

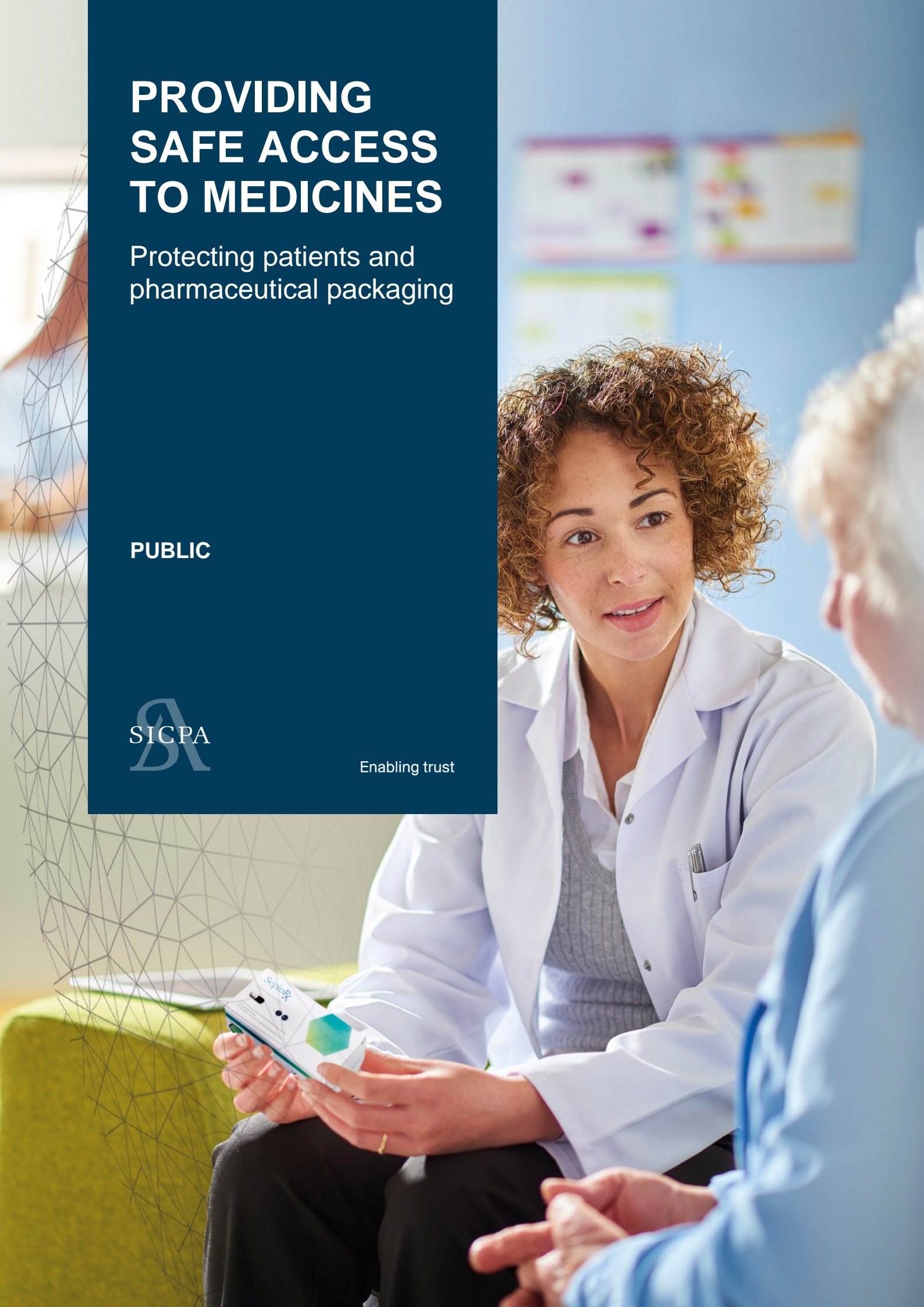
PROVIDING SAFE ACCESS TO MEDICINES

Protecting patients and
pharmaceutical packaging

PUBLIC



Enabling trust



Providing safe access to medicines: Protecting patients and pharmaceutical packaging



Imagine a parent giving a sick child what they think is a life-saving medication. But the child dies because the drug turns out to contain no active pharmaceutical ingredient.

Human lives behind the statistics

Accurate figures for fake and falsified medical products are hard to come by. The World Health Organisation (WHO) estimates that up to 30% of medicines sold in developing markets in Africa, Asia and Latin America are fakes, as are up to 8% of medical devices.ⁱ The issue may be more acute in developing countries, but counterfeiting of medicines and medical devices also occur in developed countries.

In 2012, the United States Food and Drug Administration issued warnings of a fake cancer drug that entered the US medical distribution system.ⁱⁱ German customs seized nearly four million counterfeit pills in 2015, a year.ⁱⁱⁱ Behind these statistics are millions of

patients who rely on access to an essential medicine or medical device to manage a disease or to stay healthy.

The cost of success

Over the last century, the pharmaceutical industry invested in research and development, driving progress in both innovative drug discovery and improved patient access. Yet that success faces a life-threatening risk from counterfeiting.

What makes the threat urgent today is an expected rise in chronic diseases such as cancer, diabetes and heart diseases. Chronic diseases will account for 57% of the “global burden of disease” by 2020, up from 46% in 2001, says WHO^{iv}

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To manage such illnesses, patients are often required to take, over a long time, regular doses of a treatment often delivered using a medical device. As chronic diseases rise, so does the risk of patients coming across fake medications or fake medical devices.

Fighting the counterfeiting virus

The need to act is urgent. The technologies to do so are on the market. However, the true challenge lies elsewhere.

“Counterfeiting is like a virus that attacks healthy, successful brands and puts at risk the patients who rely on them for their health and well-being,” said Fabienne Le Tadic, Executive President for Product & Brand Protection at SICPA SA.

A global provider of secure identification, traceability and authentication solutions and services, SICPA brings decades of experience in product security, including over 10 years working with healthcare clients. Over the decades, the company has implemented its security solutions on an industrial scale under some of the most stringent regulatory conditions and in some of the most challenging locations in the world.

Tackling the root causes

What drives counterfeiting? “Greed,” said Ms Le Tadic. “Counterfeiting is an illicit business, but a profitable one.” For criminals, the financial incentive is high. Different sources estimate fake medicines and medical devices at up to USD 200 billion per year. That figure exceeds the GDP of Greece in 2016.^v

“To fight counterfeiting, you have to tackle the root causes. Just focusing on technology is not effective. That’s why SICPA takes a holistic approach,” she said. That approach makes the company unique.

Using a risk management approach

SICPA brings its clients its end-to-end risk-management process. It starts with a full security assessment and needs definition.

That is vital for identifying weak spots, especially since many healthcare companies work with many partners along their value chain.

Pharmaceutical companies today may, for example, be outsourcing their research to contract research organisations (CROs) or their production to contract manufacturing organisations (CMOs). Combined with the high value of the products themselves, such complexity makes certain pharmaceutical companies vulnerable to supply chain infiltration, as well as product tampering and counterfeiting.

Designing a robust solution

Another step in SICPA’s process and part of its success with clients is designing the security solution in close partnership with each client, so that the solution fits that client’s business needs and processes. While the client brings valuable insights into the problems they face, SICPA offers a comprehensive portfolio of material and digital security technologies, most of them unique and hard to copy.

By combining different technologies, SICPA designs security solutions that are robust and reliable – hallmarks of the company. “It does not matter how sophisticated your technology is if it is not robust or if it does not work when used in real life and under real conditions,” Ms Le Tadic explained.

Need for performance monitoring

The SICPA risk management process does not end with design. SICPA accompanies its clients through the phase of system deployment and all the way to performance monitoring.

“We are especially attentive to the needs of our pharma clients. They operate under some of the strictest regulations in the world. Knowing their challenges and constraints, we aim to minimise the impact on the manufacturing process when deploying and operating our security solutions,” said Fabienne Le Tadic.

“Likewise, real-time performance monitoring is vital if you want to take action against a counterfeiter and enforce your rights when you do find someone trying to fake your product,” she added, pointing to PLASTIWARD™ that SICPA developed and launched with Clariant.

For pharmaceutical and medical device companies seeking to protect patients against counterfeit products, PLASTIWARD™ is in-product protection system for plastic medical devices and pharma packaging that brings protection as close as possible to the medicine.

The turnkey system enables pharmaceutical company inspectors to check instantaneously if a plastic medical device is real or not. The data is uploaded onto a secure inspection platform that offers real-time monitoring. By pooling this real-time field-inspection data, companies can create a reliable, real-time picture of what is happening on the ground and take speedy countermeasures if needed.

Providing safe access to medicines

“Healthcare companies have the mission of providing access to safe medicines. Our mission is to make sure that that access is safe, too,” said Ms Le Tadic.

“For SICPA, our company motto – Enabling Trust – is more than a promise. It is our commitment to work with companies to offer consumers peace of mind every time they choose a product or brand,” she added.

CONTACT

For further information, contact us:

- SICPA: info@sicpa.com
- Clariant: fightthefake@clariant.com

REFERENCES

ⁱ Source: <http://www.who.int/medicines/services/counterfeit/impact/TheNewEstimatesCounterfeit.pdf>

ⁱⁱ Source: <https://www.fda.gov/drugs/drugsafety/ucm291960.htm>

ⁱⁱⁱ Source: <https://www.euractiv.com/section/health-consumers/news/fake-drugs-cost-eu-billions-of-euros-its-health-and-its-jobs/>

^{iv} Source: http://www.who.int/nutrition/topics/2_background/en/

^v Source: <http://databank.worldbank.org/data/download/GDP.pdf>