

Fake Coronavirus Medicines, Tests and Protective Equipment – Proof of Originality More Important than Ever

The demand generates the offer. Where there is an acute lack of protective equipment, testing and medication in the fight against the coronavirus, product fraud is already growing rapidly.^{1,2,3} Even in exceptional times like these, criminals do not shy away from putting counterfeit and inferior goods into circulation, directly putting the public, healthcare workers and patients in harm's way. Often, in the race against time, less attention is paid to where the goods have come from. For controls and authentication of products, therefore, simple and quickly verifiable indicators are needed to determine where the goods come from and whether they are genuine.

Special care should be taken when buying products on the internet, a popular platform for selling counterfeit products. Here you can also encounter companies that do not deliver the goods after prepayment, or simply put unsafe replicas or completely ineffective products on the market.

Especially now, when drastic measures are being taken to stem the spread of the virus, safe protective equipment that meets the prescribed standards is essential. Nobody wants to



The FMD requires a unique identifier to verify the authenticity of each medicine plus an anti-tampering device – in this case a VOID label.

imagine what will happen if counterfeit protective equipment does not have the promised properties to intercept the viruses. Especially when they are used in hospitals, where staff have daily direct contact with infected persons.

Fake tests that give false or unreliable results prevent containment of the virus. People who are thought to be healthy can transmit the virus unhindered and the spread cannot be stopped. Devastating consequences that would overwhelm even the best healthcare systems would result.

Criminals target all types of products, knowing that the profit margins will be high – fake airbags and unsafe toys, to name but two areas. It has been said that to sell fake medicine is 20,000 times more profitable than selling narcotics on the street and with laws that mean punishments are far less severe, it is no wonder that this sector of healthcare is targeted so frequently.

All types of medicine, for example, counterfeit spare parts for medical devices or respiratory equipment might fail to fulfil the desired function, if they are of insufficient quality.

And it is important to kill the myth that it is only lifestyle medicines that are bought online. That is not the case at all. Looking at 2300 respondents to a survey carried out by ASOP EU⁴, when

asked what medicines they wanted to buy, their answers revealed that all types of medicine are being bought. So we are talking about antibiotics (which is very concerning when linked to the rise of antimicrobial resistance), anti-cancer treatments and blood pressure-lowering medication, to name just three. So it is clear that ALL types of medicines are being bought online.

So what are the health consequences and impact on the hundreds of thousands of individuals who are buying medicines online?

The WHO in 2017 characterised these and stated that adverse events due to incorrect ingredients gave rise to:

- A failure to cure or prevent future disease, thereby increasing mortality, morbidity and the prevalence of disease,
- The progression of antimicrobial resistance and drug-resistant infections,
- A loss of confidence in healthcare professionals, health programmes and health systems,
- An increase in out-of-pocket and health system spending on healthcare,
- Lost income and productivity due to prolonged illness or death.

In recent years, therefore, numerous



Technically highly complex labels encourage the user to check the authenticity of products in a user-friendly way, and it is intuitive and motivating to do so. For instance, this label changes irreversibly when it is peeled off from a package, uncovering an additional code. The user, equipped with a smartphone, is guided through the verification in a self-explanatory manner.



Opened locks visuals appear when the user opens the medicine. Language-free, self-explanatory symbols document the initial opening. The security printing uses VOID technology and the hologram, as on banknotes, also makes the originality obvious.

regulations have been rolled out across many countries that enable authentication traceability of individual serialised prescription medicines. In addition, these regulations often insist on tamper-evident devices to give double the protection.

In Europe, the Falsified Medicines Directive¹, since February 2019 requires every prescription pack to be uniquely serialised with a barcode, as well as having a tamper-evident seal. At point of dispensing, the pharmacist then checks the pack to be authentic and also checks that the tamper-evident seal has not been compromised.

So this important Directive greatly enhances the security and integrity of the legitimate supply chain. In addition, the Directive obliges every Member State in the European Union to sell “medicines at a distance” and the retailer (in most cases pharmacy shops) have simply to register with their national health authority.

And if they are selling medicines via the internet, then each page of their website must display a logo which is described as the common logo which, when clicked on, routes through to a page that shows it has been registered.

Each Member State is legally obliged to inform the public of the purpose of this common Logo and to explain exactly what a falsified medicine is.

ASOP EU has held a number of meetings with the Member States to share the various advertising campaigns, but it soon became clear that many



VOID tapes ensure that a shipping carton can be checked to ensure that the contents have not been opened in transit. This ensures that the original contents cannot be replaced with counterfeit products.

Member States are not carrying out public-facing information campaigns. And so we would urge governments to address this issue and create campaigns to raise awareness.

In response to the newly released report by the European Union Intellectual Property Office (EUIPO) and the Organisation for Economic Cooperation and Development (OECD)⁶, entitled “Illicit Trade in Counterfeit Pharmaceutical Products”, Mike Isles, Executive Director of ASOP EU – a non-profit patient safety organisation dedicated to making the internet a safe place to buy medicines (where it is legal to do so) – said at the launch conference that:

“Demand is fuelling the supply.”

After all, it is you and I that are going online to buy medicines. If we did not then there would be no market, and no need for criminals to supply. With medicines being sold via social media and with 96% of the 35,000 websites

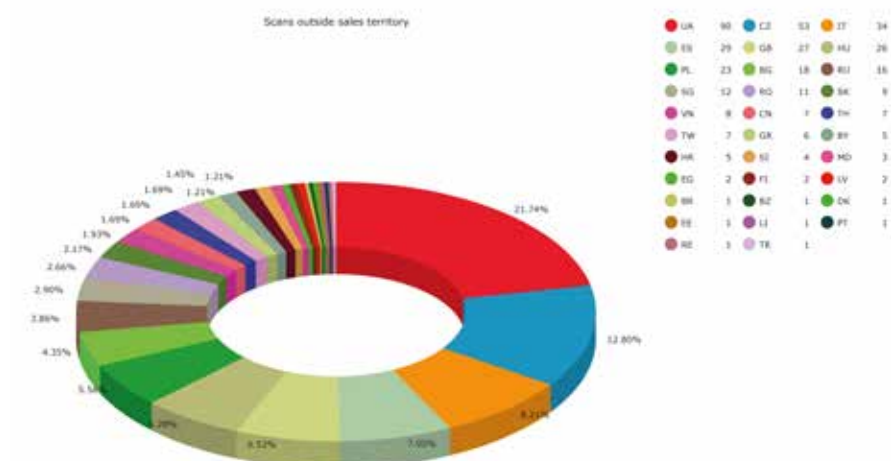
selling medicines worldwide operating illegally, it is a problem that urgently needs solutions.

“There is no one silver bullet so it requires many silver bullets and coordination amongst myriad public- and private-sector partners. And with an estimated 130 million people potentially buying medicines across Europe, urgent action is needed. This is especially important as we see false and predatory promises and misguided advertisements around potential treatments or cures for COVID-19, as well as fake tests [and] medical devices.”

It follows, therefore, that manufacturers and users should protect themselves equally by means of good identification marking, proof of originality and protection against tampering of the packaging, and by paying attention to secure distribution channels.

REFERENCES

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2. European Medicines Agency COVID-19: Beware of falsified medicines from unregistered websites <https://www.ema.europa.eu/en/news/covid-19-beware-falsified-medicines-unregistered-websites>
3. FDA STATEMENT Coronavirus (COVID-19) Update: FDA Alerts Consumers About Unauthorized COVID-19 Test Kits <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-alerts-consumers-about-unauthorized-fraudulent-covid-19-test-kits>
4. Alliance for Safe Online Pharmacy in the EU (ASOP EU). Data taken from an educational website derived from a Google AdWords campaign. 2300 respondents provided valuable information on age, gender,





Where demand is greater than supply, product fraudsters are attracted. The penalties for putting life-threatening counterfeits into circulation are low when compared with other types of criminality, such as narcotics being sold on the street, despite the fact they can be deadly.

medicines bought, reasons for buying, knowledge of internet and pharmacy – data on file

5. The Falsified Medicines Directive (2011/62/EU) https://ec.europa.eu/health/human-use/falsified_medicines_en
6. European Union Intellectual Property

Office (EUIPO) and the Organisation for Economic Cooperation and Development (OECD) "Illicit Trade in Counterfeit Pharmaceutical Products, 23 2020 23 <https://euipo.europa.eu/ohimportal/en/web/observatory/trade-in-counterfeit-pharmaceutical-products>



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Dr. Marietta Ulrich-Horn holds a PhD in philosophy from the University of Vienna, and an MBA from the Vienna University for Economics and Business and the Carlson School of Management, Minnesota. She is co-founder and CEO of SECURIKETT®, a company offering a wide range of product protection solutions: complex security labels for physical product protection, and the digital cloud solution CODIKETT® for track & trace in global applications. MILLEPEDIA®, one of the latest IT product developments, makes interoperability possible. The motto is: authenticate, identify and locate the original. Marietta has been delegated by the Austrian Standards Institute to actively contribute to the emergence of European and International standards on authentication, traceability by UIDs (unique identifiers), tax bands and tamper evidence.



**Mike
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Mike is the Executive Director for the Alliance for Safe Online Pharmacy in the EU (www.asop.eu), a non-profit Community Interest Company (CIC). With over 30,000 fake pharmacy websites targeting Europe on any given day, this multisectoral organisation's mission is to enable patients to buy their medicines online safely – where it is legal to do so. Its Members and Observers involve many key internet stakeholders. Its aim is to produce concrete voluntary actions that will make a real difference and ultimately benefit the health and safety of patients. Mike is Executive Director of the European Alliance for Access to Safe Medicines (www.eaasm.eu). Mike is also European Medicines Partnership Director for International Health Partners (www.ihpuk.org).