

Technology targets counterfeit drugs

Counterfeit drugs endanger the lives of millions of people worldwide. New regulations aim to introduce technologies that will help better protect patients.

Every year, 14 million people worldwide are diagnosed with cancer. The World Health Organization (WHO) expects this number to continue to rise over the next 20 years. In many cases, patients can be treated and, increasingly, even cured. But the necessary medicines are expensive. Often, they are sold for several hundred US dollars. And, what's more, they do not always contain the badly needed active agent. More and more criminals are offering fake drugs in exchange for money.

According to WHO, one in 10 drugs sold worldwide is counterfeit. Whereas in Europe, fake drugs make up just 1 percent of those sold, in Africa, around 80 percent of drugs are affected. Counterfeit drugs can either contain the wrong dosage or no active agent at all. Too little of an active ingredient will not help to treat or cure an illness. In fact, the patient may even develop a resistance to the ingredient that renders the real medicine ineffective. This means that counterfeits are not only harmful – they can even prove to be fatal.

From antibiotics and potency pills to hepatitis vaccines – there are ineffective imitations circulating for almost every type of drug. Criminals take aim at online drugstores and shops where people buy drugs and lifestyle products anonymously. In fact, nowadays, trading in counterfeit pills, powders and drops has become even more profitable than narcotics trafficking.

VERIFYING PACKAGES

It's extremely difficult for consumers to tell if pills are fake. In most instances, pharmacists must rely on seals to judge the origin of their supplies. In some countries, authorities have launched initiatives to help all parties involved to better distinguish illegal copies from original products. Turkey introduced packaging serialization several years ago. The USA has also put a system in place to trace original medications. Now, the EU is getting ready to join them with a new policy: as of February 9, 2019, even the smallest disposable unit of a prescription medicine must carry a barcode that incorporates a serial number composed of several elements. This code will allow every single package to be clearly identified. Manufacturers will send all their serialization information to a shared data center, "the EU Hub", where the drug serial numbers assigned during production are stored. From the hub, the information is forwarded to national systems – so pharmacists can check a product's validity before passing it on to a patient.

HIGH STANDARDS FOR MANUFACTURERS

New regulations may force pharmaceutical companies to upgrade their technical equipment, but methods to increase drug safety also protect their business. If a brand attracts attention because of an increase in counterfeits, the manufacturer may suffer both damage to their image and a loss in sales – even if they have done no wrong. With elaborately and expensively developed and produced drugs, international pharmaceutical markets are highly competitive. And customers can be extremely demanding. A stated aim of the pharmaceutical industry is to produce goods to "Japanese quality" – that is, to an extremely high standard. In Japan, harmless deviations in tablet appearance or the tiniest scratches on their glass containers can force manufacturers to take back entire batches of otherwise flawless medicine. Japanese consumers are highly sensitive to imperfections and regularly reject drugs that people in other parts of the world would settle for.

Initially, under the new EU regulation, the external packaging of drugs must be tagged; this will soon be followed by glass vials. But the stickers bearing the required safety features can be easily damaged, which is why the sector feels certain that the current labeling guidelines are only a first step. To comply with future regulations, manufacturers will need advanced solutions that allow them to tag even the smallest units and furnish them with specific information.

LYODATA™ IDENTIFIES VIALS

Bioactive substances are sensitive and can lose efficacy after a short time period or if exposed to direct sunlight. To make injectable drugs more stable and facilitate their transport, manufacturers use freeze dryers. First, liquid is extracted from the medication. What remains is the "cake" with the formulation's properties unaltered. Prior to administration, a doctor transfers the liquid back into the "cake" to achieve the required texture. Up to 100,000 vials can be freeze-dried simultaneously. To track a vial's position within the dryer or its exact time of loading or discharge, GEA has developed a unique procedure in collaboration with Schott and Heuft: LYODATE™ clearly identifies each and every vial. During production, a glass vial is furnished with all its product's manufacturing data, scratch-free. The type and volume of information provided can easily be expanded and – using the serial number – assigned to a specific vial.

