, then they make up the difference by adding their own boxes to the order.”

Since 2008, IMPACT and Interpol have mounted operations tackling counterfeiting in east Africa and Asia and have been working with governments in developed countries against the Internet trade in counterfeit medicines. The operations are building up a better understanding of who they are up against, says Plançon. “So far we can say we are disrupting some networks,” she adds. “It’s difficult to say we have fully dismantled them, but they have been harmed for sure.”

Destroying networks is only one of the aims. At this early stage IMPACT’s other objectives are to build public and government awareness as well as cooperation between stakeholders and national enforcement agencies. Transnational cooperation is essential to tackle sophisticated, transnational criminal networks involved in counterfeiting, Plançon says.

There too, IMPACT sees positive results. In the aftermath of two “Storm” operations in south-east Asia, IMPACT wants to foster cooperation in intelligence exchanges and training. The first IMPACT/Interpol-coordinated operation



Counterfeiters use sophisticated methods to copy genuine packaging.

in 2008 targeting Internet sites trading illicit or counterfeit medicines had participation from eight countries. The second operation in 2009 involved 25 countries, including Australia, Canada, Israel, New Zealand, Singapore, South Africa, Thailand, USA and 16 European countries. It identified more than 1200 web sites engaged in illegal activity, closed 153 sites and made 12 arrests, according to Interpol.

Still, health experts and IMPACT say enforcement remains severely handicapped by weak laws and regulations for tackling counterfeiters. “Obstacles to effective action include the lack of a clear worldwide consensus on what constitutes a counterfeit drug and the fact that activities that are illegal in one country may be legal in another,” Graham Jackson, editor of the *International Journal of Clinical Practice*, commented in January.

Six years ago the International Conference of Drug Regulatory Authorities asked WHO to draft an international convention, but it has been a difficult process. No consensus has yet been reached on the text of the convention, and some governments remain opposed to the proposal. Measures to strengthen the legal framework for enforcement continue to be discussed. Plans to raise the issue at the World Health Assembly in May 2009 were pre-empted by the H1N1 influenza pandemic and hopes have refocused on this year’s upcoming Assembly. ■