

The theft of medicines in the EU

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Key results of the MEDI-THEFT project about the current status of the theft of medicines in the EU and the most relevant and common criminals' modi operandi.

Authors

Marco Dugato
Cosimo Sidoti



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Key results of the MEDI-THEFT project on the current status of the theft of medicines in the EU and the most relevant and common criminals' modi operandi

Authors:

Marco Dugato (marco.dugato@unicatt.it)

Cosimo Sidoti

Università Cattolica del Sacro Cuore di Milano
Transcrime – Joint Research Centre on Transnational Crime
Milan office (headquarters):
Largo Gemelli 1 - 20123 Milan (Italy)
Phone: +39 02 7234 3715/3716; Fax: +39 02 7234 3721

www.transcrime.it

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info@medi-theft.eu

The project MEDI-THEFT – Data sharing and Investigative Platform against Organised Thefts of Medicines is an EU co-funded project under the ISF-P Programme. The project aims at counteracting the theft and laundering of medicines by boosting effective investigations, strategic analysis and cross-border cooperation between public and private stakeholders through the development of an intelligence-based platform. This platform will allow to:

1. Collect, share and analyse information related to the theft of medicines to identify and prevent criminals' modi operandi;
2. Produce and share early warnings and alerts to prevent stolen medicines and medical devices to re-enter the legal market;
3. Support and improve joint transnational investigations related to the theft of medicines.

MEDI-THEFT has been launched November 1st, 2021.

For more details:

info@medi-theft.eu;

www.medi-theft.eu

Project MEDI-THEFT is implemented by



Preface

Lack of communication between public administrations and academia implies that researchers are often not aware of “good practices” developed by practitioners in specific fields. This is particularly relevant for complex issues touching different disciplines due to the lack of a common framework that collects and makes available the extent of scientific knowledge developed by public offices. As a consequence, detailed academic studies may be published without accounting for the already existing findings and procedures in place. This often results in a looping mechanism of citations that creates a sort of parallel self-referential universe from which public administration is excluded.

The fight against pharmaceutical crime, in its various forms, is certainly an example of this vicious mechanism. The different tasks entrusted to separate directorates of the Ministries of Health, national competent authorities, customs, specialised or generic law enforcement agencies, state laboratories, other authorities or local administrations often lack synthesis and sharing of the conducted activities. This lack prevents researchers from obtaining useful elements for their scientific analyses on these topics.

In the EU-funded projects on pharmaceutical crime coordinated by AIFA during the last decade, the relationship with universities has always been a priority. This is because AIFA acknowledges the added value of a dialogue between those who can implement practical initiatives and those who can look at the problems from a broader and external standpoint. This cooperation allows more effective identification of links or trends and brings original and significant contributions to the improvement of the adopted strategies.

In this vein, the collaboration with Università Cattolica del Sacro Cuore-Transcrime, as partners in the MEDI-THEFT project, is important for increasing the awareness of public administrations about a relevant and dangerous pharmaceutical crime: the theft and laundering of medicines. This crime is multifaceted and widespread all over the world, but it is adequately contrasted only in a few countries, such as Italy and the UK. Studies like the one reported in this report provide a broad and clear analysis of the characteristics of this crime as well as of the possible counteracting strategies. These findings are based on the positive experiences that the administrations and law enforcement agencies involved in the project have already witnessed and validated in their operational impacts.

The main objective of the MEDI-THEFT project is the dissemination of good practices in the fight against pharmaceutical crime, particularly the theft of medicines. This study is one of the results of this project. Hopefully, it will increase the awareness of this topic and contribute to the implementation of tools and procedures at the EU level, following the example of the strategy that starting from 2014 allowed Italy to eradicate this crime forcing criminals to look elsewhere for new targets and markets.

Domenico Di Giorgio
Head of Inspection & Certification Department
Agenzia Italiana del Farmaco (AIFA)

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Acronyms and abbreviations

AIFA - Italian Medicines Agency

CIS - Counterfeit Incident System

COVID-19 - Coronavirus disease 2019

CSA - Crime-Script Analysis

EDQM - European Directorate for the Quality of Medicines & HealthCare

EMEA - Europe, the Middle East and Africa

EU - European Union

EUIPO - European Union Intellectual Property Office

FMD - Falsified Medicines Directive

GDP – Good Distribution Practice

GMP – Good Manufacturing Practice

GPS - Global Positioning System

IIS - Incident Information Service

IPED - Image and Performance-Enhancing Drugs

LEAs - Law Enforcement Agencies

MS – Member States

NCA – National Competent Authority

PSI – Pharmaceutical Security Institute

OCG - Organised Crime Group

OECD - Organisation for Economic Co-operation and Development

OTC – Over the counter-medicines

PPE – Personal Protective Equipment

TAPA - Transported Asset Protection Association

UK – United Kingdom



What is the theft of medicines?

The theft of medicines and medical devices is a relevant component of the illicit trade in pharmaceutical products. However, a precise and widely accepted definition of this crime is still missing. This is partly because the concept of theft of medicines entails a wide range of illicit conduct, from small-scale thefts committed for personal usage to large-scale and highly organised criminal schemes (PSI, 2022).

In general, all thefts of medicines fall under Article 8 of the Medicrime Convention, which covers those pharmaceutical offences that are not included in the notion of counterfeiting (Council of Europe, 2015, p. 12). The theft of medicines is also encompassed by Interpol's definition of pharmaceutical crime as "the manufacturing and distribution of counterfeit or falsified (spurious/fake/falsely labelled) pharmaceuticals or medical devices, through licit and illicit supply chains, involving: (a) theft; (b) fraud; (c) diversion; (d) smuggling; (e) illegal trade; (f) money laundering; (g) corruption" (Interpol, 2012, p. 6).

The MEDI-THEFT project defines the theft of medicines as **any illegal taking of medicines or medical devices, usually perpetrated by organised criminal groups or networks, with the goal of either reintroducing the illicitly stolen products into the legal supply chain or selling them on the black market.** This definition reflects the project's focus on more serious and organised criminal activities.¹

1. This definition considers both medicines and medical devices in accordance with the definition of medical products provided by the Medicrime Convention. This is reasonable in the context of the MEDI-THEFT project considering that the interested parties involved in the crime, as victims or conniving actors, are often the same for thefts of medicines, medical devices, or PPE. However, the two categories of products have clear differences that affect the appeal to criminals and the consequent characteristics of the thefts or the criminal paths that stolen products follow after the crime.

Why focus on the theft of medicines?

The pharmaceutical sector has always been appealing and vulnerable to criminal activities (Vander Beken, 2007). Most of the political and research attention on pharmaceutical crimes has focused on counterfeiting. However, the theft of medicines can generate both direct and indirect relevant impacts that extend far beyond the value of the actual stolen products (Riccardi et al., 2014; Shepherd, 2015).

Specifically, stolen medicines and medical devices are not subjected to any quality standards related to distribution practices. Therefore, they might harm the patients who use them (Riccardi et al., 2015; Venhuis et al., 2018). Further, this crime raises regulatory and enforcement costs, as well as higher healthcare expenditures, hurting public authorities and national healthcare systems (OECD & EUIPO, 2020). Finally, the theft of medicines also impacts manufacturers, legitimate traders, and transportation companies who lose profits due to both the thefts and the associated efforts introduced to prevent, combat, or remedy them (Savona et al., 2018).

These considerations underscore why increasing the knowledge about the theft of medicines and contrasting this crime must be a priority for both public authorities and private stakeholders operating in the pharmaceutical sector.

Aims and methodology

Comprehensive knowledge about the theft of medicines is pivotal to increasing the awareness of public and private stakeholders and informing the implementation of more effective countermeasures. Unfortunately, the extant information on this crime is far from complete (Di Giorgio, 2022).

On the one hand, there are still few comparable and focused data or systematic studies on this crime, despite the evidence that the theft of medicines is a widespread and harmful practice. In specific, most of the currently available information in the EU focuses on Italy as a result of successful operations conducted by the Italian authorities to combat this issue (Di Giorgio, 2020). These operations followed a peak in thefts from Italian hospitals and transport routes that occurred at the beginning of the previous decade (Riccardi et al., 2014, 2015). Although, evidence indicates that theft of medicines was occurring in many other countries throughout Europe (Brüls & Wyer, 2016; Ekwall et al., 2016).

On the other hand, most of the currently available information relates to judicial cases and law enforcement operations that occurred years ago. For example, the Volcano Operation in 2014-2015 placed an important spotlight on this crime by illustrating for the very first time the transnational nature of the theft of medicines and the underlying role played by criminal organisations (AIFA, 2014b; Di Giorgio, 2015, 2020). However, later evidence indicates that, despite these successful operations, criminal organisations have continued their activities by developing new *modi operandi* or expanding their business to other countries (Di Giorgio, 2020; Di Giorgio & Russo, 2019). This calls for the need to update the current understanding of this crime.

Consequently, one of the aims of the MEDI-THEFT project is to analyse data and information from a wide range of different qualitative and quantitative sources in order to present an updated view on the current status of the theft of medicines across the EU and a description of the main *modi operandi* for stealing and reselling pharmaceutical products.

The following table summarises the data that was collected and examined by the project.

LITERATURE



Existing studies and specialised reports regarding pharmaceutical crimes or other associated activities (e.g., cargo crimes, counterfeits).

OSINT



News or press releases reporting cases of the theft of medicines or medical devices across EU MS between 2015 and 2022 (April). This collection relies on the **Nexis® Data Lab/Metabase**, a repository of international, national, and local sources which consists of more than 85,000 news sources from over two hundred countries in over ninety languages.

DATABASES



Data on thefts of medicines collected and provided by:

- **Pharmaceutical Security Institute (PSI)**: data on the thefts of medicines between 2018 and 2020;
- **Transported Asset Protection Association (TAPA)**: data on the thefts of medicines from cargo in the EMEA region between 2017 and 2022 (June);
- **Italian Medicines Agency (AIFA) and Carabinieri**: data on the thefts of medicines reported in the Medicrime/Fakeshare database in Italy during 2019.

SURVEY



Comparable information across EU MS on both the theft of medicines and the regulatory framework collected through a survey conducted in 2022 by Project MEDI-THEFT with the support of the Council of Europe's European Directorate for the Quality of Medicines & HealthCare (EDQM). This survey collected information from Health Regulatory Authorities in 16 EU MS and other 8 countries bordering the EU. To reach a more complete EU coverage, the results have been integrated with the survey carried out by AIFA in 2019 within the framework of the activities of the European Expert Group "Delegated act on survey features for medical products for human use" for the EU countries not responding to the MEDI-THEFT survey.

JUDICIAL FILES



Official documents from judicial cases related to the theft of medicines or medical devices that allow for the collection of detailed information about criminals' *modi operandi*.

INTERVIEWS



Interviews with key experts, from both public authorities and private companies, that procure detailed information on the key characteristics of the theft of medicines as well as representative case studies. The interviewees were representatives of LEAs, prosecutors' offices, health regulatory authorities, hospitals or end-vendors, international organisations, pharmaceutical companies, transportation companies, and parallel traders.

Magnitude of the theft of medicines in the EU

Providing an accurate estimate of the magnitude of the theft of medicines is challenging considering the shortage of reliable or exhaustive data about this crime. Indeed, most of the thefts suffered by pharmaceutical companies, transport industries, and healthcare premises are either not reported to the authorities or are not properly classified due to the lack of a shared definition of the problem (e.g., they are categorised as generic thefts) (Shepherd, 2017). This is further amplified by the lack of a common European reporting system that would ensure consistency in the monitoring of these events (Di Giorgio, 2020). Therefore, the available quantitative information should be considered partial and only indicative of the issue as a whole.

Amongst the few existing datasets gathering systematic information on the theft of medicines, the Counterfeit Incident System (CIS) managed by the PSI collects data on major thefts and other criminal events involving pharmaceutical products worldwide. In 2020, CIS reported 103 cases of major thefts with an estimated value of over \$100,000 (PSI, 2021). The United Kingdom (UK), France, and Russia were the European countries that experienced the greatest number of thefts.

Focusing specifically on cargo thefts, the data from the Incident Information Service (IIS) of TAPA showed a significant rise in the TAPA EMEA region² in 2020, reaching 67 cases in a single year and recording a 97% increase in comparison to 2017. However, 2021 data marked a downtrend with values more in line with earlier figures (TAPA, 2018, 2019, 2020, 2021, 2022).

With respect to Europe specifically, a survey conducted by Project MEDI-THEFT asked NCAs in 24 countries, whether they recorded any thefts of medicine from 2017 to 2021. This information was further integrated for the countries that did not answer using the data collected by AIFA in 2019 in a similar survey (Di Giorgio, 2020)³. Figure 1 shows the yearly average number of reported thefts of medicines to NCAs by country. A few countries (Italy, France, Sweden, and Spain) averaged more than thirty cases per year.

These results must be viewed with caution considering inconsistencies in the definitions of theft used and the different reporting rates across countries. Nevertheless, these results indicate that the issue is spread across the EU.

At first glance, the relatively low numbers of reported events appear to suggest that the theft of medicines is a minor issue. However, these reported crimes likely underestimate the actual number of thefts that have occurred. Indeed, 52% of the NCAs responding to the MEDI-THEFT survey believe that the figures they provided are underestimated, whereas only 38% of them think that they are reliable. For example, according to the data collected by PSI, cases of illegal diversion of pharmaceutical products are on the rise and currently account for most of the reported criminal events regarding pharmaceuticals (Figure 2). Since some of the diverted products are likely the result of theft or fraud, the high number of diversion cases could entail a comparable high number of thefts of medicines.

2. The TAPA EMEA region includes European, Middle Eastern and African countries. However, in the four years examined the recorded incidents in the TAPA EMEA region belonging to EU MS and other European countries account for around 98% of the total recorded events.

3. These countries are Bulgaria, Croatia, Cyprus, Greece, Ireland, Latvia, Lithuania, Luxemburg, Poland, and Iceland. Data for the UK are provided by AIFA as taken from the Fakeshare database.

Figure 1 Yearly average number of reported thefts of medicine to NCAs by country from 2017 to 2021⁴

Sources: Author’s elaboration of data from the MEDI-THEFT Survey and Di Giorgio (2020)

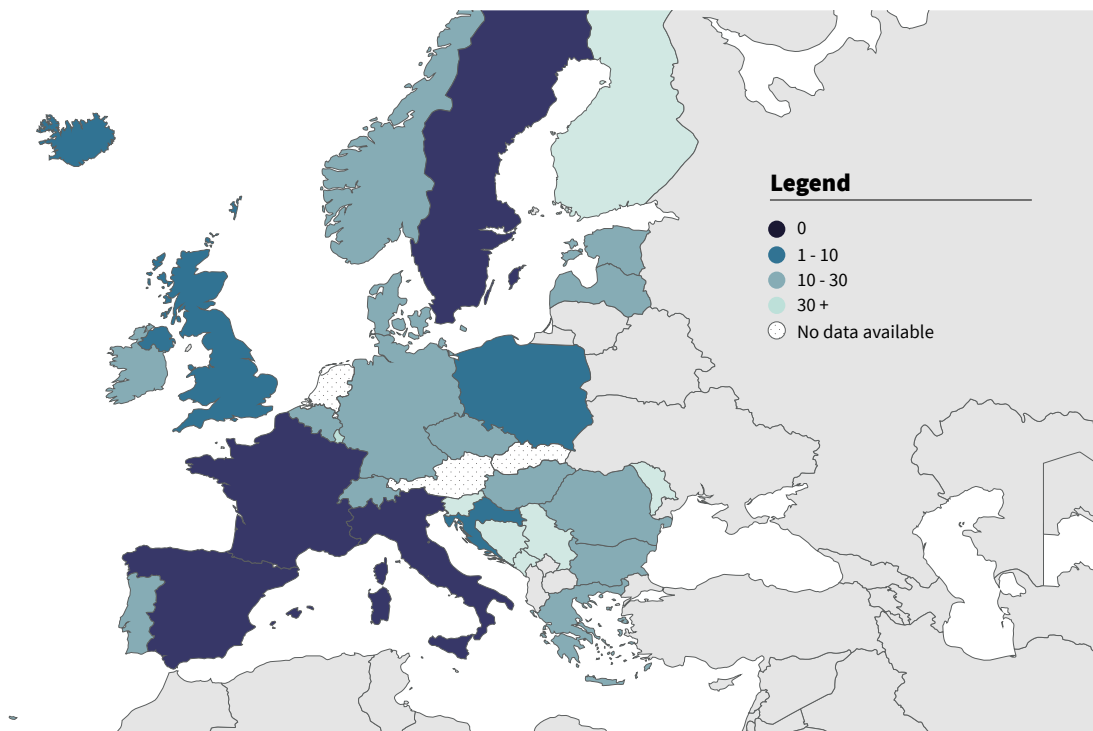
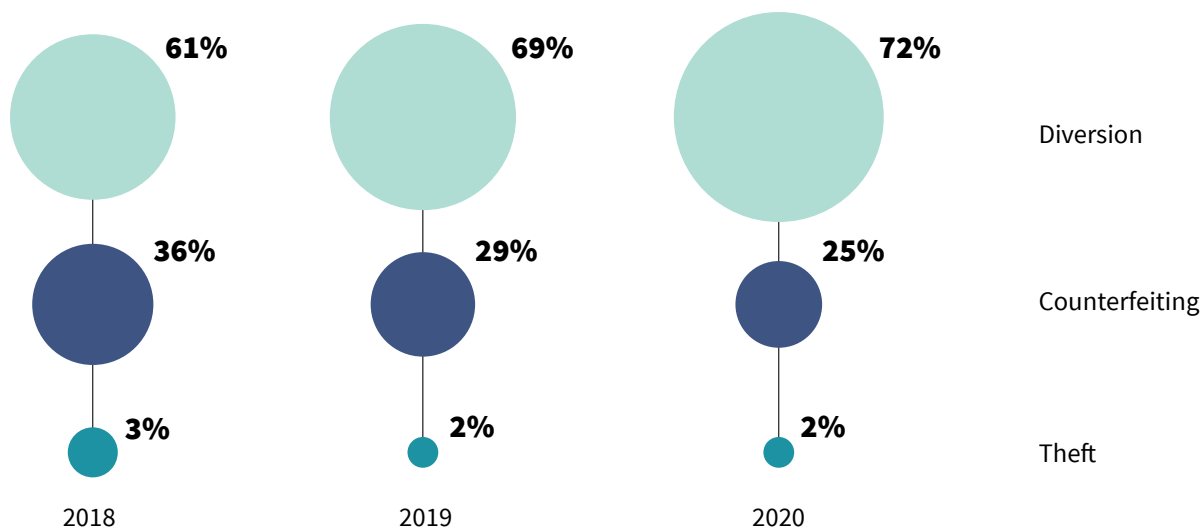


Figure 2 Proportion of events by type of the total number of events between 2018 and 2020 worldwide, as reported by PSI

Source: PSI (2021)



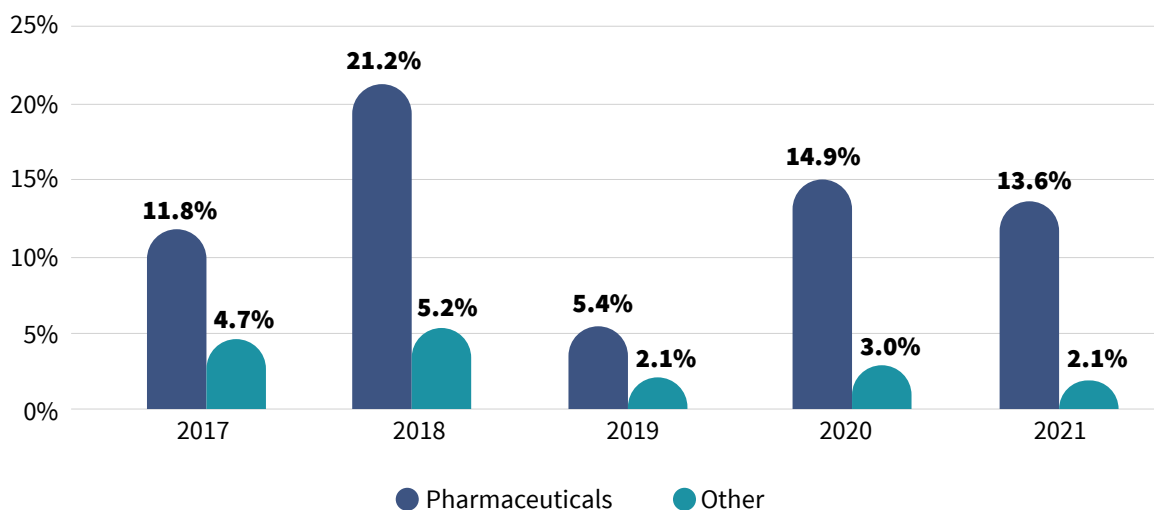
An additional indication of the increase in thefts of medicines is the significant number of cases of “lost” medicines recorded within healthcare facilities or during shipments. These losses could mask actual thefts, particularly when they involve vulnerable or appealing products (Di Giorgio, 2020). These latest considerations suggest that several cases of the theft of medicines can easily go unnoticed in light of both the lack of a proper system through which to report or classify these events and the limited awareness among the actors involved in the supply chain.

4. For Bulgaria, Croatia, Cyprus, Greece, Ireland, Latvia, Lithuania, Luxemburg, Poland, and Iceland data refers to 2018 and 2019.

Furthermore, even if the available figures were accurate, a single case of theft of medicine can amount to several thousand or even millions of euros. Therefore, it only takes a few cases each year to cause substantial economic losses for private companies or national healthcare systems. For example, in the TAPA EMEA Region, the proportion of major crimes⁵ among cargo thefts of pharmaceutical products is significantly higher than the same proportion among cargo crimes involving other products (Figure 3).

Figure 3 Proportion of major cargo crimes (€100,000 or more) on the corresponding total number of cargo crimes by type of theft between 2017 and 2021 in the TAPA EMEA Region

Source: TAPA (2018, 2019, 2020, 2021, 2022).



Given the lack of homogeneous and official statistics on the theft of medicines, the MEDI-THEFT project conducted a systematic scraping of news and press releases related to the theft of medicines across EU countries in twenty-four languages.⁶ This information complements the other available data to delineate a more complete overview of the theft of medicines. Furthermore, it allowed for the identification of relevant case studies that were used to analyse criminals' most common *modi operandi*.

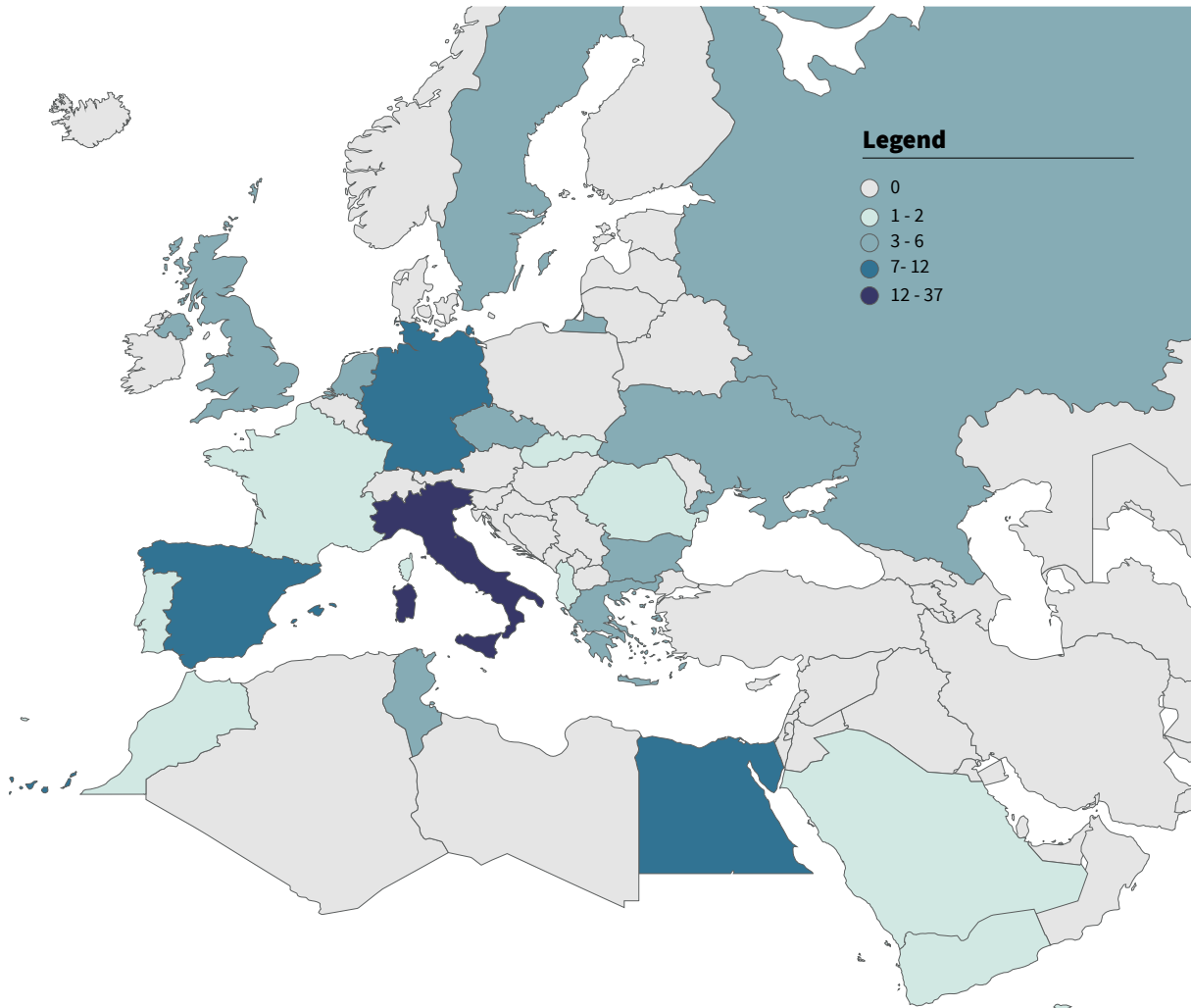
This search identified 1,177 news between 2015 and 2022 (April). These records were examined further, resulting in the identification of 87 unique and relevant cases. These cases involved 16 different EU MS or geographically close non-EU countries as either the location of the theft or the destination/transit countries of the stolen products (Figure 4). These results demonstrate how the theft of medicines impacts more countries than the ones in which the medicines are stolen given the transnational nature of the reselling channels used by criminals.

5. Major thefts are those events where the value of the stolen products is greater than €100,000

6. The queries that were used to scrape the news repository considered the presence of the words "Theft," "Robbery" or "Burglary" in association with the words "Medicine," "Pharmaceuticals" or "Medical devices," and focused on European sources only. The considered languages were Bulgarian, Croatian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Italian, Latvian, Lithuanian, Polish, Portuguese, Romanian, Russian, Slovak, Slovenian, Spanish, Swedish, and Ukrainian.

Figure 4 Most relevant cases of theft of medicines between 2015 and 2022 retrieved from news and press releases by country mentioned

Source: Transcrime's elaboration.



A typology of criminal schemes

The MEDI-THEFT project analysed the available evidence related to cases of the theft of medicines or medical devices in order to classify them as recurrent criminal schemes. The information on the cases of theft of medicines was retrieved mainly from judicial documents, news and press releases, interviews with relevant stakeholders and databases of reported crimes.

Seven criminal schemes were identified. A criminal scheme must be intended as a general pattern that defines a cluster of analogous cases in which criminals share similar *modi operandi*. Some of these criminal schemes are in accordance with the results of a recent study by AIFA (2020), while others derive from new information that emerged out of the analysis of the collected cases.

This chapter summarises the main traits of these criminal schemes adopted by criminals when engaging in the theft of medicines.

1.



SCHEME 1: INTERNATIONAL ILLICIT TRADER

This criminal scheme aims at stealing large quantities of high-priced medicines to reintroduce them into the legal supply chain, usually in other EU MS.

This scheme was a significant criminal opportunity, especially from 2014 to 2018. Today, it is declining because of the strategies adopted to prevent it. For example, the reinforcement of security measures in hospitals, the implementation of more efficient trackability systems, and increased coordination and information sharing between EU MS. Furthermore, the Falsified Medicines Directive (FMD) was enacted in 2019 with the dual aim of better regulating the parallel trade and developing a more effective standard of verification.



ACTORS

The primary role in this scheme is played by networks of criminals specialised in the reintroduction of stolen products into legal supply chains via the use of falsified documents. These groups coordinate and take advantage of contacts in both legal and illegal markets.

First, they typically contract local gangs or thieves or rely on infiltrated or corrupt employees in hospitals, warehouses, and transportation couriers to steal the medicines. Second, they connect with conniving pharmaceutical wholesalers or professionals in the healthcare sector to resell the stolen products. They also establish shell companies or deal with conniving companies that help them launder the stolen medicines.



TARGETS AND METHODS OF STEALING

This scheme targets large quantities of mainly hospital prescription medicines. Despite ordinarily being covered by national health systems, these products are nevertheless very expensive and their value is significantly higher compared to many other products within and beyond the pharmaceutical sector.

These thefts are usually highly planned. There are several different points in the supply chain where these medicines can be stolen, including manufacturing plants, cargo, warehouses, and hospitals. The selection of the target of the theft depends on two main factors: the expertise of the thieves and the cooperation of corrupt or infiltrated employees.

Thieves can enter the sites by breaking doors, windows, or walls, although in some cases they simply enter through unattended or unlocked entrances. Hospital pharmacies are especially vulnerable given the high turnover of employees and a lack of security measures. Although production facilities and warehouses are typically more protected against external thefts, highly organised criminal gangs may also target them. Perpetrators sometimes receive a list of products to steal, which is provided by conniving employees along with maps of the site or the precise locations of the medicines within storage rooms.

Thefts or robberies from cargo occur during primary distribution, either en route or in parking and rest stop areas. The cargo may be stolen fully or only partially. Thefts are often conducted by forcing the doors or slashing the curtains of the vehicles when they are parked or when drivers are resting in service areas. A less common method is stopping or assaulting moving trucks along motorways. This strategy is usually the most violent. Finally, other methods of cargo theft entail corruption or threatening the drivers.



TRANSPORTATION AND SELLING

Once stolen, the medicines are transported and stored in illegal warehouses. They are inventoried and laundered relying on the establishment of *ad hoc* shell companies that provide the false documentation. No further movements usually occur before products are sold and moved to their final destinations.

Afterwards, the laundered medicines are reintroduced into the legitimate pharmaceutical supply chain mainly through parallel trading using conniving or bogus wholesalers. Legitimate parallel exporters – who are either unaware or financially motivated – lawfully purchase the illicit products from these conniving or bogus companies and export them to the importing countries. Bogus companies are ordinarily based in countries with laxer transparency requirements, in order to elude controls and investigations.

The final destinations of stolen medicines are hospitals or other legitimate medical premises like private health clinics that buy these products usually unwittingly.

2.



SCHEME 2: SUPPLIERS

This criminal scheme aims at stealing low quantities of high-priced medicines on commission in order to export them into countries where these products are either unavailable or not covered by the respective national health systems, or to sell them in the same country if the patients' "out-of-pocket" expenditure is high.

This criminal scheme is apparently increasing. Thefts are usually conducted in EU countries, while the destinations of the stolen medicines are primarily in non-EU countries.



ACTORS

Organised crime groups lead this scheme by operating transnationally and coordinating the activities of various functional units through pre-existing networks or community ties. The thefts are commissioned to specialised gangs or criminals who are tasked with stealing the required products. Then, members of the main criminal group or the same local gangs that commit the thefts manage the transportation of the stolen products to the destination countries. Finally, the sale of the stolen medicines is primarily handled by professionals in the pharmaceutical sector. Through their professional networks, they are in contact with the clients or medical facilities that buy the products on the black market.



TARGETS AND METHODS OF STEALING

This scheme targets small to medium-sized quantities of prescription medicines that are either unavailable or not covered by the national health systems in the destination countries, which makes them unaffordable for local patients. Ordinarily, these thefts are commissioned directly by healthcare facilities or professionals in the destination countries, acting as brokers between the thieves and patients.

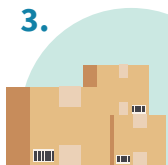
The medicines are primarily stolen from hospital pharmacies. However, warehouses and production facilities are also potential targets. Simple theft or burglary are the two main methods used by criminals. Since the crimes occur on commission, a new recent trend in the supply of these medicines is to offer sample products to potential customers. In these cases, criminals break into the facilities where medicines are stored and take some pictures of the available products. The client/broker can immediately receive these photographs for confirmation, or the pictures can be kept as a portfolio to be shared with other potential clients. Criminals may also grab one or two packs of medicines as samples.



TRANSPORTATION AND SELLING

The stolen products are kept in illegal warehouses or facilities and then transported abroad inside personal luggage (“ant-smuggling”) or through postal services as deliveries from legitimate companies or individuals. These products are then sold on the black market to private medical premises, such as health clinics or private doctors, or wealthy individuals either directly or through conniving professionals.

3.



SCHEME 3: GENERALISTS

This criminal scheme aims at stealing medium to large quantities of low-value over-the-counter (OTC) medicines or other prescription medicines and generic medical devices to supply local pharmacies or private medical facilities.

Compared to the previous two schemes, this one has a more local dimension since products are stolen and resold usually within the same country.



ACTORS

Professionals in the legal pharmaceutical market, such as pharmacists, doctors, or wholesalers are the key players in this scheme. They exploit their knowledge and extended networks in the healthcare sector to launder and sell stolen products while commissioning the thefts to local criminals. These thieves usually do not specialise in the theft of medicines, but they are active in a wide range of criminal activities and deal with all sorts of products.



TARGETS AND METHODS OF STEALING

The targeted products are large quantities of all kinds of OTC or prescription medicines and generic medical devices. Although they are not remunerative products, there is broad demand for them amongst the population. Moreover, there is less monitoring of these products by authorities and most of them can be sold directly to clients in legal businesses (e.g., pharmacies, convenience shops).

These medicines are stolen from cargo, hospitals, and pharmacies. Cargo theft occurs during both primary and secondary distribution. However, the latter stage is more commonly targeted in this criminal scheme considering the opportunistic nature of this crime. The preferred method is usually to steal the entire cargo or a portion of it while the truck is parked or left unattended during a delivery. In some instances, thieves follow the delivery trucks and steal the products immediately after they have been delivered. Other methods involve deception or fraud in which criminals pretend to be the real recipients of the products or infiltrate local delivery companies. Burglary and robbery are the most common methods for stealing medicines from hospitals or other pharmacies. Since these products are often stored with fewer security measures, it is also possible for criminals to steal these products by entering hospitals or healthcare facilities during daylight, pretending to be hospitalised, employees or relatives of patients.



TRANSPORTATION AND SELLING

The stolen medicines are kept in proprietary warehouses, which are ordinarily linked to the legal premises run by the criminals, and no further transportation is undergone prior to the final sale.

The final clients are typically unwitting local pharmacies, healthcare premises owned or managed by the criminals, or individuals via online channels. Stolen products are either sold via fake online pharmacies

and marketplaces or reintroduced into the legal supply chain by falsifying their supporting documents, so that they appear to come from legitimate companies. Unauthorised e-pharmacies are websites that look legitimate to deceive customers. In some countries, it is illegal to sell some type of medicine online, but the lack of awareness of the general public helps this selling channel spread amongst the population.

4.



SCHEME 4: RECYCLERS

This criminal scheme aims at stealing expired medicines, pharmaceutical waste or brand new medicines in order to provide counterfeiters with samples of new or highly requested products.

The destination of stolen products involves mainly counterfeiting laboratories at the local level or in countries where the largest production of counterfeit medicines is located.



ACTORS

The key players in this scheme are criminal groups that engage in the counterfeiting of medical products. These organisations hire local criminals to commit the thefts. These thieves are not highly professional and exploit the opportunities created by the vulnerabilities in the legal supply chain (i.e., garbage thefts). The stolen products are then provided to criminals specialised in the falsification and adulteration of stolen medicines. This scheme often needs the involvement of conniving professionals in the pharmaceutical sector, in order to know both the types of products that are in higher demand and how to retrieve them.



TARGETS AND METHODS OF STEALING

The products targeted are wasted or expired products or small quantities of recently released pharmaceuticals in the legal market. The latter products are highly appealing to counterfeiters because they are not supplied in many countries, thus creating a demand for potential buyers.

In order to steal medicines specifically for the purpose of counterfeiting, the places where thefts occur are primarily hospitals or other healthcare facilities. Thefts from cargo or production sites are less frequent and usually entail small-scale burglaries or thefts supported or perpetrated by conniving employees.



TRANSPORTATION AND SELLING

The stolen medicines are transported and stored in illegal warehouses or moved directly to the illegal production facilities of counterfeiters.

Cooperation between thieves and counterfeiters also takes place in the fencing of stolen products. In recent years, the evidence shows that criminals are increasingly resorting to altering or counterfeiting the packaging or labels of the stolen products in an attempt to elude the controls of national authorities or legitimate operators who are destined to unwittingly receive the stolen medicines.

5.



SCHEME 5: DEALERS

This criminal scheme aims at stealing medical products that can be used in illicit or recreational activities in order to sell them on the black market (either offline or online).

These thefts occur across all of the EU and the destinations are often local markets. However, the growth in online sales may present new business opportunities for criminals by virtue of opening up access to other markets in the EU or beyond.



ACTORS

The main actors in this scheme are brokers who primarily belong to specific sectors such as, for example, fitness and sporting (e.g., gym managers or owners, bodybuilding instructors, staff members of sports teams and federations), animal sports (e.g., breeders, veterinarians, and drivers), beauty and cosmetics, or sex-related services and adult entertainment (e.g., adult movie actors or producers, managers of escort agencies and sex shop owners).⁷ Most of these individuals have no prior criminal records and often operate as retailers, selling the stolen products directly to the clients by exploiting their legitimate professional affiliations and relationships. Some of them are also wholesalers, selling to other retailers, who often work in the same professional environment.

Stolen medicines are supplied to these brokers by individuals working in the healthcare sector (e.g., pharmacists, physicians, hospital employees, and employees of pharmaceutical and para-pharmaceutical companies) or by external thieves hired for this specific purpose. The latter includes both cargo crime specialists in primary distribution and local gangs who resort to more opportunistic thefts during the last mile of distribution, as well as from hospitals and warehouses. Alongside direct sales to individuals or conniving businesses, the stolen products are increasingly being resold online which provides opportunities for dispersed actors to connect with one another.



TARGETS AND METHODS OF STEALING

The targets are specific medicines known as lifestyle or image and performance-enhancing drugs (IPEDs) (Di Giorgio, 2022; Turnock, 2020). The most common of these are anabolic steroids, EPO, insulin, stimulants, weight loss products, and medicines for erectile dysfunction. Further, several cases of the theft of veterinary drugs have also been recorded. Although these medicines are ordinarily not highly profitable, the demand for them is high in particular environments (e.g., professional bodybuilding, animal racing, sports, cosmetics, and adult entertainment). However, the increased usage of IPEDs amongst the general population has led to an overall increase in demand.

IPEDs are stolen from a wide range of places or facilities, including cargo, warehouses, hospitals, and pharmacies. The *modus operandi* involves primarily healthcare employees and the physicians who also work in these facilities. The legitimate roles they play in their businesses, organisations, or professions allow them to mask their illegal activities. Low-level healthcare employees often contribute to the supply of these products by helping to steal them, while doctors may purposely divert the products by stealing or falsifying prescriptions. Medicines are stolen from cargo or warehouses by personnel from transportation and wholesale businesses. External thieves also contribute to the supply by carrying out thefts during both primary and secondary distributions, warehouses, hospitals, and pharmacies.

7. See also Antonopoulos and Hall (2016) and Paoli and Donati (2014).



TRANSPORTATION AND SELLING

After being stolen, these medicines are transported and stocked in illegal warehouses or stored in conniving businesses. Then, they are sold online in unlicensed pharmacies or marketplaces. Alternatively, the medicines are provided directly to individuals via face-to-face interactions, which often rely on conniving or unwitting legal businesses (e.g., gyms and sex shops).

6.



SCHEME 6: TECHNICIANS

This criminal scheme aims at stealing high-priced medical devices or equipment and selling them abroad either on the black or secondary markets.

Thefts are usually committed in EU MS, while the final destinations include countries both within and outside the EU.



ACTORS

This scheme is managed by transnational criminal networks mainly based outside the EU that take advantage of already existing community ties or flows of illicit products across countries to facilitate the movements of the stolen products across borders. Small groups committed exclusively to the thefts reach the target places and then return to their origin countries immediately after the crime is completed. Other operative units are involved in transporting small quantities of the stolen medical devices in personal luggage (“ant-smuggling”) to the destination countries. Alternatively, these groups outsource the transportation of the stolen products to either conniving transport couriers or postal services.

With respect to laundering and selling, criminals connect with professionals in the healthcare sector, who are needed to whitewash medical devices through fictitious or conniving companies and subsequently sell them, either directly to the final clients or to legitimate wholesalers on the secondary market. As most of these devices are easy to damage, rendering them useless and unsellable, these professionals also offer valuable expertise on how to handle them.



TARGETS AND METHODS OF STEALING

The targeted products are small quantities of high-priced medical devices of small size and weight (e.g., endoscopes, surgical drills, or optical medical equipment). The lower awareness about their vulnerability to crime and the fewer safety measures can make these products even more attractive to criminals than medicines. Moreover, these medical devices can be easily stored and transported in hiding.

Hospitals and other public or private healthcare facilities are the primary places where thefts occur. For example, some thefts of optical medical devices have been recorded in optician shops or private doctors’ offices. The thieves commit burglaries at night by breaking and entering the premises, or, alternatively, stealing the products by entering healthcare facilities by pretending to be hospitalised, acting as a relative of a patient, or by disguising themselves as doctors. There is also frequent collusion with the internal personnel of these facilities.



TRANSPORTATION AND SELLING

The stolen medical devices are directly transported abroad, usually to non-EU countries, either through regular delivery services or concealed in personal luggage by airplane or private means of transport. Criminals often rely on already established smuggling routes and channels (e.g., drug trafficking, counterfeits). Sometimes, conniving transport couriers or legitimate postal services are used to ship the stolen products.

The most common final clients are witting or unwitting hospitals and other legitimate medical premises. Stolen products are sold at competitive prices on the black market or as reusable items on the secondary market via the use of fake documentation. Products can either be sold in the home countries of criminal organisations or resold back to the EU markets or other high-priced countries (e.g., the United States).

7.



SCHEME 7: MERCHANTS

This scheme aims at stealing large amounts of low-priced medical devices or personal protective equipment (PPE) that are in broad demand amongst the general population, in order to sell them either on the black market or to conniving or unwitting legal businesses.

The COVID-19 pandemic has favoured this scheme by boosting both the demand for and the circulation of large amounts of these products. The destinations for the stolen medical devices can be both EU and non-EU countries. However, this scheme is often locally based given the low level of organisation of the perpetrators.



ACTORS

Small and medium-sized criminal groups are primarily active in this scheme. These groups are not highly organised and are often not specialised in pharmaceutical crimes. They are able to exploit opportunities for stealing large quantities of medical devices through their local connections and illegal activities within their territory. Their connections usually comprise conniving employees in transport and courier services as well as professionals in the import/export or healthcare sectors. While the formers facilitate the commission of the crimes or organise the logistic services needed to transport the stolen products, the latter manage or support the subsequent sale of the stolen products.



TARGETS AND METHODS OF STEALING

The targeted products are large quantities of medical devices or PPE that are ordinarily characterised by their small size and low to medium value (e.g., facemasks, ventilators). Criminals steal pharmaceutical products from cargo during transportation or when stored in warehouses. The main strategies used for cargo theft include either the theft of a full truckload or a partial theft of the load in parking and rest stop areas. Burglary is the most common method used to steal from warehouses. There is frequent collusion with employees in both transportation companies and warehouses.



TRANSPORTATION AND SELLING


Large quantities of stolen medical devices are transported and kept in illegal warehouses by the thieves. According to both the quantities that are stolen and the management capacities of the criminal groups, the selling channels are diversified between the marketing of the products on the black market and their reintroduction into the legal supply chain using fake documents provided by conniving professionals or bogus companies.


In the case of laundered products, the clients are unwitting healthcare premises or other legitimate businesses (e.g., pharmacies and convenience shops). Sales in the black market directly target citizens through conniving legitimate businesses (e.g., pharmacies, convenience shops), street vendors, or online channels, such as social media (e.g., Facebook, Telegram, Twitter, and Instagram), marketplaces, or dedicated websites.


Main characteristics of the theft of medicines

The available evidence suggests that these criminal schemes should not be considered mutually exclusive, but rather as a concatenated flow of actions that can also co-exist and be performed in parallel. Similarly, the same criminal actors may be involved in multiple schemes and interchange their roles depending on the specific tasks and competencies required for the execution of the crime.

In general, the analysis of the identified criminal schemes highlights that:

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1. The theft of medicine is widespread. Notwithstanding the lack of precise and complete data, the available information indicates that thefts of medicines and medical devices occur in most countries across Europe. Moreover, most of the identified criminal schemes highlight the transnational nature of this crime, not only affecting the countries where the thefts are committed but also those where the stolen products are transited or sold.
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2. The theft of medicines is a complex crime. The theft of medicines involves and connects a wide range of different criminal and illicit acts beyond the mere stealing of products. The level of complexity varies according to the specific characteristics of the criminal schemes, such as the quantity and type of stolen products; the economic profits generated; the possible cross-border nature of the trafficking; and the existence of a pre-existing organised structure engaged in other types of illicit trafficking.
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3. The theft of medicines is an organised crime. To manage this complexity, criminals' activities tend to be decentralised to specific functional units (e.g., thieves, transporters, fences, and retailers) that are coordinated by a management group, usually in charge of brokering or coordinating the different actors. These criminal networks are often loosely structured and only occasionally linked with more traditional criminal organisations. Especially in the case of major crimes, yielding high profits, these criminal organisations are ordinarily entrepreneurial and extremely market-oriented.
- 

4. The theft of medicines is various and evolving. The identified criminal schemes highlight how thieves can target different products, rely on various methods for stealing them, and exploit several channels to sell them to both witting and unwitting clients. This creates a wide range of opportunities for criminals operating in this illegal market, allowing them to choose among alternative products or locations primarily for opportunistic reasons. Finally, evidence demonstrates how criminals have been able to adapt rapidly to respond to the countermeasures adopted or to take advantage of emerging scenarios (e.g., consequences of COVID-19).

5.



The theft of medicines is often facilitated by conniving professionals. Criminal organisations lean heavily on conniving professionals, employees, or brokers along the pharmaceutical supply chain. First, they take advantage of their occupations to steal or facilitate the stealing of the products. Second, based on their expertise, they can establish whitewash mechanisms and broker between criminals and clients in order to sell stolen products. Third, these actors also help to either set up bogus companies or mediate with conniving ones to commit the thefts or favour the “laundering” process of the stolen products.

Assessment of the regulatory framework

Given the transnational nature of many criminal schemes related to the theft of medicines, almost every country is potentially vulnerable to this crime. The likelihood of a country becoming the origin (where the thefts occur), transit (where stolen products are moved or where bogus companies are created), or destination (where stolen products are sold) point for this crime depends on various factors. Most of these factors relate to specific characteristics or existing asymmetries in the regulation of the legal pharmaceutical market and the national healthcare systems that can favour or attract criminal activity.

Therefore, the report concludes with an assessment of the regulatory framework of the pharmaceutical market in the EU, which involves examining five different dimensions identified as being related to the theft of medicines.

SPECIFIC LEGISLATION AND ENFORCEMENT

Effective legislative action against the theft of medicines is necessary to productively combat this crime. The implementation of specific laws impacts the prevention of the theft of medicines by, amongst other things, enabling better identification and monitoring of the issue (i.e., by increasing awareness amongst all involved actors and distinguishing it from other criminal activities) and facilitating more adequate investigative measures and sanctions, including cooperation at the national and international level.

Currently, only six EU MS have ratified the Medicrime Convention and, hence, have specific offences for counteracting pharmaceutical crimes. Other countries may not have similar provisions. For example, 35% of the countries responding to the MEDI-THEFT survey do not have a specific criminal law relative to the theft of medicines. The consequence of this is that the criminal justice system may deem thefts of medicines to be minor offences, thus neglecting the profoundly deleterious impact this crime can cause.

REPORTING SYSTEMS AND PROCEDURES

With respect to the reporting procedures, eleven EU MS currently make use of no institutional reporting systems related to pharmaceutical crimes. Moreover, amongst the countries that do have reporting channels, only Italy and the UK use systems specifically devoted to cases of theft and diversion, while the systems in other countries relate to cases of falsification, counterfeiting and quality defects.

The information collected by the MEDI-THEFT and AIFA surveys also highlights that in six EU MS there is no legal obligation for any of the actors involved in the legal pharmaceutical supply chain to report thefts of medicines to their NCA. However, the results of the survey also show that several actors report thefts of medicine to NCAs even if it is not mandatory by law. This is a positive indication of the presence of effective cooperation between NCAs and other entities or authorities, albeit the lack of formal obligations may cause less reliable and systematic reporting.

COOPERATION AND DATA SHARING

Detection and counteraction of the theft of medicines are often hindered by a lack of communication between healthcare authorities, customs agencies, law enforcement agencies, judiciary systems, and the private sector. Cooperation and information sharing are not only necessary in reporting but also during investigations and trials.

The fact that only nine countries have access to a database or a blacklist of stolen medicines underscores the need for greater cooperation and data sharing amongst the involved stakeholders. Among the survey respondents, only Italy considers these databases as both accurate and updated. The majority of the respondents (84%) claimed that these databases are mainly not updated and about half of them (46% of the total) consider these databases and blacklists as both not updated and inaccurate. Further, none of the EU NCAs are involved in informing local enforcement authorities on pharmaceutical thefts and how to report them, while only Italy and Latvia communicate with stakeholders through a central database that is connected with the pharmaceutical traceability system.

SUPPLY CHAIN CONTROLS

The different criminal schemes shed light on how the infiltration of the legal pharmaceutical sector is one of the primary methods through which criminals are able to steal, traffic, and fence medicines or medical devices. This calls for the need to improve due diligence and controls over the legitimate actors involved in the entire pharmaceutical supply chain.

Currently, the certificates of Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) are the principal tools for both certifying the reliability of legal companies operating within the pharmaceutical industry and preventing criminal infiltration of the supply chain. However, available data on GMP and GDP non-compliance must be viewed with caution, insofar as they may be biased by both the efficacy of the inspections and the completeness of the information reported to EMA.

Besides improving the GMP and GDP certificates and corresponding inspections, private companies should also strive to enhance their procedures for increasing transparency and trust amongst legitimate actors in the supply chain. This implies the strengthening of the due diligence and know-your-customers analysis conducted both prior to and during the contractual agreements as well as increasing adherence to international standards, such as those provided by TAPA regarding logistic companies.

REIMBURSEMENT AND PRICING POLICIES

Sizeable price differentials between countries can incentivise criminals to divert and smuggle legitimate products from one market to another. In this regard, asymmetries in both the pricing policies and reimbursement regimes of pharmaceutical products adopted by different states may lead some of them to become either origin or destination points for stolen goods.

For example, external price referencing is the most common approach adopted by EU MS, which implies that prices are set according to the benchmark prices for either identical or similar medicines in comparable countries. This means that the prices that are set in one country directly influence the prices in other countries, thus potentially leading to unaffordable medicines or causing fewer or delayed launches of new drugs in lower-income countries. Moreover, reimbursement regimes can also influence the illegal demand for medicines. Low or limited reimbursement regimes create the incentive to acquire illicit pharmaceuticals at lower prices, determining the vulnerability or attractiveness of the country to criminal activities.

Conclusions

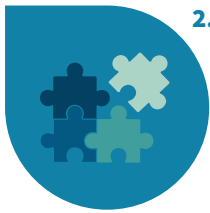
This report summarised the analysis conducted by the project MEDI-THEFT highlighting the current information about the magnitude of the theft of medicines and medical devices across the EU; delineating a typology of the main criminal schemes used to steal and re-sell pharmaceutical products; and providing an overview of the current regulatory framework related to this crime.

Three main conclusions can be drawn from these results, which also support the subsequent activities of the MEDI-THEFT project.



1.

Systematic, complete, and reliable data on the theft of medicines are still missing. Evidence indicates that this crime is a serious issue in many EU MS and has a deleterious impact on national economies and the health of citizens. However, the available quantitative data are often lacking and inconsistent across countries. The underestimation and underreporting of the theft of medicines derive from many factors, including the lack of a shared definition of this crime type, low awareness by public authorities and private actors, and the absence of effective reporting systems in place to collect this information.



2.

The criminal schemes identified testify to the complexity of this crime. The theft of medicines comprises a wide range of different criminal behaviours that are often transitional in nature and require the involvement of several actors with distinct roles or competencies, including the participation of conniving legitimate professionals or companies. Combating the complexity and variety of this crime type requires paying ongoing attention to new or emerging criminal *modi operandi*, not to mention the adoption of coordinated actions between public and private stakeholders and across different countries and jurisdictions. Thus, it is fundamental to increase both the sharing of information and the level of cooperation between all the relevant actors.



3.

The current regulatory framework regarding the theft of medicines remains inadequate in many EU MS. On the one hand, this generates asymmetries and loopholes that are potentially exploited by criminals to operate with greater impunity. This makes the theft of medicines a high-reward and low-risk activity. On the other hand, the lack of consistent legislation or common procedures for dealing with this crime hinders the possibility of correctly monitoring and effectively counteracting it. This calls for the direct engagement of public authorities to support the revision and strengthening of some of the current legislation or policies. The goal should be to develop more effective forms of prevention for this crime by eliminating the opportunities provided by current regulation or inefficiencies in its implementation.

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