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Contribution
by
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Trade in falsified medicines: a danger to health and development

Falsified and substandard medicines represent an incredible risk to the global safety of populations around the world. It is estimated that even in the most secure markets, at least one percent of all drugs in circulation are counterfeits.¹² These numbers rapidly spike in certain geographical areas. As the WHO states, 10 percent of medicines circulating in low- and middle-income countries (LMIC) are substandard. In the African continent alone, fake medicines correspond to an average of 42% of the total medicines available on the ground², reaching levels of 70% in certain countries³.

It is important to understand the multiple issues and differences found in unfit products on the market. Falsified medicines refer to fake drugs that are introduced as real, authorized substances. These are medicines that are designed to mimic real products and that unaware patients might take in place of real cures. Counterfeit drugs instead are medicines that are not conforming to trademark laws, or that do not comply with intellectual property rights. Whereas, substandard medicines are authentic products that fail to meet either their quality standards or specifications. Manufacturers of substandard drugs may also repackage expired official medicines, substitute a later expiration date, or use the package of an alternative substance as if it was an original product.

Falsified, substandard and counterfeit medicines can have horrifying consequences on one's health, as the active substances could bring to aggravated permanent health issues, adverse side effects, treatment failures, resistance, toxicity, and even death. These have a difference with respect to diverted medical goods, as these last ones refer to medicines that were meant for a specific market, which instead are illegally sold in a different region. All these represent a substantial threat to people, Governments and Pharmaceutical companies.

The counterfeit pharmaceutical business results in €188 billion annual sales, making it the largest sector out of the €1.6 trillion in illicit goods sold yearly worldwide⁴. These illegal activities have a negative impact on the economic growth of a country, undermine good governance, challenge citizens' trust in Governments, threaten political stability, can cause health and safety implications for citizens, and damage the brand image of companies. Unfortunately, the issue of counterfeited medicines has such a dominant presence as a result of high profitability, paired to a low risk of persecution, a low risk of detection and weak enforced penalties.

As hard drug trafficking has been highly targeted by authorities and the penalties associated to it have highly increased, illicit crime has reverted its attention towards medical counterfeiting. This last criminal activity has in fact lower penalty implications and often involves duplicates which are cheaper to fabricate. About 30 percent of countries worldwide lacks efficient drug regulatory agencies, making it less difficult for criminals to act.

Also governments bear the unpleasant consequences of medical fakes. The effects are varied and touch many aspects within the stability and wellbeing of a society. Fake pharmaceuticals decrease the population's life expectancy, curb public confidence in healthcare, and reduce healthcare

¹ [fighting-counterfeit-pharmaceuticals.pdf \(pwc.com\)](#)

² [-eng.pdf \(who.int\)](#)

³ [fighting-counterfeit-pharmaceuticals.pdf \(pwc.com\)](#)

⁴ [fighting-counterfeit-pharmaceuticals.pdf \(pwc.com\)](#)

policies efficiency. All this while failing to address the parallel trade and the fuelling of organized crime groups. This has a concrete financial impact. Countries will see their healthcare support investments increase, while witnessing their population's life expectancy and wellbeing decrease, facing a decrease in tax collection. In another case scenario, states will experience the write off of investments into youth education, as a result of the loss of many thousands of years of productive lives.

Falsified and substandard medicines are in fact responsible for over 1,000,000 deaths a year⁵. If these were considered a disease, they would be on the top 10 most deadly illnesses, as the number of deceases is equivalent to the Hepatitis-B and -C yearly mortality, combined.

Substandard, falsified, and counterfeited medicines are often difficult to identify, detect, and track. The copies are intended to look as similar as possible to the real drug, sometimes tricking also trained eyes. This is why it is fundamental for regulatory bodies to put in place systems able to detect, prevent, and reduce the issue as early and comprehensively as possible. The technologies best fit to address the problem can be classified as physical (such as the authentication security features hereunder), digital (such as track & trace, potentially secured by blockchain), or a combination of the two.

A physical solution would make the best use of authentication technologies. Notwithstanding limited resources and enforcement capabilities, authorities can effectively combat falsified and substandard medicines through solutions that integrate traceability, anti-tampering, and authentication features.

For traceability, marking the secondary packaging with a unique 2D barcode allows capturing data on the product and recording it in a central database for subsequent verification. However, without any authentication capabilities, it remains possible to print the 2D barcode of an original product on a counterfeited one or to recycle reused packaging that should have been decommissioned. To determine if the product is carrying a duplicate code and distinguish a genuine from a fake product, many manufacturers use traceability proprietary security features in addition to serialisation.

By requiring a governmental secure seal to be applied to all products, authorities benefit from a standard approach that can be securely verified and authenticated by all stakeholders. Serialisation and authentication are not sufficient to prevent the reuse of packaging and the manipulation of its content. Anti-tampering features, such as folding boxes closed with glue, film wrappers, sleeves, breakable tearaway closures and seals, should be mandatory, to provide evidence of packaging integrity.

SICPA can provide solutions that encapsulate these physical and digital aspects, including also the above described authentication security features. These allow an exhaustive and comprehensive protection against counterfeits and illicit trades. The relevant solution needs to comply with a range of factors, including the location in which a solution is to be implemented, the market structure (e.g. who purchases the products; how is the supply chain organized; who administers the products...), the technology pervasiveness (e.g. what type of cell phone are mostly used in the implementation area; what type of optics; is there a stable internet reach – for example in rural areas..), the degree

of intensity of illicit trade, the budget, and much more. In addition, SICPA's solutions can include a range of digital features to best suit the market and customer's needs. Some examples include a

⁵ [A Global Model to Reduce Deaths from Counterfeit Drugs in the Pharmaceutical Industry | American University, Washington, D.C.](#)

verification feature secured by the block chain, authentication apps, and digital security systems to enforce process integrity.

Market leader in security inks and leading provider of secured authentication, identification, traceability and supply chain solutions, SICPA is a long-trusted partner to governments, central banks, high security printers and the industry. Every day, governments, companies and millions of citizens rely on its expertise, which combines material-based covert features and digital technologies, to protect the integrity and value of their currency, personal identity, value documents, e-government services, as well as products and brands. True to its purpose of Enabling Trust through constant innovation, SICPA aims to further an Economy of Trust worldwide, where transactions, interactions and products across the physical and digital worlds are based on protected, unforgeable and verifiable data.

Amongst SICPA's multiple industry focuses, the Health Security Solutions (HSS) scope ensures the authenticity of pharmaceutical and medical products such as diagnostics, drugs, vaccines, medical equipment, and key documents (tests, certificates, prescriptions). Moreover, SICPA is dedicated to developing new solutions that will help authorities monitor and anticipate health risks, reinforcing their autonomy and enhancing their systems' response to health crises.

Founded in Lausanne in 1927, headquartered in Switzerland and operating on five continents, SICPA employs about 3000 people.