

Fake Medications? Suggestions and Approaches to Help Ensure that Patients and their Family Members are Not Left Worrying

Cancer diagnosis. A male patient is in his 80s and his general physical health is no longer amenable to chemotherapy. The team of specialists decides on a treatment regimen consisting of daily pills combined with infusions every 14 days. The package of 30 pills requires a prescription and the cost is in the four-digit range.

The entire family is happy that there is still a small chance that the cancer can be contained. It goes without saying that at the beginning of the therapy, side-effects cannot be ruled out. Still, after 10 days of treatment, the patient is having early, yet very drastic symptoms not listed on the package insert. Suspicion sets in. Are the pills inside the box truly the original tablets? A search online shows the medication is available at a variety of prices.

The Pharmacist Placed the Order for the Medication Online. Was there a Gap in the Supply Chain?

We assume that everything was proper and legitimate in this case and that the content of the packaging was actually an original product. Yet how could we have been able to prevent these doubts that spread throughout the family?

Until recently, only those medications purchased online were considered dangerous – 90% of all products purchased from internet pharmacies have been shown to be fake. Organisations such as ASOP – Alliance for Safe Online Pharmacies – are supporting the official efforts in Europe and the US aiming to improve the situation, in particular by educating users about the dangers of this illegal yet convenient and anonymous way of buying medications online.

However, the more parcel shipping is becoming an everyday part of the supply chain, the greater the vulnerability of stationary pharmacies to potential fraud.

With its Directive 62/2011, the EU has introduced stringent measures to ensure

that prescription drugs can be traced back to their origin: a unique code for each package, allowing for tracking, and tamper-proof sealing for the package are intended to guarantee this.

Can the Code be Falsified? Weaknesses in the Implementation of EU Directive 62/2011

In the specific example of very expensive cancer therapy, let's first take a closer look at the unique code: For a medication with pricing in the four-digit range, it would definitely pay off for fraudsters to reprint a few codes that are already on the market. If the faked packs are scanned at the pharmacy first, before the original product, the duplication of the code may in fact only be noticed when the counterfeit product is already in use. This may happen only rarely, yet patients are never involved in any way in the scanning and posting processes that take place at the pharmacy or hospital. The patient is considered to be too immature.

While unique codes could actually provide invaluable additional benefit to the patient, such as reading out the package insert, general information on how best to deal with the illness, etc., in the current set-up of the system, the patient or the customer at the pharmacy does not even

notice that a specific code is even being verified.

The Patient should Take Full Advantage of the Digital Benefits of the Unique Identifier

The principle of multiple use of a UID (Unique Identifier) is not yet being used in the EU. Both general and patient-specific information can be linked to the security code via the Codikett platform or other trusted services, for example, by making dual use of the code, so to speak. This would increase the patient's trust in the drug and calm his relatives, while integrating the patient's data into the verification process at the same time. This in particular would be critical in order for him to be prepared for the fact that in all likelihood the trade of medications online will become more and more liberalised, e.g. as a first step for non-prescription medicines. The patient should definitely learn to pay close attention to the codes!

How Safe is Medication Packaging and its Sealing?

This is where the greatest risk lies for a medication in the four-digit cost range. All along the supply chain, it is rather easy for fraudsters to exchange the genuine content for a placebo and seal the package



Codikett as well as other security web services can connect more information to the obligatory unique identifier, thus involving patients in the EU path for patient safety.



Sealing labels should attract users' attention, e.g. by displaying a distinct opening indication upon removing, called "VOID"-effect. These effects with clear messages are difficult to counterfeit.



without it being noticed, and then divert the genuine medication obtained this way, e.g. in another part of the world.

The safety aspect of sealing was effectively argued away in the course of the implementation of EU Directive 62/2011. While ISO 21976:2018 (Packaging — Tamper verification features for medicinal product packaging) well stipulates that the securing of packaging should be planned and implemented on a risk basis, direct sealing of boxes is often used to secure even very expensive medications or those at risk of being counterfeited. However, this does not provide for any visible evidence of tampering when the package is cut open and re-sealed. So not a bit of "tamper verification" as it is referred to in the guideline. Yet, also for sealing labels, it seems that quite often not much effort is being put forward to protect them against reproduction by counterfeiters and fraudsters. Here as well, ultimately the patient is rarely involved.

In talks with quite a few patients, we find that most are not even aware of the fact that seals or direct sealing of boxes are being used – at best, they only observe it subliminally.

The free market is taking a different approach here: the new Amazon guideline for providers of hygiene articles prescribes clearly visible, easily noticeable and conspicuous seals for cosmetics and medical products. Hopefully, this will bring about a different thought process for the implementation of FMD as well.



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