



BEST PRACTICES
to manage cases of thefts of medicines in the 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:

- collect, share and analyse information related to the theft of medicines to identify and prevent criminals' modi operandi;
- produce and share early warnings and alerts to prevent stolen medicines and medical devices to re-enter the legal market;
- support and improve joint transnational investigations related to the theft of medicines.

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

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ABBREVIATIONS

AIFA – Italian Medicines Agency

CRAVED – Concealable, Removable, Available, Valuable, Enjoyable and Disposable

EDQM – European Directorate for the Quality of Medicines & HealthCare

EFPIA – The European Federation of Pharmaceutical Industries and Associations

EMA – European Medicine Agency

EU – European Union

FMD – Falsified Medicines Directive

GDP – Good Distribution Practice

GMP – Good Manufacturing Practice

HMA – Heads of Medicines Agency

IFPMA – International Federation of Pharmaceutical Manufacturers & Associations – IFPMA

LEAs – Law Enforcement Agencies

LEOs – Law Enforcement Officers

MAH(s) – Marketing Authorization Holder(s)

MS – Member States

NCA(s) – National Competent Authority(ies)

PSI – Pharmaceutical Security Institute

TAPA – Transported Asset Protection Association

UI – Unique Identifier

UK – United Kingdom

US – United States

WGEO – Working Group of Enforcement Officers

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THE FRAMEWORK: WHY TO LOOK FOR PHARMACEUTICAL THEFTS?

Collecting data about thefts of medicinal products is necessary to understand the possible extent of this phenomenon to combat it and remove the risk of falsified medicines entering the supply chain and posing a threat to public health. The general lack of knowledge derives, in part, from the scarcity and inconsistency of the available data on thefts due to the high level of unreported or misreported events.

VALUABLE, ACCESSIBLE AND DISPOSABLE GOODS ATTRACT THIEVES



This statement is obvious but true.

Many guidelines on theft-related risk analysis (see *References 1 on page 32*, and *2 on page 33*) underline the characteristics of the goods that are most frequently stolen – **an accessible product, of high value and easy to sell, is a magnet for thieves.**

Small scale thefts (such as shoplifting of steroids or other medicines which can be sold in local gyms) and broader laundering schemes (such as the ones of the “Volcano Operation”, where stolen hospital medicines were laundered via falsified invoices and infiltrated into the EU distribution chain) are both based on an easy access to the “supply” (medicines in hospital pharmacies or in distribution warehouses, which were not protected/monitored sufficiently) and to efficient and established “selling channels” (local black market, infiltrated distribution chains, illegally operating websites...).

IF IT CAN BE SOLD, IT IS VALUABLE



This statement is also true.

If criminals can access a suitable distribution channel, they will use it either for high value or cheaper products, modifying quantities and features of their supply/selling practices: systematic shoplifting or “distraction” of small quantities of inexpensive products (see *Reference 3 on page 34*) may be as profitable as a more obvious attack on a lorry transporting several medicines (see *References 4 on page 35*), or as a raid on a high price drugs warehouse (see *References 5 on page 35*).

There are many different modi operandi for medicines thefts, targeting different products and channels: it is a mere matter of features, for a same recurring and widespread process. Similar modi operandi can be grouped in schemes: in the MEDI-THEFT Report “**The theft of medicines in the EU**” (Transcrime, October 2022 – <https://www.medi-theft.eu/publications/>) have been identified 7 criminal schemes:

schemes targeting medicines

- **International traders** stealing large quantities of high-priced medicines for the purpose of reintroducing them into the legal supply chain mainly in other countries within or outside the EU
- **Suppliers** stealing low quantities of high-priced medicines on commission to export them to countries where these products are either unavailable or not covered by the national healthcare systems
- **Generalists** stealing large- or medium-sized quantities of either low-value medicines or generic medical devices to furnish local pharmacies or private medical facilities
- **Recyclers** stealing expired medicines or pharmaceutical waste to provide organisations of counterfeiters with samples or materials about either new or highly requested products
- **Dealers** stealing medicinal products that can be used in illicit or recreational activities for the purpose of selling them on the black market

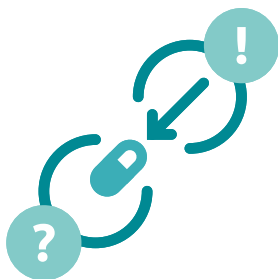
schemes targeting medical devices

- **Technicians** stealing high-priced medical devices or equipment and selling them abroad, either on the black or secondary markets

- **Merchants** stealing large amounts of low-priced medical devices that are in high demand amongst the general public, in order to sell them on the black market or to either conniving or unwitting legal businesses

If in your country you have thieves (both shoplifters or organized crime structures), it is almost certain that they will also target medicines.

STOLEN MEDICINES WILL ALMOST ALWAYS BECOME FALSIFIED MEDICINES



Stolen medicines are often sold in the black market (as well as on the street or on the web), to customers who are often aware of their origin; in other rare cases, medicines are stolen in the framework of a broader criminal scheme, and then left in the rubbish without any attempt to sell on.

But in most of the cases that have been investigated since 2013, stolen medicines are infiltrated in the legal distribution chain, through any accessible loophole, by “laundering” them with paperwork falsely stating their nature, origin, traceability/history.

Consequently, according to the definition in **Directive 2001/83/EC (art. 1, c. 33)**, they become falsified medicinal products and subject to the specified measures aimed at protecting public health from falsification.

THEFTS ARE OFTEN CONSIDERED AS A LOCAL ISSUE, AND THEREFORE ARE USUALLY LOCALLY REPORTED



As discussed in the above mentioned MEDI-THEFT Report “**The theft of medicines in the EU**” (Transcrime, October 2022 - <https://www.medi-theft.eu/publications/>), all the available evidence indicates that theft of medicines is widespread across Europe and the rest of the world, and that it involves complex schemes that connect different criminal and illicit acts beyond the mere stealing of products.

Since the most commonly reported kind of medicinal product theft is shop-lifting (see [Reference 6 on page 36](#)), definitely a local issue, aimed at personal use or at local black market distribution of products (such as opioid and doping substances), the common practice is to keep the investigations at a local level, without reporting the cases to a central competent authority.

In the absence of a formal obligation to report the cases to the medicines/medical devices National Competent Authorities (NCAs), or to a central specialized police force, local cases will be filed locally, remaining unnoticed.

It is important to underline that when an added value is not perceivable, even the reporting obligation may lack efficacy*, but when reporting is generating a perceivable added value for the involved stakeholders, as for the Italy/UK strategies (targeting MAH and LEA as main partners – see [Chapter 3 on page 14](#)), the reporting channels may be activated in an efficient way.

MEDICINES ARE STOLEN EVERYWHERE, EVEN IN YOUR COUNTRY BUT YOU WILL NOT BE AWARE OF IT, IF YOU DO NOT LOOK FOR DATA



Data from the two surveys managed by AIFA/EC (2019) and MEDI-THEFT (2022), confirm that the highest reporting rate in Europe with respect to thefts is related to countries who were part of the **FAKESHARE** project (Italy, Spain, UK), aimed at setting up the European thefts database and the ad hoc reporting channels.

During the project, AIFA (Italian NCA) supported MHRA (UK NCA) in setting up a “Law Enforcement Officer Day”, where (see [Chapter 3, par. United Kingdom on page 20](#)) over 40 Heads of the local police units filing theft reports were trained, regarding the opportunity of reporting the cases to the central

* As for the Dir. 2011/62/EC article requesting wholesalers and trader to report the authorities any “suspicious offer” for medicines, that did not generate a number of signals in line with the cases that were investigated in the last 10 years.

FAKESHARE database fed by MHRA, and educated about the existing organized schemes allowing international laundering of stolen medicines.

After one year, the number of reported cases started growing, and today the filed reports of thefts from other countries, such as the UK, outnumbered those from Italy, the coordinator of the initiative. Medicines are stolen everywhere, but thefts are generally not reported to the national/international network dealing with medicinal product crime: another confirmation of the evaluation that was already shared with the EC in the AIFA White Paper and publications regarding medicinal product thefts (see [Reference 7 on page 36](#)),

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WHERE IS THE DATA?

Data collection about pharmaceutical theft helps in evaluating the possible extent of this phenomenon, a threat to public health that has to be combatted as any other kind of medicines falsification.

Beyond this context assessment exercise, data gathering regarding medicinal product thefts is also mainly aimed at launching rapid alerts (see *Chapter 4, par. Choose your partners in data gathering on page 26*) in order to prevent the infiltration of the stolen medicines, whose quality is no longer guaranteed, in the distribution network.

Some basic information is needed, regarding brand names, package, quantities, batch numbers and expiry dates (but also **Unique Identifier** codes, if available); moreover, some information regarding the incident may help in building a “bigger picture”, seeing the connections between different cases: type of event (theft, robbery, loss...), date and location, and also the indication of the police force unit receiving the incident report, as a reference for follow up actions.

All of this data is already gathered at some level: collecting and organizing them will request an evaluation of the partners to involve in order to set up proper channels of communications with them.



TRACEABILITY SYSTEMS

In the EU medicines bear a **Unique Identifier (UI)** which is traced in the **European Medicines Verification Organization (EMVO)** traceability system; stolen medicines packages can be notified to the system, via “decommissioning” of their UI so they cannot be sold in the legal supply chain. It would be possible to generate ad hoc reports for NCAs for further investigations, when an alert is triggered by a “stolen package” and NCAs could verify the incidence of this kind of cases by checking traceability data.

With respect to the EU traceability system, as for Article 39 of the Commission Delegated Regulation (EU) 2016/161 (of 2 October 2015, supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use), NCAs can only access data contained in the repository system of their Member State for the following purposes:

- supervising the functioning of the repositories and **investigating potential incidents of falsification**;
- reimbursement;
- pharmacovigilance or pharmacoepidemiology.

Whenever NCAs need to access data for these purposes, they do so via pre-defined reports issued by the system.

In Italy, the traceability system for medicines managed at central level also include data regarding thefts: MAH should report the cases, and share the official police file of the case together with a few basic data: dates, quantities and batch numbers impacted.

The “**Volcano Operation**” demonstrated that the turnover time for laundering stolen medicines is quite short (in the range of 2–4 weeks between the incident and the final selling point of the laundered products), whilst reporting to the traceability system (focused on reimbursement, more than on “disappearing/destroyed products”) may be completed in 6 months: this is the reason why AIFA set up a “parallel database” where MAH and distributors may upload data about thefts in real time, allowing the launch of alerts and public announcements, instead of using the already available traceability data, that is used for intelligence purposes, i.e. for validating the analysis and for finding connections between products and operators.

Approaching the structure managing the traceability data in your country (the *National Medicines Verification Organization*, if it is part of the EU traceability system) may be useful for starting an evaluation on availability and accessibility of data regarding thefts.



LAW ENFORCEMENT: LOCAL UNITS, COORDINATING STRUCTURES

Generally, thefts are reported to local police force units (see *Chapter 1, par. Thefts are often considered as a local issue, and therefore are usually locally reported on page 5*): the data to report is not defined by general rules, based on National practices, but at least name of the product, quantity of the stolen packages and date/places of the event (together with information not relevant for NCA investigations and alerts, as the value of the stolen goods) are always filed, whilst batch numbers, UI and traceability information are mainly recorded when there are procedures in place, or when experienced enforcement officers are involved in the investigation.

Furthermore, Police forces' data is not easily shared, due to the restrictions related to the Prosecutors' activities: however, it may be possible to set up a cooperation strategy between NCA and enforcement units, if a central specialized police force is in place (as Carabinieri NAS in Italy and OCLAESP in France), or if the NCA also manages enforcement activities (as MHRA in the UK), since this specialized unit may liaise between Prosecutors and NCA, or directly manage the data that the NCA may need for supporting investigations, launching an alert or applying the specific measures aimed at protecting public health from falsification (as for art. 117a, c.3 of the Directive 2001/83/EC, since stolen medicines usually become "falsified medicinal products" – art. 1, c. 33 of the same Directive).

As abovementioned, thefts are reported locally, and an ad hoc communication channel between the field and the central unit is needed, in order to convince the local Police Forces to timely share any report with the central coordination units, as obtained in the UK through the cooperation between MHRA and the over 40 enforcement units gathering reports at local level (see *Chapter 1, par. Medicines are stolen everywhere, even in your country but you will not be aware of it, if you do not look for data on page 6*). The cooperation with a central coordination unit for the enforcement is an important step in setting up a channel for gathering data on medicinal products thefts.



MARKETING AUTHORIZATION HOLDERS

Medicines are often stolen when under the responsibility of MAH, from lorries or logistic warehouses: but even when thefts occur elsewhere (e.g. in hospital pharmacies), some MAH may receive information regarding the incident involving their product, since stolen medicines could for instance be replaced through a (non scheduled) order for purchase, or insurance companies could request MAH the confirmation of the value of the stolen goods.

MAH could then receive information regarding thefts, directly or indirectly: when a traceability system is in place, it may also be possible that MAH are requested to send the system a “decommissioning report” related to the stolen products, but even if there is not such an obligation, MAH may be interested in sharing the information with the NCA, if there are initiatives aimed at coordinating/supporting the investigation on the cases, at a central level.

In Italy, the cooperation with MAHs was a key factor in the development and in the implementation of the Italian thefts database. It started through a series of operative meetings managed by the national association Farindustria (<https://www.farindustria.it/>), and later involving other MAHs associations (as Egualia and AIP: but also the European and International associations – the European Federation of Pharmaceutical Industries and Associations – EFPIA and the International Federation of Pharmaceutical Manufacturers & Associations – IFPMA, attended to some of the discussions on the case, directly or through technical structures such as the Pharmaceutical Security Institute – PSI). The DB evolved in the FAKESHARE database (gathering data from Italy and other EU MS), and in the current MEDI-THEFT platform, that could extend the data gathering and the blacklist dissemination to the rest of the EU and beyond.



DISTRIBUTION NETWORK: WHOLESALERS, LOGISTIC SERVICES, PHARMACIES

The direct target of the thefts (i.e. the organisation that was the subject of the incident) must report the incident to the police as soon as feasible: when the victim is a technical structure (wholesaler, hospital pharmacy...) the detail of the information is usually in compliance with the one requested for launching alerts or feeding databases, since the data in the report is normally generated through the same software managing the warehouse, whilst when the incident is reported by non-technical operators (such as drivers) to non-specialized police forces, some data (mainly, batch numbers) may be considered as “non relevant” with respect to the possible investigations and then be missing.

When the incident reports are filed, the access to the data will request an interaction with law enforcement units: setting up a cooperation with the distribution network, by involving the national associations of wholesalers, logistic companies, hospital pharmacies, pharmacists, would allow to define procedures for an operational sharing of data in parallel with the report filing (e.g. by adding the NCA in carbon copy in the note to the enforcement unit). The selection of a few focal points in the associations is also critical, since thefts happen randomly, with rare recurrences of incidents in the same organisation, it is important to have experts supporting at a central level the local structures, when an incident occurs

The cooperation with the national associations may also help in developing awareness raising initiatives, such as training courses and guidelines for operators (as the one developed in Italy for hospital pharmacists, https://www.aifa.gov.it/documents/20142/241052/2018_LineaGuidaFurti2018_EN.pdf).



INSURANCE COMPANIES

All the structures in the medicines distribution network are covered by insurance, which generally consider thefts in their risk profiles: then, in most cases, an incident will generate an insurance claim that will consider all data

supporting the evaluation of the reimbursement, including a detailed list of all stolen products, bearing the best part (if not all) of the information of interest for the NCA.

Insurance companies associations are not a standard partner for pharmaceutical agencies, but they may be interested in supporting initiatives aimed at counteracting economic crimes in the field.

An example of this kind of cooperation may be the Italian “Padlock 2.0” project, <https://journals.sagepub.com/doi/full/10.1177/2399202618768676>, where a series of Guidelines “Benchmarks for the Safe Hospital Pharmacy” specifically focused on the prevention of medicines thefts were developed in cooperation with the insurance associations.

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GOOD PRACTICES

The absence of systems for channeling the signals from the field (the local police units, that are investigating thefts at local level) to the NCA leads to a general underreporting of thefts of medicinal products.

When you set up systems – by involving MAHs or Law Enforcement Officers (LEOs) structures in the process – you start finding data/cases: as a matter of fact, as we mentioned, the only NCA that are managing this kind of reports are those who were involved in the FAKESHARE project (prior to Brexit), setting up the channels, i.e. Italy, the UK and Spain.

We definitely need to set up harmonised practices across EU/EEA (and perhaps international authorities), as this is a gap in the system that leads to lack of systematic data gathering and sharing of information. In this view, we consider the UK and Spain experience as example of “good implementation practices” of the FAKESHARE reporting procedures, whilst Switzerland cooperation scheme between NCA and stakeholders based on the MEDICRIME Convention set up a possible “grounds” for setting up channels and systems – i.e., a “good practice” that may be extended to medical products, being designed against medicines crime, by using the existing legislative tools as a framework.

**IF YOU DON'T LOOK
FOR DATA, YOU WILL
NEVER FIND IT!**

ITALY

In Italy, the number of thefts from hospitals, has increased exponentially between 2011 and 2014. The major drivers were the introduction of life-saving expensive medicines, the price differentials between countries and the different reimbursement regimes adopted in the European Union. This situation resulted in the AIFA (Italian Medicines Agency) Counterfeiting Prevention Unit coordinating an international investigation targeting thefts (“Operation Volcano”, 2014), and setting up a number of preventive strategies that since 2014 have minimized, and in some cases, eradicated the problem.

In a nutshell, the sequence of AIFA actions may be summarized as follows:

OPERATIVE MEETING WITH MAH/LEO, STAKEHOLDERS INVOLVEMENT

Following a request for assistance by the MAH associations, AIFA scheduled during **September 2013** an operational meeting with MAH corporate security experts and law enforcement officers coordination unit, discussing the current state of the situation (number of cases, kind of stolen products, possible scenarios for the reselling the stolen goods). Since there was not a specific competent authority for the issue, AIFA involved in the project all the relevant actors that confirmed their interest: Ministry of Health traceability offices and the associations of distributors and logistic services were then invited to contribute to the initiative since the beginning.

SET UP OF DATABASE, DEDICATED EMAIL, FORM FOR REPORTING

As for the outcomes of the operational meeting, AIFA defined a strategy for setting up a designated database for stolen medicines, arranging the data gathering with an eye to the minimization of the impact on MAH: then, a dedicated e-mail was activated, and MAH were requested to report via mail any incident in real time, by forwarding the same Excel format they were using for informing the Ministry of Health traceability system (according to an already existing obligation, and its related procedures). MAH also shared data regarding previously filed incidents, as a contribution to the framework evaluation. AIFA set up a local database in its servers, by using commercial software (Access): the whole system has been operative since **December 2013**.

DATA ANALYSIS AND SCENARIOS

As soon as data was made available, it was apparent that the scenarios that were proposed for the general press (“undercover criminal hospitals” supply; thefts focused on black market products, such as doping substances) were not in line with the framework, since quantities and categories of the stolen medicines were more in compliance with the existence of a “ghost distribution network”, sorting/distributing the stolen medicines in different channels. Then, the possible scenarios for the medicines laundering/distribution were defined, and specific “awareness raising documents” were prepared for possible “sentinels” operating on the different channels – customs, IT intelligence

services, enforcement units: in particular, a list of high price hospital products that could have been exported to the EU was shared with the European NCAs on **January 2014**, asking them to report to AIFA any relevant signal regarding quality/distribution issues.

SIGNAL MANAGEMENT AND INVESTIGATION

In **March 2014**, a suspicious signal regarding a quality report on an oncology product (Herceptin) was sent to Roche Germany, and forwarded in a few hours to AIFA via Roche Italy: the product that was reported by a German parallel trader matched some records in the AIFA thefts database, and the verification of the invoices of the involved distributors in Germany, the UK and Italy, matched with the available traceability data in the Italian systems, allowed to identify traders, products and channels for the laundering/infiltration of a list of stolen hospital products.

TRANSPARENCY AND SUPPORT TO PROSECUTORS

After a preliminary report to the EU HMA Working Group of Enforcement Officers in **April 2014**, AIFA started using its FAKESHARE tools for disseminating blacklists of stolen products and for informing (via web meetings, Rapid Alert/Non Urgent Information documents, public statements) the European network, supporting the European Medicines Agency (EMA) and all NCAs in the verification of the possible infiltration of falsified medicines in all relevant channels. All relevant information were published in the AIFA website, according to the 2001/83/EC Directive principles*: this transparency focused approach allowed all interested Prosecutors offices investigating local thefts (more than 10, in Italy) to receive information and support, evaluating the local event in a broader framework context, with the opportunity of the application of sanctions related to the public health threats, instead of limiting their action to the economic damages.

* Art. 117a, c. 3: *If the medicinal product in question is suspected of presenting a serious risk to public health (...) urgent public announcements shall be issued within 24 hours in order to recall those medicinal products from the patients. Those announcements shall contain sufficient information on the suspected quality defect or falsification and the risks involved.*

FOLLOW UP

As a follow up to Operation Volcano, the set up of tools (web platforms for sharing data, databases, blacklists for operators) and the implementation in other EU MS of existing good practices (such as the Italian “counterfeit-ing prevention task force” between police, health authorities, customs, private stakeholders, developing guidelines for better protecting pharmacies and databases and scenarios for improving investigations) were promoted, as a strategy for preventing the recurrence of thefts and introduction of falsified medicines into the market; a modification of the regulation with respect to the control of parallel trade transactions was also proposed in a joint White Paper submitted to EC by the health authorities of Italy, the UK, Spain, the Netherlands, Austria. A joint pilot project EMA/AIFA on reporting suspicious offers and thefts to the AIFA database was also set up in 2018: EMA still cooperates with AIFA in this field (see below).

A summary of the Italian measures was also published in a scientific paper (“Medicine Thefts And Their Prevention: Current Approach In Italy And Future Perspectives”, Lidio Brasola, Domenico Di Giorgio, Fulvio La Bella, Marcello Pani and Giuseppe Turchetti, *Medicine Access @ Point of Care* 1–6, 2018):

The 2013 emergency situation resulted in the AIFA (Italian Medicines Agency) Counterfeiting Prevention Unit setting up a project with the Pharma Industry Association in Italy (Farmindustria) in order to create a shared database. One of the primary targets of this initiative was for industry to share with AIFA information about stolen medicines, that is, product, manufacturer, batch details, quantity and so on: the database was populated, and the data were then collated and analysed in order to better understand the real framework. Another action was to organize that information in order to let AIFA both investigate and respond to theft cases, and refer to those data against medicines crime in general.

Strong protection of the network via strict importing rules for parallel distribution and traceability systems for medicines,

cooperation between enforcement and health authorities and sharing of information and intelligence allowed Italy to counteract criminals and avoid the infiltration of falsified medicines into the legal supply chain. Web tools such as FAKESHARE also contributed to the disruption of this illegal network. 'FAKESHARE' is a project coordinated by AIFA and co-funded by the 'Prevention of and Fight against Crime' Programme of the EU—aimed at developing coordinated initiatives (such as investigation, campaigning, training) against the illegal distribution of medicines, with the goal of optimizing the use of resources in activities developed at national and international level, by:

- Ensuring coordination of investigation activities and police force initiatives;
- Targeting the illegal web distribution of medicines;
- Sharing information between countries with similar scenarios.

FAKESHARE developed and offered a web platform and cooperative web tools for strategic prevention and action against the use of the Internet as a support to the distribution of falsified medicines and, in general, for counteracting pharmacrime. FAKESHARE II extended the area of use and the scope of the web platform: first, by enlarging the cooperation to MS in which there is a history of regulating (and investigating) e-pharmacies, to non-EU MS bordering the Union (a possible 'door of access' for illegally supplied medicines) and to other countries; and second, by extending the gathering and the sharing of data to all activities against medicines crime (including thefts of medicines and investigations on social networks), instead of limiting the activities to rogue e-pharmacies. Up to July 2015, these preventive measures led to the arrest of more than 60 people in eight different police operations in Italy.

The effect of the investigation and of the preventive measures put in place through the “Volcano Operation” has impacted on the occurrence of thefts as a whole.

EMA

EMA works closely with the European Commission and EU Member States in implementing the falsified medicines Directive.

Marketing and manufacturing authorisation holders are obliged to report to EMA if they detect any (suspected) falsification of a **centrally authorised medicine** that could pose a risk to public and animal health (see *Chapter 2, par. Traceability systems on page 8*).

Therefore EMA maintains a reporting system consisting of an inbox and a dedicated template (Falsified medicinal product report template). Marketing and manufacturing authorisation holders are required to use this system to notify EMA of a suspected and confirmed falsified medicines and also about any suspicious offer(s) received.

On being notified of a (suspected) falsified medicine, EMA informs the concerned national competent authorities, who are responsible for investigating the supply chain and deciding on any market action.

EMA also informs the parallel distribution network about confirmed falsified products or medicine theft. It does so proactively, in order to prevent re-introduction of illegal units into the supply chain.

More information is available at the following webpage: *Falsified medicines: reporting obligations | European Medicines Agency (europa.eu)*

UNITED KINGDOM

Prior to Brexit, MHRA was part of the EC co-funded project FAKESHARE II, coordinated by AIFA and focused on medicines thefts: in this framework, a specific “Law Enforcement Officers Day” was organized, training the Heads of all local police units in the UK territory regarding the phenomenon of medicines thefts, and the opportunity of sharing the data regarding local thefts with MHRA, for further sharing with the European level through the FAKESHARE database.

The main concepts of the training were the ones summarized in the MHRA website pages that are now focused on this form of pharmaceutical crime, such as this recent post GDP operators, published in the MHRA Inspectorate blog by Terry Madigan (<https://mhrainspectorate.blog.gov.uk/2019/09/16/supply-chain-security-part-1-introduction/>).

Reporting stolen and missing medicines to MHRA

Why report to MHRA?

A main MHRA aim is to ensure that the medicines supply chain is safe and secure, so it is important that the risk of theft and diversion of medicines is managed in order to safeguard public health. It is therefore a GDP concern that incidents which pose significant risk are reported to MHRA, irrespective of whether they are reported to the police, Home Office or insurance companies. When reports are received, this enables the GDP inspectorate to look out for the stock and allows Intelligence and Enforcement departments to add this information to their database, which may help with separate cases.

When?

This depends on the event (missing or definitely stolen), product type, quantity and any other factor that influences risk to public

health. If it is deemed not to be a significant risk, then the justification for this decision should be included in your deviation report. Your quality risk management process should help identify what action to take – which may include reporting to MHRA. For high-risk mislaid stock, it may be better to report this following initial investigation and then later report as found, rather than delay the reporting.

What?

Report:

- *the date when the event was first noted*
- *products*
- *quantities*
- *batch numbers (if known)*
- *details of location*
- *contact details*
- *police incident number or Home Office reference, where relevant*

The MHRA strategy for the implementation of the systems for channeling and sharing signals was definitely effective: considering this kind of pharmaceutical crime as a threat for public health, MHRA underlined in training and communication targeting law enforcement officers and private stakeholders, that (...) whether pilfered for personal use or stolen in bulk for diversion, opportunistic or planned, the theft of medicines has a broad impact that increases risk to public health and risks the integrity of the medicine supply chain, structuring procedures for fostering the signalling.

As a proof of the success of this strategy, it may be underlined that even if, considering the amount of UK medicines distributed, the proportion of theft is low, the current level of cases to the FAKESHARE database reported by MHRA

exceeds those AIFA receives from the Italian network, that was established since 2013.

SPAIN

The Spanish Agency for Medicines and Medical Devices (AEMPS) has an established procedure for notification published on its website at the following link:

https://www.aemps.gob.es/industria-farmaceutica/industria_distribucion_medicamentos_instru_comunica_trafico_ilicito/

Communication of these events to the competent authorities is mandatory, in accordance to Royal Decree 782/2013, on distribution of medicinal products for human use. All agents involved in distribution activities should inform corresponding health authorities of any fact or suspicion knowledge related to improper consumption of medicines or their diversion to illicit traffic, and this includes theft (suspected or confirmed) or robbery.

An excel file should be completed and submitted with relevant data, such as name of the medicine stolen/lost, batch number, expiry date, MAH, place, units, languages and sent it back via mail. Depending on the circumstances, it is required that the cases are also notified to the Police, and information on the filing should be provided.

Additionally, the Technical Committee of Inspection (CTI) (harmonization/coordination forum for inspection services, central and regional) , has published recommendations to facilitate the assessment that may be carried out by wholesale distributors. This document proposes a set of drugs (watchlist) to be monthly evaluated for the detection of possible unusual sales patterns.

Although this procedure is specially oriented towards those events that could be linked to the diversion of medicines to illicit traffic; they necessarily have to take account of the type of medication involved, the number of units affected or their circumstances. For this reason, all thefts and suspected deviations

must be reported, while losses will depend on the circumstances and quantity of the affected units.

Regarding the type of product or the affected amount required to notify, the criteria to follow is linked to the type of product and the characteristics of the event that occurred: as a general rule, it is important to notify any loss of especially sensitive products or products with risk of deviation, such as narcotics and psychotropic drugs, anabolics, hormones, phosphodiesterase-5 inhibitors, vaccines or those with a high price or demand in the market. However, it is also important to report the loss of a large amount of any other medicine, or events that cannot be considered normal losses linked to the manufacturing process.

It is important to notify as soon as possible after a first collection of the available data. It is common for the agents involved to notify AEMPS of the theft or loss while they carry out their own internal investigations and take corrective measures, and later communicate the results to AEMPS, especially if the units have finally been located. This allows AEMPS taking relevant measures quickly, which is especially important if actions are considered necessary at the national and/or international level.

On the other hand, the Technical Committee of Inspection (CTI) organise symposia and workshops to harmonise criteria and a homogeneous implementation of the pharmaceutical legislation in our country.

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SWITZERLAND

“Good practices” against pharmaceutical thefts: introduction of mandatory reporting of thefts in Switzerland

In 2011, Switzerland was one of the first signatory states of the Council of Europe Convention on the counterfeiting of medicinal products and similar crimes involving threats to public health (Medicrime Convention, CETS No. 211). In connection with the implementation of the Convention, which Switzerland helped to draft, legislative changes have been made to the Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA). These changes apply since 1 January 2019.*

In accordance with the Convention, the **Swiss Agency for Therapeutic Products, Swissmedic**, has assumed the role of national single point of contact (SPOC) within the scope of the revised TPA. Whereas Swissmedic has been developing and fulfilling the role of SPOC for many years, the revised legislation put this role and the cooperation scheme on a legal footing. Swissmedic maintains a close collaboration with the points of contact at customs, the Federal Office of Police (fedpol), public prosecutors' offices and other stakeholders, making cooperation and information exchange very efficient.

The ratification of the Medicrime Convention has brought along more tools for preventing and fighting illegal medicinal products in the national market. One of the most crucial tools is the obligation of manufacturers and distributors of therapeutic products to notify Swissmedic of any suspicion regarding illegal trading in medicinal products by third parties that come to their knowledge in connection with their activities, their products or the products' components. Suspected illegal trading in medicinal products also includes suspected falsified products, suspicious offers, diversion and thefts. The introduction of the obligation to report illegal trading was deduced by a provision in the

* Art. 59 paragraph 3bis TPA: SR 812.21 – Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA) (admin.ch) – <https://www.fedlex.admin.ch/eli/cc/2001/422/en>

Convention, pursuant to which Medicrime signatory states shall introduce effective measures for preventing illegal supplying of therapeutic products. As illegal trade often occurs across the borders, this obligation to report to the national SPOC also is necessary to ensure international co-operation on prevention.

It is important to note that the obligation to report theft of medicinal products is not limited to offences committed Switzerland, but also covers thefts of medicinal products abroad, if these products are destined for the Swiss market. An information sheet regarding the mandatory notification as well as an electronic reporting form that enables quick and easy reporting can be found on the Swissmedic website: *Report regarding suspected illegal trading in medicinal products* - https://www.swissmedic.ch/swissmedic/en/home/humanarzneimittel/market-surveillance/medicinal-products-from-the-internet/meldung_verdacht_illegalen_arzneimittelhandel.html

As thefts of goods generally are only reported to police and to insurance companies, this reporting obligation of pharmaceutical companies and retailers is crucial for an overview of the stolen medicinal products. Only with an overview on national and international basis including all the detailed information on stolen packs and batches, the reintroduction of stolen products (which would become falsified medicinal products) into the market can be prevented.

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4

DRAFT OF A MODEL PROCEDURE

- Choose your partners in data gathering
- Set up the cooperation strategy
- Build the database or connect to the existing ones
- Analyze your data and set up scenarios
- Set up a forum for discussion
- Use the existing experiences

CHOOSE YOUR PARTNERS IN DATA GATHERING

Data gathering regarding medicines thefts is mainly aimed at launching rapid alerts* for avoiding the infiltration of the stolen medicines, whose quality is no longer guaranteed in the distribution chain, through documentation falsely stating their origin.

The basic set of data regarding an incident should include:

- brand names,
- packages,
- quantities,

* *When a defect or a falsification of a medicine is verified and poses a health risk, restrictive measures are taken, and where appropriate, communication is also given through the NCAs websites and the media. Whenever necessary, an international Alert notice is disseminated to all EU MS through the **Rapid Alert System (RAS)**, the network for the exchange of information regarding this kind of issues between Member States.*

- batch numbers
- expiry dates
- (Unique Identifier codes, if available).

The selection of the partners will be based on the possible sources for those data, and on the common practices in places at National level, with respect to the cooperation between authorities and private stakeholders (see [Chapter 2 on page 8](#)).

In Italy, the initial partnership set up in 2013 initially involved MAH (through their National associations) (see [Chapter 2, par. Marketing authorization holders on page 11](#)), and was then extended to distributors and logistic service providers; private stakeholders agreed to share in real time any data regarding thefts that was reported to them, allowing AIFA to feed a database that was then used for intelligence purposes, and for creating blacklists of products that were shared with the European distribution network.

AIFA also had the support of the traceability offices of the Ministry of Health, and of the specialized police forces (Carabinieri NAS), in the validation of data and in the dissemination of blacklists and model scenarios for investigation.

FAKESHARE has been a vehicle for partners to promote this “team building” activity: in the UK, MHRA involved the local enforcement units, by organizing a “Law Enforcement Officer Day” (see [Chapter 3, par. United Kingdom on page 20](#)): more than 40 Heads of local unit were trained by MHRA in cooperation with AIFA, and a procedure for timely sharing any pharmaceutical theft report with MHRA, and feeding the FAKESHARE thefts database, was established.

SET UP THE COOPERATION STRATEGY

Only the timely sharing of information makes possible the issuing in real time Rapid Alerts and blacklists for operators, that in turn allow the subjects to whom the offer is addressed to assess any anomalies, such as extremely discounted prices.

The collaboration of all operators — local and hospital pharmacists, wholesalers, depositaries, MAHs, logistic service providers, Police Forces — is therefore essential; in the absence of a legal obligation (that was already proven as a not always efficient way for building the channel), this may be achieved via formal agreements between the NCA and the relevant central associations of operators that will be involved in the data gathering exercise, but also informally, through the set up and the promotion of ad hoc tools, aimed at encouraging signalling.

Any kind of approach should then consider some criticalities in data management, that could be addressed in the agreement/regulation/procedure that will be defined: restrictedness of some data (a key point when managing information made accessible by Prosecutors/police forces), levels of access to the database/blacklists, distribution of alerts and study documents – are just some of the points that may be considered, as for the already established experiences that were discussed in the previous chapters.

In order to support this kind of process, in some countries, as in Italy, the NCA set up *ad hoc* systems for reporting, such as downloadable online forms to be filled in with the requested information and sent to a dedicated e-mail address, preferably in a timely manner (within 48 hours from the event), since a good timing allows to inform the operators to whom these could be offered, through the timely updating of web based blacklists/databases, and the launch of any “Rapid Alerts” to be sent to the National and International network.

As already explained, it is important to generate and to highlight an added value for reporting, in terms of services (short terms: access to blacklists, generation of rapid alert...) and operative results (medium terms: reduction of the impact of the phenomenon, as for the experiences reported in [Chapter 3 on page 14](#)).

Even a formal reporting obligation may lack efficacy, if an added value is not clear: the Dir. 2011/62/EC article requesting wholesalers and trader to report the authorities any “suspicious offer” for medicines did not generate a number

of signals in line with the cases that were investigated in the last 10 years, for instance.

BUILD THE DATABASE OR CONNECT TO THE EXISTING ONES

Data gathering should be managed by optimizing the use of resources: a standard Excel form sent via email, with standardized fields allowing an easy copy-paste in a basic database may be enough for starting the exercise.

The export of the list of stolen product as a “blacklist” for police forces and operators, to be shared through a restricted web area, could represent the first basic “counteraction tool”, to be promoted in cooperation with the partners of the project, allowing the involvement of more actors.

Standard form for feeding the existing FAKESHARE database are already available in the AIFA website: connecting to this database allows to access to the web based blacklists and tools that were used for previous investigation and activities managed at EU level.

ANALYZE YOUR DATA AND SET UP SCENARIOS

In addition to the production of blacklists, the collection of data on thefts in a systematic way allows to obtain a picture of the phenomenon that can be used to evaluate the possible sale channels for the stolen products – an “intelligence” exercise.

Once the data collection system is set up, you should consider what elements and connections should be looked for, in order to understand if you are facing an international drug laundering organization or a gang of local criminals; once you have evidence, you may decide how to act, and how to make law enforcement units and NCAs or others to cooperate in an efficient way.

As reported in the MEDI-THEFT Report “**The theft of medicines in the EU**” (Transcrime, October 2022 – <https://www.medi-theft.eu/publications/>), there are many different scenarios for the laundering of stolen products – the main ones being black market (local/web based) and infiltration of legal distribution network (locally/internationally): the AIFA scenarios approach applied in the “Volcano Operation” (see <https://www.aifa.gov.it/-/operation-volcano-the-herceptin-case>, p. 8) is a good example of the possible outcomes of the analysis, aimed at building the possible “bigger picture” and the indicators allowing to confirm the right scenario between the possible ones that will be defined, with the desirable follow up of focusing the counteracting activities and the investigations.

SET UP A FORUM FOR DISCUSSION

Involve all stakeholders you are cooperating with in a forum, regularly meeting for discussing trends, analyzing data, cases and signals: informal discussion allows MAH and enforcement units to timely share reports on unconfirmed cases, supporting NCA in evaluating any possible “ground for suspicion”, or in connecting partial information in a broader picture.

As a possible reference, the Italian (informal) “Technical Table in Counteracting Pharmaceutical Thefts” (TTF) that is coordinated by AIFA, with the participation of MAH, professional associations, distributors, Prosecutors, Police Forces and traceability offices, is meeting quarterly since 2014: TTF was instrumental to developing investigations and other initiatives aimed at strengthening the reporting channels (e.g. development of guidelines for hospital pharmacies, training sessions, studies...), and allowed AIFA to adapt its strategies to the evolution of the phenomenon.

USE THE EXISTING EXPERIENCES

Copying the good practices already in place is a very good way for optimizing the use of resources, in particular when dealing with an issue that is not

considered (or recognized) at a relevant level of priority, like this one: then, check for forms, procedures, databases in the websites of the structures and institutions already dealing with the issue, eg

- MEDI-THEFT (<https://www.medi-theft.eu/>),
- AEMPS (https://www.aemps.gob.es/informa/ni-icm_mi_04-2016-procedimiento-robos/),
- AIFA (<https://www.aifa.gov.it/en/crimine-farmaceutico>),
- Swissmedic (<https://www.swissmedic.ch/swissmedic/en/medicrime/report-falsified-medicinal-products/report-illegal-therapeutic-products-trade.html>),
- MHRA (<https://mhrainspectorate.blog.gov.uk/2019/09/16/supply-chain-security-part-1-introduction/>) and
- EMA (<https://www.ema.europa.eu/en/human-regulatory/post-authorisation/compliance/falsified-medicines-reporting-obligations>),

...and feel free to write us (medicrime@aifa.gov.it) for any request or clarification.

The MEDI-THEFT platform will include tools for supporting your evaluations: check the best practices, databases, procedures already published, as a reference for your work.

Check also the AIFA website - <https://www.aifa.gov.it/en/crimine-farmaceutico> - for more studies and publications to download.

5

REFERENCES

1

Some guidelines summarise the characteristics of the goods that may become a target for thieves under the acronym “**CRAVED**” – **Concealable, Removable, Available, Valuable, Enjoyable, and Disposable**: as far as medicines are concerned, we could at least consider this definition as partially applicable to the different categories of stealable pharmaceutical products, that may be for instance concealable, removable and enjoyable (e.g. a nurse stealing steroids for personal doping use), or available, valuable and disposable (e.g. the “Volcano Operation” scheme – high cost anticancer medicines stolen in Italian hospitals and sold to the EU network).

The acronym **CRAVED** will help you remember which goods are most stolen. These are Concealable, Removable, Available, Valuable, Enjoyable, and Disposable:

- **Concealable.** Things that can be hidden in pockets or bags are more vulnerable to shoplifters and other sneak thieves. Things that are difficult to identify or can easily be concealed after being stolen are also at risk. In some cases, thefts may even be concealed from the owners of goods, as when timber or bricks left lying around on building sites are stolen.
- **Removable.** The fact that cars and bikes are mobile helps explain why they are so often stolen. Nor is it surprising that laptop computers are often stolen since these are not only desirable but also easy to carry. What is easy to carry depends on the kind of theft. Both burglars and shoplifters steal cigarettes, liquor, medicines, and beauty aids from supermarkets, but burglars take them in much larger quantities.
- **Available.** Desirable objects that are widely available and easy to find are at higher risk. This explains why householders try to hide jewelry and cash from burglars. It also helps explain why cars become more

at risk of theft as they get older. They become increasingly likely to be owned by people living in poor neighborhoods with less off-street parking and more offenders living nearby. Finally, theft waves can result from the availability of an attractive new product, such as the mobile phone, which quickly establishes its own illegal market (see box).

- **Valuable.** Thieves will generally choose the more expensive goods, particularly when they are stealing to sell. But value is not simply defined in terms of resale value. Thus, when stealing for their own use, juvenile shoplifters may select goods that confer status among their peers. Similarly, joyriders are more interested in a car's performance than its financial value.
- **Enjoyable.** Hot products tend to be enjoyable things to own or consume, such as liquor, tobacco, and DVDs. Thus, residential burglars are more likely to take DVD players and televisions than equally valuable electronic goods, such as microwave ovens. This may reflect the pleasure-loving lifestyle of many thieves (and their customers).
- **Disposable.** Only recently has systematic research begun on the relationship between hot products and theft markets, but it is clear that thieves will tend to select things that are easy to sell. This helps explain why batteries and disposable razors are among the most frequently stolen items from American drug stores.

See the following reference for details on the CRAVED acronym:

→ <https://popcenter.asu.edu/content/step-31-know-products-are-craved-thieves>

2

WHAT IS STOLEN? Organized Retail Crime (ORC) theft can target a wide range of goods — everything from razors and beauty products to baby formula. They target high-value items that are easy to hide and sell online. Most of the products are small and easy to grab without triggering in-store alerts. In fact, it is

hard to narrow down which items they target because it is extremely diverse. However, most of the target items feature these characteristics:

- High-value and/or high demand
- Easily accessible
- Easily concealed
- Widely available
- Easily sold/converted into cash

Items like cosmetics, medicines, baby goods, and energy drinks are small and accessible without employee assistance. Traditionally, these types of items are expensive and have a wide demand.

Transcrime recently published a book chapter and a study on Organized Retail Crime in Italy:

→ <https://www.routledge.com/The-Private-Sector-and-Organized-Crime-Criminal-Entrepreneurship-Illicit/Zabyelina-Thachuk/p/book/9781032056609>

→ https://www.transcrime.it/wp-content/uploads/2020/08/L-Organised-Retail-Crime-ORC-in-Italia_06_20.pdf

There are also many independent studies available in the web:

→ <https://www.lvt.com/blog/what-is-organized-retail-crime>

3

The investigative thesis suggests that the medicines were systematically stolen from pallets or parcels to be shipped to pharmacies, in small quantities, in order to avoid to make the shortfall evident to the recipient, who only later complained about the shortage to the distributor. Subsequently the organization, through a structured network of illegal sellers set up with the goal of satisfying the high demand of customers in the area, would have stored

the stolen goods in makeshift warehouses (e.g.) and subsequently sold to their customers – pharmacies, OTC pharmacies and stores selling pet products. During the first waves of the spread of Covid-19 (2020) it turned out that the network of acquaintances of the associates required, with greater insistence, antipyretic drugs.

It emerged in the investigations of the enforcement units involved in the investigation (Carabinieri – NAS, Catanzaro unit), about 14,000 packages of medicines for human and veterinary use were stolen (commercial value, about € 115,000): 1,650 packages of medicines were recovered and seized.

A recent Italian case:

→ https://www.salute.gov.it/portale/news/p3_2_1_2_1.jsp?lingua=italiano&menu=notizie&p=nas&id=2394

4

PORT ALLEN – A lorry transporting medicines was carjacked on a motorway highway, and the thieves stole more than a quarter-million dollars in drugs.

→ <https://www.wbrz.com/news/pharmaceutical-truck-carjacked-in-port-allen-thieves-stole-300k-worth-of-drugs/>

5

Between Sunday 2 and Monday 3 August the thieves broke into the Delpharm Takeda company in Crosa street. The criminals, after entering the premises, went to a refrigerated room where they took away some barrels of chemotherapy drugs (active ingredients), that were declared to be worth about one million euros.

→ <https://www.novaratoday.it/cronaca/furto-milionario-farmaci-cerano.html>

6

Shoplifting is a national epidemic from which the Upper West Side is not immune. Mike DeAngelis, a spokesman for CVS, told WSR in an email that losses due to retail theft across the country have increased 300% since the pandemic began. According to the NYPD, citywide shoplifting in 2021 was up by 36% over 2020 — from 32,358 incidents to 43,864.

With respect to the status of retail crime and shoplifting, Transcrime published an EU report in 2019 and an only Italian update in 2021:

→ https://www.crimetech.it/index.php?file=projects&id_progetto=21&id_page=8

→ https://www.crimetech.it/index.php?file=projects&id_progetto=29&id_page=8

There are also other independent studies available in the web:

→ <https://www.westsiderag.com/2022/02/15/drug-store-shoplifting-leads-to-locked-down-locations>

7

All the AIFA key publications may be downloaded in the Agency website:

- **Theft of medicines – Trend of the phenomenon over the years (update 2019)** (D. Di Giorgio ed., IPZS publishing: ISBN 978-88-240-2794-6, 2020)
- **Medicrime vs Volcano: A practical case study on how the Council of Europe Convention could improve the fight against pharmaceutical crime** (D. Di Giorgio, D. Russo ed., Council of Europe, 2019)
- **Thefts of medicines in Italy/Furti di farmaci** (D. Di Giorgio ed., AIFA, 2017)

- **Operation Volcano–The Herceptin Case: White Paper** (D. Di Giorgio ed., AIFA/AGES/AEMPS/IHZ/MHRA, 2015)

→ <https://www.aifa.gov.it/en/crimine-farmaceutico>

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