

The threat of pharmaceutical crime in the EU and beyond





THE THREAT OF PHARMACEUTICAL CRIME IN THE EU AND BEYOND

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KEY FINDINGS

This report outlines the threat of pharmaceutical crime in the EU and beyond, as assessed by Europol. It aims to raise awareness of the ways criminal networks exploit consumers and industry in generating illegal revenue through producing and selling counterfeit medicines.

Key Findings:

- ▶ Intellectual property crime (IPC) targeting the production and marketing of a wide range of pharmaceutical products – either sub-standard, falsely labelled or falsified – is a growing threat in the EU, fostered by international organised crime.
- ▶ Pharmaceutical crime has a direct impact on public health and safety as it affects individuals, communities and national healthcare systems, generates enormous financial losses for legitimate companies, undermines brand credibility but also endangers investments in research.
- ▶ Pharma criminals target a wide range of products, especially anticonvulsant or antiepileptic drugs, synthetic opioids, anti-cancer drugs, erectile dysfunction and antidiabetic medicines, pseudoephedrine, doping substances (i.e. hormone and metabolic regulators), painkillers, antioestrogens, antivirals, hypnotics, antihistamines and anxiolytics.
- ▶ Diversion from the legal supply chain, through unlawful acquisition via falsified or stolen prescriptions, or via legitimate sales, is a common *modus operandi* driven by market needs, medicines value and legal supply challenges.
- ▶ Social media and online marketplaces, both on the surface and on the dark web, continue to be central to the trade of counterfeit pharmaceuticals. These platforms provide various degrees of anonymity and target wide audiences, making it challenging to identify the criminal actors involved.
- ▶ The misuse of a number of prescription and over-the-counter medicines as well as other health products for recreational use, psychoactive effects, weight loss, performance enhancement and/or cosmetics, is set to remain a widespread and growing phenomenon. Steadily increasing demand will generate continuous opportunities for organised crime.

BACKGROUND

The pharmaceutical industry is a critical sector for global health security, innovation and research and it is worth billions of euros within the EU alone. Such a profitable market entices criminal actors and networks toward the production and commercialisation of illicit pharmaceutical products. The illicit market of counterfeit pharmaceuticals and health products – either sub-standard, falsely labelled or falsified – generates enormous financial losses for legitimate companies, undermines brand credibility but also endangers economic development in the form of investments in research. Most importantly, pharmaceutical crime has a direct impact on public health and safety, as it affects individuals, communities and national healthcare systems.

The proliferation of fraud schemes concerning pharmaceutical and health products skyrocketed during the COVID-19 pandemic as criminal networks took advantage of worldwide shortages and traded in fake test kits and uncertified and unauthorised treatments. The threat intensified with the distribution of substandard and falsified health products¹ (SF), such as medical and personal protective equipment and even falsified COVID-19 vaccines².

Following the winding down of the pandemic, criminal networks continued to adapt to emerging trends and market fluctuations. A growing shortage of pharmaceuticals in several Member States, including those that are of critical importance for patients³, viciously continues to fuel said criminal market. This Intelligence Notification describes how criminal actors are exploiting these shortages, diverting and infiltrating the legal supply chain, and marketing and selling falsified medications in the EU and beyond.

¹ 'Substandard' health products originate from legitimate manufacturers but fail to meet quality standards. 'Falsified' health products are medicines that deliberately misrepresent their identity, composition, or source. They can include products with incorrect ingredients, no active ingredients, or fake packaging. The intention behind falsified products is to deceive consumers about their origin and efficacy. According to the World Health Organization (WHO), counterfeit pharmaceuticals are a subset of falsified products, typically involving unauthorised replication of brand-name medicines. Counterfeit drugs may look identical to the real product but contain no active ingredient, the wrong ingredient, or the wrong amount of the correct ingredient. While all counterfeit drugs can be considered falsified, not all falsified or substandard products are counterfeit. Regardless, each category poses significant risks to public health and requires targeted strategies for detection and prevention.

² EUIPO & Europol, (2022), 'Intellectual Property Crime Threat Assessment', accessible at <https://www.euipo.europa.eu/en/publications/ip-crime-threat-assessment-2022>

³ Heads of Medicines Agencies, 'Availability problems of medicinal products for human use', accessible at: <https://www.hma.eu/human-medicines/availability-of-medicines.html>

THE CRIMINAL ACTORS BEHIND PHARMA CRIME

The variety of pharmaceutical crime often leads to a diverse range of sub-standard, falsely labelled or falsified health products and associated criminal activities. Criminal actors involved in pharma crime are known to operate in a networked ecosystem in which cooperation is fluid and resembles business model structures, with the systematic engagement of crime-as-a-service providers such as technical experts, legal and financial advisors, who facilitate the criminal process⁴.

These individuals engage internationally, with associates allocated to the various steps of the criminal process spread across the route of operations. The widespread abuse of legal business structures and ultimately the online distribution channels create a thick shield of anonymity for the actors involved. Law enforcement in the EU successfully manages to seize tonnes of illicit pharmaceuticals and SF products before they reach the end-users⁵, however such actions do not seem to be able to thwart the criminal endeavours nor the structures behind them, given that information about criminal actors remains largely unknown.

⁴ Europol-EUIPO (2024), 'Uncovering the ecosystem of intellectual property crime: A focus on enablers and impact', accessible at: <https://www.europol.europa.eu/publications-events/publications/uncovering-ecosystem-of-intellectual-property-crime>

⁵ Europol (18 October 2024), '47 Sedative pills traffickers arrested', accessible at: <https://www.europol.europa.eu/media-press/newsroom/news/47-sedative-pills-traffickers-arrested>

THE CRIMINAL PROCESS

The illicit market of counterfeit pharmaceuticals and SF health products is global and growing. Criminal actors and networks operating in the EU are involved in either import, export as well as in the production of illicit products. In the EU, criminal actors run **clandestine laboratories** for the production of counterfeit pharmaceuticals. EU-based laboratories are often small scale, and require relatively limited human resources and equipment to manufacture and assemble the products, which makes them harder to detect⁶.

Criminal actors, disregarding safety precautions and product quality, work in makeshift laboratories and in unhygienic conditions, where toxic ingredients and inadequate levels of active ingredients are mixed together. In addition, the production of counterfeit pharmaceuticals also poses **serious environmental risks** of contamination of air, soil and water, especially when disposing of the manufacturing waste.

Asia remains the main source region for the supply of SF health products as well as of raw materials, which are also increasingly imported from Türkiye. In the illicit production sites, criminals mix together illicitly acquired raw materials with other harmful substances in the form of tablets, powder, liquid, etc., and make use of sophisticated packaging features to imitate genuine products, including replica holograms, logos, and even serial numbers. They also exploit tools such as 3D printing and, in the future, Artificial Intelligence (AI) is set to enhance counterfeiting techniques which will, in turn, further facilitate automated production.

Diversion and theft occur when a genuine pharmaceutical product, approved for sale or distribution, is intercepted or stolen and misused thereafter. Factors such as market needs and the value of medicines as well as challenges related to the legal supply chain function as crime incentives for criminals to choose diversion as their *modus operandi*.

The diversion and theft are carried out with the support of colluding employees, doctors or pharmacists⁷. Theft of medicines may occur anywhere throughout the supply chain, at the manufacturing site, during transit, at distribution centres, in warehouses, at pharmacies, or even in hospitals⁸.

In 2022 Europol received intelligence from the French authorities concerning pharmacies purchasing excessive volumes of prescribed medications from legal suppliers for trafficking to countries outside the EU, in particular Vietnam. Investigations revealed that a pharmacist (who was also the owner of a pharmacy) in France was the organiser of the criminal network involved in trafficking legal medication to Vietnam. The medications were then smuggled by couriers (in one case, by a family accompanied by their two-year-old child) to Asia⁹.

⁶ EUIPO & Europol, (2022), 'Intellectual Property Crime Threat Assessment', accessible at <https://www.euipo.europa.eu/en/publications/ip-crime-threat-assessment-2022>

⁷ Europol (21 January 2020), '48 arrested and 6 organised crime groups dismantled in medicine trafficking operation', accessible at: <https://www.europol.europa.eu/newsroom/news/48-arrests-and-6-organised-crime-groups-dismantled-in-medicine-trafficking-operation>

⁸ PSI, (2023), 'Measuring Pharma Crime', accessible at <https://www.psi-inc.org/pharma-crime>

⁹ Europol-EUIPO (2024), 'Uncovering the ecosystem of intellectual property crime: A focus on enablers and impact', accessible at: <https://www.europol.europa.eu/publications-events/publications/uncovering-ecosystem-of-intellectual-property-crime>

Criminal actors exploit other weak links in the global supply chain, especially when the criminal process involves different countries, importers, retailers and distributors¹⁰. Importation into the EU may be supported by false invoices and customs. Free trade zones are often misused for transit, due to lenient regulations and limited customs control¹¹.

Pharmaceutical crime is facilitated by **legal business structures**, allowing criminal networks to establish and infiltrate these entities, presenting a facade of legitimacy for their criminal activities. The infiltration and abuse of pharmaceutical companies and pharmacies is critical, especially if the illegal activity involves the diversion or theft of legitimate goods¹². Commercial warehouses and transport companies are prime examples of compromised enterprises that are essential for the distribution of these illicit products.

Most EU-based illicit laboratories and collection centres supply multiple distributors¹³, with criminal actors relying primarily on postal and courier services to ship counterfeit pharmaceutical products marketed online. The trade in illicit pharmaceuticals happens mostly **on the surface web**, using targeted adverts on social media or instant messaging applications, which lead to temporary websites that often imitate well-known e-commerce marketplaces. Increasingly, **dark web marketplaces** are used for the sale of falsified pharmaceuticals, as they offer additional anonymity, making it more challenging to identify and shut down the illicit operations. Criminal actors also resort to instant messaging applications and dark web marketplaces in order to target customers outside the EU.

Illicit supply meets targeted demand. Criminal actors involved in the sale of hormonal substances infiltrate the **fitness industry** and especially gymnasiums, where the use of such products is in high demand. **Social commerce**, involving social media influencers who endorse and promote genuine brands but also counterfeits (often knowingly) through their own self-acclaimed “dietary and nutrition” channels, are becoming a main marketing vehicle for illicit hormonal substances¹⁴.

¹⁰ OECD, EUIPO, (2020), ‘Trade in Counterfeit Pharmaceutical Products, Illicit Trade’, accessible at: https://www.oecd-ilibrary.org/governance/trade-in-counterfeit-pharmaceutical-products_a7c7e054-en

¹¹ Ibid

¹² Europol-EUIPO (2024), ‘Uncovering the ecosystem of intellectual property crime: A focus on enablers and impact’, accessible at: <https://www.europol.europa.eu/publications-events/publications/uncovering-ecosystem-of-intellectual-property-crime>

¹³ EUIPO & Europol, (2022), ‘Intellectual Property Crime Threat Assessment’, accessible at: <https://www.euiipo.europa.eu/en/publications/ip-crime-threat-assessment-2022>

¹⁴ Europol-EUIPO (2024), ‘Uncovering the ecosystem of intellectual property crime: A focus on enablers and impact’, accessible at: <https://www.europol.europa.eu/publications-events/publications/uncovering-ecosystem-of-intellectual-property-crime>

TARGETED COMMODITIES

In the EU, seizures of anticonvulsant or antiepileptic drugs, synthetic opioids (i.e. tramadol¹⁵ hydrochloride and fentanyl), anti-cancer drugs, erectile dysfunction medicines, pseudoephedrine, doping substances (i.e. hormone and metabolic regulators), painkillers, antioestrogens, antivirals, hypnotics, antihistamines and anxiolytics¹⁶ highlight a dangerous trend where individuals seek medicinal and health products without a prior medical nor professional consultation.

Another worrying trend involves the diversion and misuse of prescribed medication¹⁷ and further illicit trade in Semaglutide¹⁸, primarily prescribed to treat diabetes, but increasingly being misused by individuals striving for accelerated weight loss. High demand by those seeking quick ways to lose weight is creating serious global shortages for diabetes sufferers. Criminal actors primarily use fake prescriptions to obtain genuine diabetes pens for onward illicit resale at a higher premium but also distribute falsified products, mainly imported from outside the EU.

Counterfeit diabetes pens may contain incorrect or insufficient amounts of the active ingredient, rendering it ineffective in managing blood sugar levels or assisting with weight loss. The use of counterfeit pens can increase the risks of diabetes-related complications, further endangering the health of victims.

The wide use of performance-enhancing drugs (often called “roids”) to enhance muscle mass and boost strength is on the rise, yet more evidently within the bodybuilding community, at both amateur and professional levels. Aside from the unethical approach, the use of doping substances provokes serious and even lethal risks to human health. Responding to an ever-growing demand, this illicit market is very profitable. Trafficking in hormonal substances is also facilitated by legal loopholes and relaxed implementation of regulations and enforcement. These products are often distributed and labelled as ‘food supplements’ or ‘other vitamins’, which generally makes detection more challenging.

In May 2024, the Italian authorities searched the logistical base of a criminal group operating from San Marino. Investigators identified a rural underground lab set up for the production, labelling and packaging of doping products.

Police seized vast quantities of doping substances in the form of vials, tablets, capsules, bottles and packaging, all intended for sale in Italy as well as around EUR 180 000 in cash.

¹⁵ Tramadol is a strong pain medication used to treat moderate to severe pain that is not being relieved by other types of pain medicines. Tramadol is a synthetic opioid and acts in the brain and spine (central nervous system) to reduce pain.

¹⁶ Europol, (10 December 2020), ‘Medicines and doping substances worth €73 million seized in Europe-wide operation’, accessible at: <https://www.europol.europa.eu/media-press/newsroom/news/medicines-and-doping-substances-worth-%E2%82%AC73-million-seized-in-europe-wide-operation>

¹⁷ Information contributed to Europol.

¹⁸ Semaglutide is a diabetes medicine used with diet and exercise to treat adults whose Type 2 diabetes is not satisfactorily controlled. It can be used on its own in patients who cannot take metformin (another diabetes medicine) and be used as an ‘add-on’ to other diabetes medicines. It is a solution for injection in prefilled pens and can only be obtained with a prescription and injected. Accessible at: <https://www.drugs.com/semaglutide.html>

The suspect allegedly imported pure nandrolone, an anabolic steroid classified as a narcotic drug in Italy. His trafficking routes spanned all over Europe and as far as China¹⁹.



Figure 1 – Picture of doping substances seized in Salerno. Source: NAS Carabinieri

¹⁹ Europol, (13 February 2024), 'Fake medicines worth EUR 64 million off EU Markets' accessible at <https://www.europol.europa.eu/media-press/newsroom/news/fake-medicines-worth-eur-64-million-eu-markets>

EUROPOL’S RESPONSE

Addressing pharma crime requires a multi-disciplinary approach that encompasses all key stakeholders such as law enforcement, health authorities, patent holders, the manufacturing industry, as well as digital service providers. Cooperation and intelligence sharing amongst law enforcement and private parties continue to be key in tackling this criminal activity, leading to successful operations and considerable seizures of counterfeit packaging containing falsified medication across Member States and beyond.

Between April and October 2023, Europol coordinated the fourth edition of Operation SHIELD. Law enforcement, judicial, customs, medical and anti-doping authorities from thirty countries across three continents joined forces in this global effort targeting the trafficking of counterfeit and misused medicines and illicit doping substances.

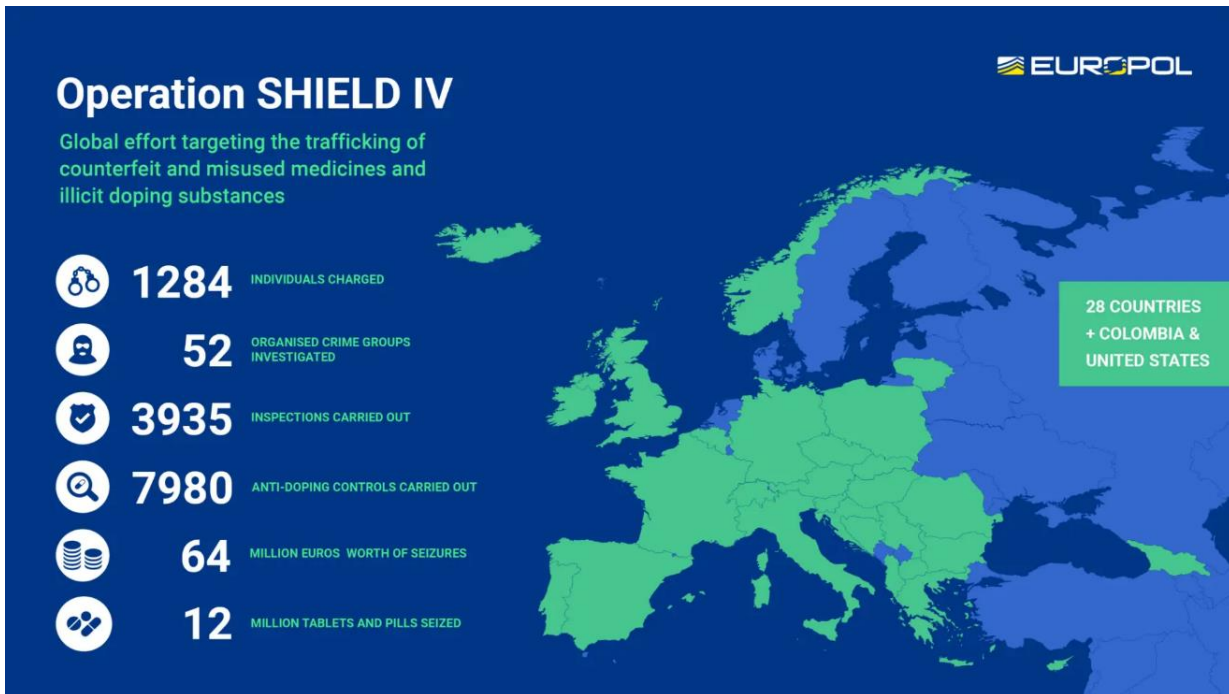


Figure 2 – Operation SHIELD IV data (between 01 April and 14 October 2023). Operation SHIELD is a Europol coordinated operation, to target trafficking of counterfeit and misused medicines and doping substances. Source: <https://www.europol.europa.eu/media-press/newsroom/news/fake-medicines-worth-eur-64-million-eu-markets>

The operation was also supported by the European Anti-Fraud Office (OLAF), the European Union Intellectual Property Office (EUIPO), Frontex, the World Anti-Doping Agency (WADA) and national medicine agencies²⁰.

²⁰ Europol, (13 February 2024), ‘Fake medicines worth EUR 64 million off EU Markets’ accessible at <https://www.europol.europa.eu/media-press/newsroom/news/fake-medicines-worth-eur-64-million-eu-markets>

OUTLOOK

The increasing risks targeting consumer health and safety and the economic losses for the pharmaceutical industry and the research sector make pharma crime a major concern that needs to be continuously monitored in the future. The misuse of a number of prescription and over-the-counter medicines as well as other health products for recreational use, psychoactive effects, weight loss, performance enhancement and/or cosmetics, is set to remain a widespread and growing phenomenon. Steadily-increasing demand, which negatively affects the legitimate supply chain, will continuously generate opportunities for organised crime.

The EU has a robust legal framework for the licensing, manufacturing and distribution of medicines, all indicated within the Directive on falsified medicines for human use²¹, which enables only licensed pharmacies and approved retailers to offer medicines for sale, including legitimate sale via the Internet. Since 2013, the EU's Falsified Medicines Directive (FMD) rolled out an end-to-end verification system to protect the legal supply chain. It includes two safety features on all prescription medicines placed on the EU market²², namely a unique identifier and an anti-tampering device²³. Despite the legislative measures, large volumes of genuine medication are still falling into the hands of criminal actors, while the engagement of professionals, as well as of illegal online pharmacies posing as legitimate vendors, continues to surge.

Pharmaceutical crime will continue, so long as the demand remains high and criminal actors continue to consider IP crime as a low-risk, high-profit endeavour. Misuse of medicines for recreational use and social commerce will continue to encourage and sustain the illicit market of counterfeit pharmaceuticals. Similar to other related intellectual property crimes, pharmaceutical crime may interact with other crimes such as fraud, money laundering, tax evasion, labour exploitation, corruption and document fraud.



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²¹ Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products, available at: <https://eur-lex.europa.eu/eli/dir/2011/62/oj>

²² Applicable in the EU and EEA on 9 February 2019, except Greece and Italy which should transpose the Directive by 9 February 2025.

²³ All marketing authorisation holders, manufacturers, wholesalers and those supplying medicines to the public, are obliged to scan medicines at different points in the supply chain, thereby verifying their authenticity, and to decommission them from the database at the time of dispensing.