

Protecting Patients: The Fight Against Counterfeit Medicines (14 min read) [1]

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Myanmar, 2005: More than half a million people were infected with malaria. So it was not surprising when, in February, a young man went to a local hospital with a high fever. He complained of headaches, chills and nausea. The doctors diagnosed malaria right away and prescribed artesunate, an antimalarial agent¹. The young man's symptoms should have disappeared after a few days – but not in this case. The concentration of parasites in his blood rose even further. He went into a coma and suffered kidney failure. The doctors tried to save him, but it was too late. The infection was too far advanced.

The course of the disease was highly unusual in this case, as the compound was considered safe and is generally very well tolerated by patients. So it was investigated in more detail, with a shocking result: the administered medication contained only 20% of the active ingredient; it was a fake.

Global reach

Time and again, there are horror stories in the media about counterfeit pharmaceutical products and their – sometimes fatal – effects on humans. Recently, WHO confirmed that both generic and innovative medicines are being counterfeited, an activity that not only poses danger to patient health but also causes an impact on the economy and on jobs. It is estimated that between 30% and 70% of medicinal products in developing countries are counterfeit.

And developed countries are not immune to this trend, with estimates putting the figure at up to 7% of medicinal products as counterfeit. Anti-malarials and antibiotics are among the most commonly reported as substandard and falsified medicinal products, but all types of medicines can be affected. They can be found in illegal street markets, via unregulated websites and in pharmacies, clinics and hospitals. In 2015, the devastating death toll from malaria was 429,000. Reports estimate that up to one-third of anti-malarials are fake.

A local hospital in Myanmar

A local hospital in Myanmar: Malaria is a very common infection that healthcare professionals have to deal with on a regular basis.

Credit: Novartis Brand Lab

The entire Novartis Group, which Sandoz belongs to, is taking the fight against illegal counterfeits very seriously. And with good cause: These low-grade products are in direct conflict with the company's purpose. Sandoz is committed to improving access to high-quality medicines, medical information and healthcare for patients throughout the world. Since it was founded in 1996, Novartis has deployed investigative resources

to examine counterfeit, falsified, illegally diverted and stolen pharmaceuticals worldwide in close collaboration with law enforcement partners. Authorities around the world are provided with timely data and evidence which they can use to launch their own investigations or mount prosecutions – an essential tool in the fight against counterfeits. In 2016, this Anti-Counterfeiting program was relaunched with the active contribution and support of a special working group, under the leadership of the Novartis Anti-Counterfeiting Steering Committee. Its core ambition is to protect patients and, beyond that, the company's reputation. An ambitious cross-functional roadmap has been designed with a set of nearly 50 objectives. Since the beginning of 2017, dozens of successful enforcement cases as well as training and awareness initiatives have been launched, with internal and external stakeholders such as local police, customs and health authorities.

“Customs statistics in recent years have shown an increase in the number of counterfeit and falsified medicines seized,” said Stanislas Barro, Global Head of Anti-Counterfeiting and Chair of the Novartis Anti-Counterfeiting Working Group, which is a pillar of the company's Global Security strategy. “Such medical products represent a serious and growing problem for patients, public health and other authorities and pharmaceutical manufacturers alike. For patients who are generally unable to distinguish between authentic, falsified and counterfeit products, the health risks are enormous.” As a global leader in generic pharmaceuticals, Sandoz is particularly affected by the growing number of counterfeits. The company is therefore working closely with the superordinate Novartis Global Security.

Every therapeutic area is affected

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Barro and his team continuously monitor and improve the security of the distribution chain, as well as the security features on the packaging of Novartis products. All cases of confirmed falsified and counterfeit Novartis products are being investigated, regardless of where they were made available, such as on the internet or on local markets. “One of the main challenges lies with identifying the criminals operating these illegal networks, especially since most of them are now operating online. This requires substantial investment and resilience in the intelligence and investigation phases of the case,” Barro says. “We report confirmed incidents to local law enforcement and health authorities, so that falsified and counterfeit

medicines are seized and destroyed – and the individuals profiting from these criminal networks are brought to justice.”

Investigators on site

One example of Global Security’s recent work took place in Burkina Faso. Until then, neither the Anti-Counterfeiting case history there nor the risk map for the region were showing anything suspicious. However, at the end of June 2017, this situation changed. Global Security sent both its Forensic Expert and Regional Intelligence Officer in charge of the African market to conduct a survey on Novartis anti-malarials found in local markets in and around Ouagadougou. After just a few days onsite with several samples collected, it was clear that there was a large presence of counterfeit medicines in circulation. The Global Security experts issued a detailed forensic report and immediately informed local health authorities and law enforcement. The samples had been analyzed by a Novartis Forensic Manager: Not only would the fake medication fail to cure the disease, it also contained chemicals that could cause serious side-effects. And there is another possible consequence resulting from falsified pharmaceuticals which aggravates the situation. “It’s entirely possible that patients would lose trust in that medicines, while the genuine product is known to be the only effective curative anti-malaria treatment available in most situations,” Barro summarizes.

Content matters

“Our experience is that falsifications are often difficult to detect,” Barro explains. While counterfeit pills often look as similar as possible to the original version, their contents are surprising. Either they contain none of the active ingredient that they are supposed to contain, or the dosage is incorrect – with both situations leading to therapeutic failure. In some cases, dangerous and potentially life-threatening substances are also found, such as bacteria or harmful materials. This is particularly the case if the compounds were adulterated under poor hygiene conditions. Although one might think that counterfeiters have no interest in causing serious harm to the consumers of their goods, patient safety is secondary to profit motivation. Indeed, there are plenty of examples of dangerous ingredients in counterfeit medicines, from antifreeze to bacterial contamination to dangerously high doses of painkillers. These mixtures range from quite accurate to utterly reckless; compounds of colored clay, sealed with wax, have even been found.

- Michele Riccardi

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It's a really profitable business. The value-volume ratio is higher than for many illegal drugs.

Michele Riccardi, Transcrime

The people who operate this business cannot be pigeonholed either. "There is not only one type of counterfeiter. They range from simple retailers at a local flea market to a large scale and sophisticated criminal organizations owning tens of thousands of rogue online pharmacies and operating from many countries with very substantial financial means," Barro explains. The latter function like large, international firms and have the technology to master complex manufacturing processes themselves. And, presumably, there is an entire illegal chain: suppliers of raw materials, manufacturers, exporters, importers, distributors and others in between. Most counterfeit medicines come from India and China. To conceal their origins, the manufacturers often choose complex routes with multiple middlemen. The products head west through black market channels. Research suggests that it is not unusual for these counterfeit products to change hands more than 30 times before reaching the end customer.

Thefts with consequences

When it comes to white-collar crime and illegal supply chains like these, Michele Riccardi is all ears. For ten years, he has been investigating these cases at Transcrime, a research center at the Catholic University of the Sacred Heart in Milan, Italy. "It struck us that there were more and more media reports emerging about medicine theft. We wanted to follow up on them," he explains. Large-scale theft of prescription products, particularly for oncology, occurred at Italian hospital pharmacies during 2013 and 2014. "In Italy and many other countries, these items are covered by health insurance," Riccardi notes. "So why steal medicines that cannot be sold on the black market?" The research team was onto something bigger. The stolen cancer treatments appeared again in the UK, the Netherlands, Spain, Portugal, Finland and particularly Germany – in the legitimate supply chain. A complicated network of receivers and bogus corporations ensured that criminals could smuggle the goods back into the regular market.

A briefcase full of valuables

"It's a highly profitable business. If someone manages to steal a briefcase full of cancer medicines from a hospital, the contents may well be worth 150,000 to 200,000 euros," Riccardi says. "That is a better value-to-volume ratio than for many illegal drugs." The goods stolen from Italian pharmacies were laundered through wholesalers registered in Italy, Latvia, Hungary, Romania, Slovenia and Slovakia. With fake documentation, it seemed as if the packs came from legal sources. In reality, the Camorra (the Italian crime syndicate) and other organized criminals were involved.

Counterfeit drugs may contain:

- the original medicine in fake packaging
- no active ingredient at all (placebo)
- too little active ingredient (underdosed)
- too much active ingredient (overdosed)
- the wrong active ingredient
- toxins, impurities or bacteria

“Actually, stolen genuine medicines fall under the definition of falsified medicinal products recently proposed by the WHO. They mislead the patient as to the actual source of the pharmaceutical purchased and the way it was shipped and stored,” Stanislas Barro says. People who illegally steal and distribute cancer therapies are unlikely to observe the cold chain for storage and transport. Thus, to secure the distribution chain is one of the most important tasks in the fight against fakes. “Fortunately, our supply chain is one of the most secure in the industry. There have been very few incidents in recent years,” Barro explains.

Small changes, big impact

Even if the counterfeit itself is not toxic, substandard medicines prevent patients from receiving their required treatment. Because they are unaware that they are taking an inferior product, their conditions can worsen and, in critical cases, be fatal. Children and older people are particularly vulnerable to the real danger of cheap pharmaceutical copies. So are cancer patients, whose immune system is greatly weakened, especially during chemotherapy.

To reduce the risk of infection, legitimate medications are packed under sterile conditions and often require refrigerated storage. Medication dosages are also individual – based on the patients’ weight and stage of illness. In addition, the dosages for the same medicine may vary from one country to another, thereby potentially posing a serious threat to the health of the patients. Small dosage variations mean that the patient is not receiving the best treatment. Inaccurate medical treatment can lead to serious health problems and also mean that the treatment does not prolong life.

- Stanislas Barro

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- Our supply chain is one of the most secure in the industry.

Stanislas Barro, Global Head of Anti-Counterfeiting and Chair of the Novartis Anti-Counterfeiting Working Group

Joint action

Solving this issue requires a sustained commitment not only from national governments and international

health organizations, but also from the pharmaceutical industry and other healthcare stakeholders. Companies are joining forces and working more closely together to address the counterfeit problem via organizations such as the Pharmaceutical Security Institute, a non-profit founded in 2002. Today, it is comprised of 33 member companies dedicated to sharing information on the counterfeiting of pharmaceuticals, which paves the way for enforcement action such as raids, product seizures, arrests and prosecutions by authorities.

About 5.1 tons of counterfeit medicines were seized and destroyed in Phnom Penh, Cambodia, in 2014

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Customs have always been and will remain a cornerstone in the company's anti-counterfeiting strategy. Still, medications in the erectile dysfunction category represents the clear majority of counterfeit and falsified products seized by customs. "We need authorities also to focus on more complex categories of pharmaceuticals which are harder to detect yet represent a very high risk for the patients," Barro says. "Our responsibility is to provide authorities with enough information about our key products – especially in high-risk countries – to enable them to perform a meaningful risk analysis on a regular basis." To further intensify cooperation and raise awareness, Novartis has recently launched an ambitious customs recordation process in key countries.

Novartis is also actively cooperating with trade associations such as the Global Fund, the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), which campaigns globally against counterfeits. With an educational video and the global awareness campaign, "Fight the Fakes," it aims at warning consumers about the danger from counterfeit medicines. "Such cooperation between the private sector and trade associations is absolutely crucial," says Barro. "It is paramount that we can assure patients that products that bear our name are, in fact, our products, backed by superior, unwavering standards of quality, safety and efficacy. Our responsibility in this respect is a powerful incentive for us to get better at what we do every day."

1. <http://apps.who.int/medicinedocs/en/d/Jh2922e/2.5.11.html>

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