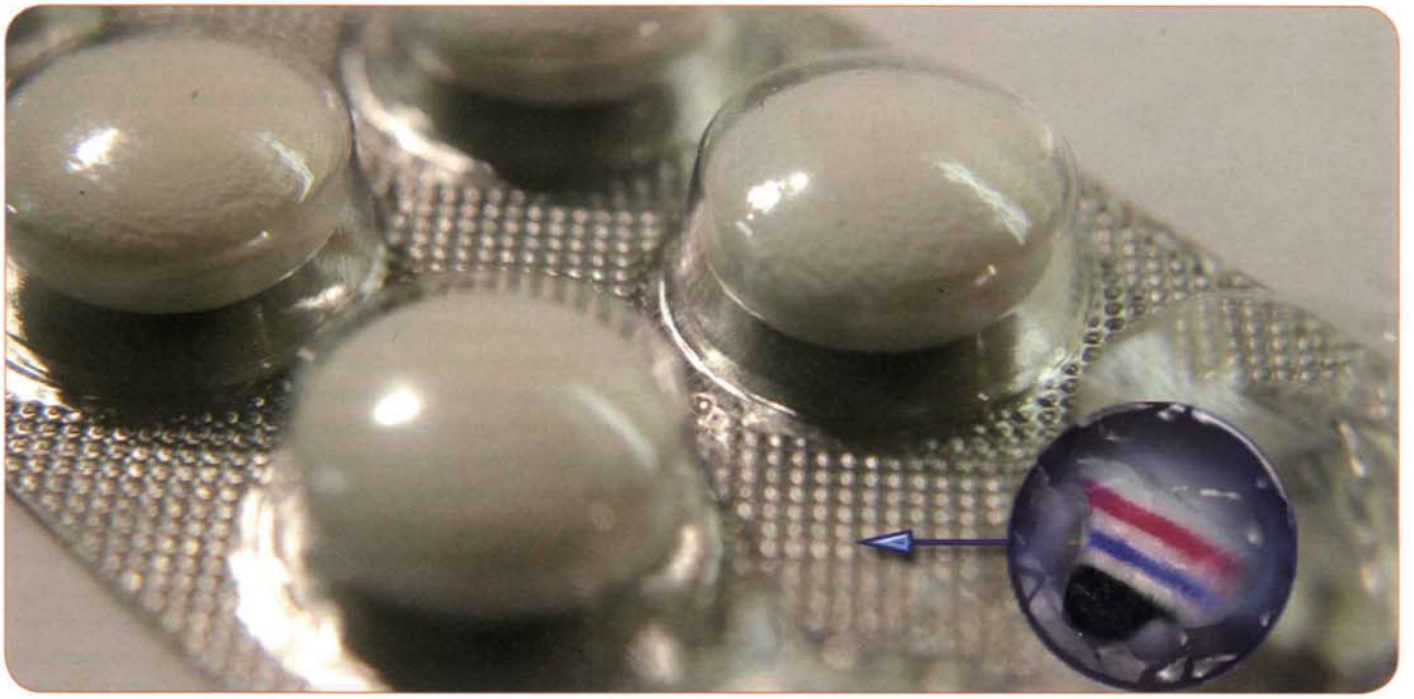
Pharmaceutical piracy: too dangerous to be ignored

Nicole Golomb, *3S Simons Security Systems GmbH*



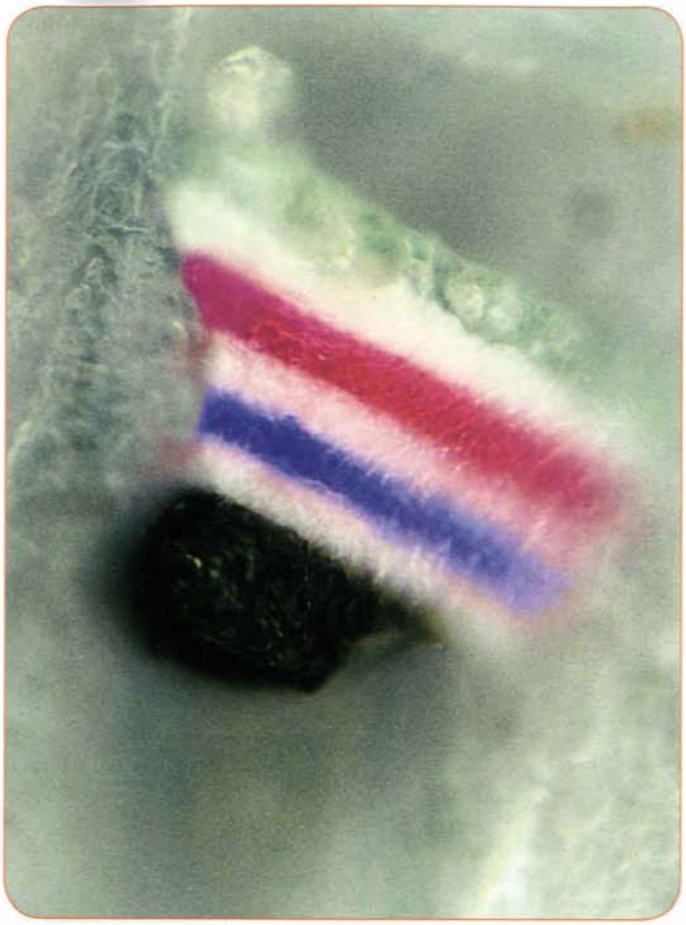
INVISIBLE TO THE NAKED EYE: PRIMARY PACKAGING MADE COUNTERFEIT-PROOF

The OECD estimates that the total sales generated worldwide with counterfeited products are about US $200 billion. This amount corresponds to approximately 2% of the international trade, or to the GDP of 150 countries. The German CCI reports that, in Germany alone, product piracy has caused economic damage of €20 to 30 billion. The dark figure is even higher. The increase of the global piracy of pharmaceutical and body care products is especially alarming, since these products present a potential danger to the health of consumers. Besides political initiatives and legal measures against counterfeiting, product traceability and effective product security are becoming more and more important.

The days when plagiarists' profit greed was limited to copying brands or electronic products are long gone. The pharmaceutical market is now becoming increasingly affected by bold product piracy. According to the World Health Organization, about 10% of all pharmaceutical products sold worldwide are copies. In the developed countries, counterfeited pharmaceutical products make up about 1% of the market share, whereas in the less-developed countries this share amounts to 30%. In 2006, 2.7 million copies of pharmaceutical products were confiscated at the external borders of the EU alone – an alarmingly high number considering that it is four times the amount confiscated just a year earlier. When also taking into account that in 2005 pharmaceuticals were still listed under "miscellaneous" in the annual report of the German organisation for protection of intellectual property (ZGR), we get an idea of how serious the present-day situation really is. In 2007, the number of counterfeit pharmaceutical products saw a particularly large increase. ZGR reports that whereas in 2006 pharmaceuticals made up about 1.5% of the counterfeit products seized, their share jumped to 10.76% in 2007. These figures more than clearly show an aggravation of the situation and the necessity for a better protection of consumers against pharmaceutical counterfeits.

WORST CASE: DEATH

According to the WHO, a counterfeit or fake drug is a medicine which is deliberately and fraudulently mislabelled with respect to identity or source. In 20% of the cases, counterfeits contain the wrong dose of an active pharmaceutical agent. More than half contain no active agent at all. Fake drugs often include toxic or allergenic substances that pose an acute threat to the life and health of consumers. Diseases that could actually be cured through the right medication are either not treated adequately, or are not treated at all. In the worst case, a treatment with fake drugs could cause the patient's death. In the developing countries, the prevalence of fake drugs for the treatment of lethal diseases like malaria, tuberculosis and AIDs has reached alarming proportions. In



SECUTAG® – THE SMALLEST MICRO COLOUR-CODE PARTICLES WORLDWIDE

Europe, so-called lifestyle products such as drugs against hair loss, obesity or erectile dysfunction are especially prone to fraudulence. Most of these drugs are purchased over the Internet. This source of supply is especially susceptible to shady business. The anonymity of the Internet and thus of the virtual dealer additionally promotes the counterfeiting business. But even the pharmaceuticals distributed by drugstores or used in hospitals are no longer safe from piracy. Expensive antibiotics and drugs for the treatment of cancer are now working their way up to the top of the list of counterfeit drugs.

LUCRATIVE BUSINESS

Pharmaceutical piracy is a lucrative business since there is a continuous demand for new drugs. The production costs of fake drugs are very low compared to those of their originals. While legitimate pharmaceutical companies constantly invest into research and development of their products, counterfeiters simply tag along with their success. The more expensive a product is in development and market price, the more attractive it becomes for counterfeiters. In addition, counterfeiters pay little or no taxes, employ cheap workers and when selling fakes of highly advertised or well-known products, they spare themselves expensive marketing. Producers of fake drugs take high fines into account, knowing that they will still be much less than the profit they will achieve. Moreover, often only the middlemen can be caught. The distribution channels are partly so complex that it is nearly impossible for authorities to trace the fakes the whole way back to their producers. Inadequate drug export and import controls, especially in the newly industrialising countries, are still considered the main cause for the flourishing business of counterfeiters.

LITTLE CONCRETE ACTION

The European Commission's survey on the seizure of fake drugs at external EU borders states that India is the main country of origin, closely followed by the United Arab Emirates and China. In 2007, China clearly led the statistics of fake drugs confiscated at German customs. In their policy document, the German Association of Research-Based Pharmaceutical Companies (VFA) warns about illegal reimports that are destined for a country outside the EU, illegally repacked there and then reimported into the European market: "Even if these products are originals, uncontrolled or inadequate storage and repacking processes as well as fake secondary packaging and patient information leaflets can pose a serious health risk to consumers caused by mix-ups and inferior product quality." Unfortunately, penalties for many offences related to counterfeiting are not commensurate with the severity of the crime and therefore insufficient to stop the import of counterfeit drugs. Over the past few years, numerous political and business initiatives have focused on the co-ordination and development of anti-counterfeiting strategies. Germany also announced its intentention to place particular emphasis on measures combatting product and brand piracy, during the G8 presidency 2007. One of the key results of the G8 summit in Heiligendamm was the Heiligendamm Process, a dialogue to be launched with the emerging market economies of Brazil, China, India, Mexico and South Africa. In 2006, the WHO founded the International Medicinal Products Anti-Counterfeiting Taskforce (IMPACT) in order to mobilise awareness and action in the fight against fake drugs. The Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK presented its new anti-counterfeiting strategy which describes all important measures in place to combat counterfeit medicines. Despite detailed strategies and promises made at the last G8 summits the Business Action to Stop Counterfeiting and Piracy, BASCAP, complains that "little concrete action has been taken".

COUNTERFEIT PACKAGING

According to the MHRA, the UK is not typically a manufacturer of counterfeit medicine; however, it is a transit point and end user market. The same applies to the Federal Republic of Germany. Therefore, it is important that companies are aware of the risk and that counterfeit products can clearly be distinguished from the originals. The most significant product characteristics required for control at customs are stored in the ZGR's database. Packaging plays a major role with regard to counterfeit drugs. Early identification of counterfeit packaging allows the prompt analysis of the content. But the most important factor is that counterfeits are immediately seized and removed from the supply chain. Each company must take appropriate measures to prevent product piracy. If a counterfeit product enters the supply chain, it is first of all the manufacturer who will be held liable in cases of damage. The manufacturer must prove that the product, which has caused the damage, is a counterfeit or that the product was repackaged in forged packaging. This might result in long and costly product liability claims which often have severe financial impacts on the business. Additionally, the reputation of the pharmaceutical companies, whose drugs have been counterfeited, will be at stake. The consumer's trust in a certain brand quickly erodes if the company is in the news for counterfeiting problems. Therefore it is essential to ensure product traceability – from the production process to the consumer. Traceability and security coding is gaining in importance because it helps to clearly identify the genuine product.

DATA MATRIX CODES FOR TRACEABILITY

Product traceability means that information is available on when, where and by whom the goods have been manufactured, processed, stored, delivered, used or disposed of. The introduction of the one-dimensional bar code has considerably improved material handling and logistics. The majority of retailers scan the bar code on a product in order to identify the item and its price. The bar code is still in use, but oftentimes it cannot provide the wealth of information required to ensure consistent product traceability. The data volume, which can be stored on the bar code, is very limited compared to the latest developments in this field. The capacity of the small and simple bi-dimensional data matrix code is impressing. It can store up to 1,556 bytes which corresponds to 3,116 numerical characters. The code can be defined according to any standard, using any type of information, such as product code, EAN code, manufacturer's code, date of production, lot and serial number. These data can be scanned by means of a digital camera or a 2D scanner.

RFID: CUTTING-EDGE, BUT NOT COUNTERFEIT-RESISTANT

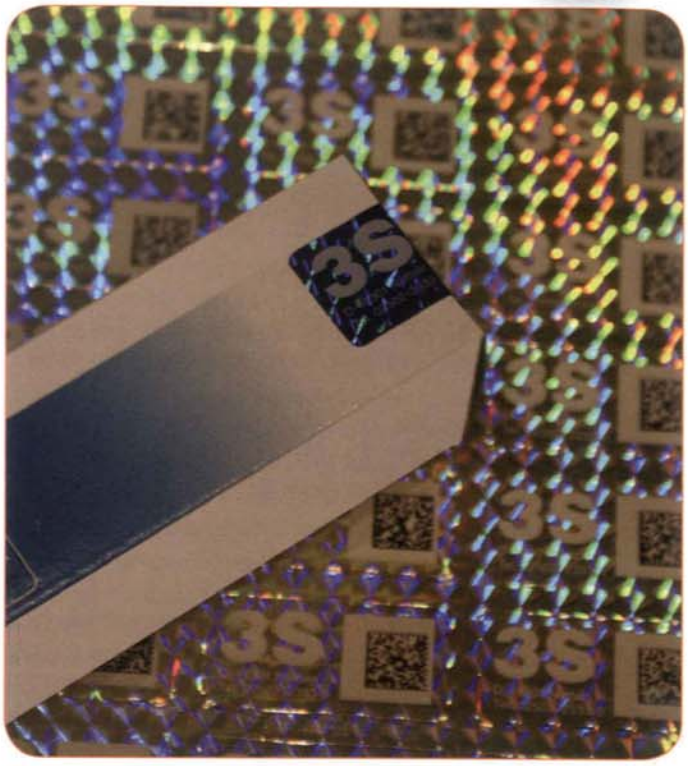
The Radio Frequency Identification Code (RFID) is another instrument designed to ensure product traceability. According to the US Food and Drug Administration (FDA), it is a tool for identifying and tracking items or people. A small memory-storage chip is placed on an item. RFID readers send out radio waves to detect tags and read their data, which can consist of just the serial number or even several pages with product-relevant information. In recent years, RFID solutions have been booming, particularly in the US. In 2004, FDA launched a pilot project with the aim to implement RFID technology across the entire pharmaceutical supply chain. However, this project was stopped after two years. Technical problems, such as difficulties in reading the data stored on RFID tags, reveal that there is still room for improvement. Nevertheless, RFID continues to be the most important traceability technology: "FDA continues to study RFID and its potential effects on medical devices. As it becomes available, FDA will communicate new information to the public through its website, the news media and other channels." For years to come, both RFID transponders and bar codes will likely be used for coding and marking pharmaceutical packaging.

MAKING TRACEABILITY COUNTERFEIT-PROOF

Even if a pharmaceutical product has been marked with a traceability code, making the product and the coding system counterfeit-proof remains an issue to be addressed. The coding systems are becoming safer, but they do not prevent counterfeiting. Today's technology allows materials, shapes, colours and labels to be perfectly imitated, so that actually nobody would ever think that they could be dealing with a counterfeit product. This is why recently more and more anti-counterfeit solutions, such as security labels and holograms, have themselves fallen victim to counterfeiting. The use of a double protection combined into one single system is highly advisable. Another security feature, which is exclusively designed to protect the product against counterfeiting, should be added to the traceability code. Micro colour code particles have become market-leading anti-piracy features, allowing manufacturers to prove that their products are genuine. This method is recognised by international law.

PRODUCT SECURITY MADE IN GERMANY

The world's smallest colour code particles with a size of 5 to 45 micrometres are produced in Germany. They consist of four to eleven different colour layers. The individual product code, which is exclusively used for the products of a specific manufacturer, is based on the combination of different colours, their sorting order and the thickness of the layers. Primary packaging and repackaging alike have been identified as vulnerable to counterfeiting in the pharmaceutical industry. This problem can quite easily be solved by combining a traceability code and a product security code. For example, secondary packaging can be marked with a data matrix code printed on a label to be used for tracking purposes. The colour code is now also applied on the label, which authenticates both the traceability code and the product. The same applies to primary packaging. Manufacturers, customs and CID officers as well as consumers can clearly identify the micro colour code particles. High costs of legal proceedings can thus be avoided and customer trust in the company's products can be maintained. The most important prerequisite for this type of security is the company's awareness of their responsibility towards the consumers, implying the necessity to make their products absolutely counterfeit-resistant.



ONE SINGLE SYSTEM SOLUTION COMBINING TRACEABILITY AND PRODUCT SECURITY

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Nicole Golomb is Marketing and Sales Manager for anti-counterfeit systems at 3S Simons Security Systems GmbH, Germany. She is in charge of the management of the specific customer projects dealing with individual applications of the micro colour-code system SECUTAG® on branded articles. Additionally, Nicole is responsible for the analysis of processing technologies in specific industries and the product protection system's integration in the different sectors.