

# FORTIFYING MEDICAL SUPPLY CHAINS

THE CASE FOR FIGHTING  
FALSIFIED MEDICINES  
**WITH DIGITAL  
SURVEILLANCE**

Spotlight  
Series

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# FORTIFYING MEDICAL SUPPLY CHAINS

## THE CASE FOR FIGHTING FALSIFIED MEDICINES WITH DIGITAL SURVEILLANCE SYSTEMS

Substandard and falsified medicines are a major threat to public health and responsible for hundreds of thousands of deaths each year – mostly in low- and middle-income countries. Digital, AI-based control systems throughout the supply chain and at end-user level can help to curb the activities of the global counterfeit crime networks.

### THE ISSUE AT STAKE

➔ **MEDICINES ARE MADE TO HEAL.** But some are made to steal. Falsified or counterfeited pharmaceuticals put millions of lives at risk, and billions of dollars in the hands of criminal gangs. From sudden death to global pandemic, this issue threatens every single person on our interconnected Earth – physically, psychologically, and financially.

The WHO estimates that currently one in ten medical products in low- and middle-income countries is substandard or falsified.<sup>1</sup> But their presence in high-income countries is also not negligible. Digital technology is rapidly worsening the problem. An estimated 50 percent of all medicines purchased over the Internet from illegal sites that conceal their physical addresses are counterfeit.<sup>2</sup>

#### CONSEQUENCES

On the individual level, consuming a substandard or falsified medical product can be lethal. **The WHO estimates that, in sub-Saharan Africa alone, counterfeit antibiotics and antimalarials are responsible for the death of 286,000 children each year.**<sup>3</sup> In some cases, a patient who believes they are taking a life-saving medication, (e.g., for high blood pressure) may actually be taking a medication where the active ingredient has been diluted or omitted altogether. In other cases, an ingredient may be swapped out for

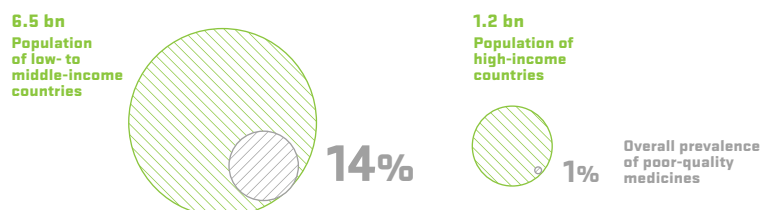
something toxic, causing adverse reactions or death by poisoning.

On the population level, substandard and falsified medicines contribute to the ever-looming threat of a pathogen-based pandemic. The main risk here is the development of antimicrobial resistance linked to subpotent antibiotics and antimalarials.<sup>4</sup>

On the financial level, as the magnitude of the problem grows and falsified and substandard medicines continue to circulate, so does the financial burden. For low- and middle-income countries, the WHO estimates an annual financial damage of about \$30 billion.<sup>3</sup>

### The counterfeit divide

People in low- to middle-income countries have a much higher risk of becoming victims of falsified or substandard pharmaceuticals.



SOURCES: OZAWA ET AL., 2018<sup>5</sup>, FRONTIER ECONOMICS, 2016<sup>6</sup>

→ On the global level, because the highest occurrence of substandard and falsified medicines is in Africa, Western institutions have tended to take on an “it’s their problem not ours” mentality. However, as the Covid-19 pandemic has drastically demonstrated, a regional health problem can become a global health disaster in almost no time at all. The interdependence of a globalized economy didn’t allow any state or region to wall itself off against the coronavirus. And the next pandemic won’t allow it, either. Protection for the poor against counterfeit medicine is protection for everyone on the planet. ←

## OBSTACLES

→ **THERE ARE SURPRISINGLY LOW RISKS** for the counterfeiters of pharmaceuticals. Their criminal activities are responsible for hundreds of thousands of deaths, but only a few hundred individuals engaged in manufacturing counterfeit medicines are arrested each year (e.g., in 2018, it was exactly 405 people, 233 of them in China).<sup>7</sup>

The low numbers are mainly down to difficulty of detection. Criminal networks often opt for small-scale shipments<sup>5</sup> and operate in the free trade zones of global trade hubs like the United Arab Emirates, Singapore, and Hong Kong (China). They serve as transit station and blur the trail from producers (mainly in China or India) to end-users (mainly in Africa and Asia).<sup>7</sup>

Additionally, in stark contrast to other counterfeit goods such as shoes or watches, there is a time limitation: the detection of drug counterfeiting is extremely difficult after fake medicines have been ingested by patients.<sup>8</sup>

### CORPORATE COMPLACENCY

While designer and luxury brands invest substantial resources in the protection of their intellectual property, pharmaceutical companies have a rather lukewarm approach to fighting counterfeits. A report by PWC-owned consultancy Strategy& even noted a “complacency” among pharmaceutical executives: “Our conversations (with these executives) revealed little enthusiasm for additional anti-counterfeiting measures, despite widespread awareness of significant vulnerabilities in current security systems.”<sup>9</sup>

One reason for this behaviour, according to Strategy&, is that these companies just had to invest heavily in implementing the

## Terminology



### SUBSTANDARD MEDICINES

Authorized medicines that have failed to pass assigned standards set out by the regulatory agencies of individual countries. A medicine may be labeled “sub-standard” even if the manufacturer made best efforts to follow protocol – due to supply chain error, such as in handling, storage, or transport.



### FALSIFIED MEDICINES

Medicines that have been deliberately and fraudulently mislabeled. This may involve dilution of the active ingredient(s) so the medicine contains an incorrect dosage, omission of the active ingredient(s) entirely, or replacement of all or part of the active ingredient(s) with a different substance.



### COUNTERFEIT MEDICINES

Medicines that are unauthorized or manufactured by entities that are not authorized to produce or market the products. Usually, these companies do not own any intellectual property (IP) or trademarks relating to the medicinal products.

**“Whenever demand is higher than supply, counterfeiters will close the gap. But when it comes to fake medicines, the result can be lethal.”**

MARGOT STUART, COO ORIGINAL SA

new EU counterfeit guideline, so why start again, this time for Africa or Asia?<sup>9</sup> This attitude shines a light on an overarching issue in combating counterfeits: the collision of national or regional regulations with global supply chains. Multiple organizations, each with its own databases and preferred methods of analysis and intervention, are all tackling the issue from different angles.

One industry’s weakness is another industry’s opportunity. Strategy& sees promising markets for technology companies to provide surveillance solutions: “Drug companies won’t necessarily have to build their own anticounterfeiting ecosystems. They can hand off all or part of the work to external providers.”<sup>9</sup> ←



## PROGRESS

**→ LAUNCHED IN 2008**, Interpol's Operation Pangea is the best-known international effort to disrupt the online sale of counterfeit products. Since it got underway, Operation Pangea has removed more than 100 million units from circulation and made more than 3,000 arrests.<sup>11</sup>

In 2013, the WHO launched the Global Surveillance and Monitoring System based in Geneva to coordinate global efforts with health and legal authorities in individual countries. The system works with WHO Member States to improve the reporting of substandard and falsified medicines, and ensures the data collected are analysed and used to improve policy, procedure and processes at all levels to protect public health.<sup>4</sup>

The WHO also launched a prequalification system for producers of pharmaceuticals, which involves a stringent review of safety and efficacy data, as well as site inspections. However, this system only covers medicines for certain diseases – mainly HIV, tuberculosis and malaria.<sup>4</sup>

New technologies are also providing new opportunities to fight counterfeiters. Blockchain technology can provide new levels of supply chain transparency and make it easier to detect fraud and identify weak points in the supply chain.<sup>12</sup>

Another promising new technology angle is mass verification by the end-user. "With the appropriate incentives we can make every smartphone user an 'enforcement agent' in the fight against counterfeits," says Margot Stuart, COO of Swiss product security company OriginAll.<sup>13</sup> In January 2021, the African Continental Free Trade Area (AfCFTA) started a partnership with OriginAll and the Future Investment Initiative (FII) Institute to eradicate counterfeit and illicitly traded products from the African continent.<sup>14</sup> ←

## WHAT CAN YOU DO?

**→ HEALTH IS A PERSONAL ISSUE**, and at the same time a global one. To combat the problem of fake medicines, we must acknowledge the interconnectedness of global health systems and outcomes. "Their" problems are also our problems – and vice versa. We share the responsibility to eradicate counterfeit products from global markets. We, the industry. We, the governments. We, the NGOs. We, the people. ←

## Most counterfeited medicines

1

### HIGHEST COUNTERFEIT VOLUME: ANTIBIOTICS

Looking at market value, antibiotics are the drugs most targeted by counterfeiters. They account for about one-third of the overall value of fake pharmaceuticals seized by customs authorities worldwide.<sup>10</sup>

2

### HIGHEST COUNTERFEIT RATE: MALARIA

According to a meta-study covering 265 studies about the prevalence of poor-quality essential medicines, anti-malarials had the highest counterfeit rate, with an overall prevalence of 19.1 percent poor-quality products.<sup>5</sup>

3

### BEST SELLING ONLINE: ERECTILE DYSFUNCTION

In Interpol's Operation Pangea, which since 2008 has targeted illicit pharmaceuticals sold online, the highest number of seizures were of fake erectile dysfunction medicines, followed by anti-depressants and anabolic steroids.<sup>11</sup>

## What can be done by decision-makers on the global, the local or the regional level?

- 🔗 We call on governments to facilitate investment in new technologies that discover fake medicines early, facilitate tamperproof monitoring via AI technologies to track counterfeit medicines, and develop apps that allow customers to report fake medicines earlier and more frequently than is currently possible.
- 🔗 We call on international institutions to develop an integrated, comprehensive framework to address this problem. Parts of this framework are unified systems for registration and reporting (spearheaded by the WHO), that should be rolled out to cover all medicines of vital importance.
- 🔗 We call on pharmaceutical corporations to abandon their complacency regarding fake medicines in low-income countries. As global players, they should be the drivers of global solutions to ensure good medicine, not laggards.
- 🔗 We call on start-ups and social entrepreneurs to fill the gaps left on the ground by imperfect control systems. Health communication networks, surveillance apps, and other high- and low-tech tools can empower medical staff, patients, and their loved ones – and deter the counterfeiters.

## ABOUT FII INSTITUTE

 **THE FUTURE INVESTMENT INITIATIVE (FII) INSTITUTE** is a new global nonprofit foundation with an investment arm and one agenda: Impact on Humanity. Global, inclusive and committed to Environmental, Social and Governance (ESG) principles, we foster great minds from around the world and turn ideas into real-world solutions in five critical areas: Artificial Intelligence (AI) and Robotics, Education, Healthcare and Sustainability. We are in the right place at the right time: when decision makers, investors and an engaged generation of youth come together in aspiration, energized and ready for change. We harness that energy into three pillars: THINK, XCHANGE, ACT. Our THINK pillar empowers the world's brightest minds to identify technological solutions to the most pressing issues facing humanity. Our XCHANGE pillar builds inclusive platforms for international dialogue, knowledge sharing and partnership. Our ACT pillar curates and invest directly in the technologies of the future to secure sustainable real-world solutions. Join us to own, co-create and actualize a brighter, more sustainable future for humanity.

This series is part of the Institute's approach to addressing issues related to the prior-itisised healthcare topics in line with SDG3 and beyond. To drive results, we will focus on infectious diseases, non-communicable diseases and other medical barriers impeding development, leveraging the advantages of technology, such as AI and robotics, as a solution for such endeavours.

To do so, the healthcare roadmap sets forth a three-step process in which inhibitors to progress are identified, potential solutions are mapped out, and organizations and individuals to partner with are approached. The main outputs of this process will be publications addressing topics relevant to these goals, hosting virtual and physical conferences to raise awareness and build momentum, working with like-minded partners to issue grants to propel innovative research, and participating in third-party events to contribute to thought leadership. ←



### Contact

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