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THEFT OF MEDICINES

Trend of the phenomenon over the years

(update 2019)

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AIFA
AGENZIA ITALIANA DEL FARMACO

Editorial Production: Fakeshare/ Italian Medicines Agency (AIFA)

Coordinator of the Publication: Domenico Di Giorgio

Data Analysis: Domenico Di Giorgio, Gianpaolo Derossi

Editor: Domenico Di Giorgio, Gianpaolo Derossi, Marta Gramazio, Serena Panicale

Book design, infographics and Illustrations: Gianpaolo Derossi

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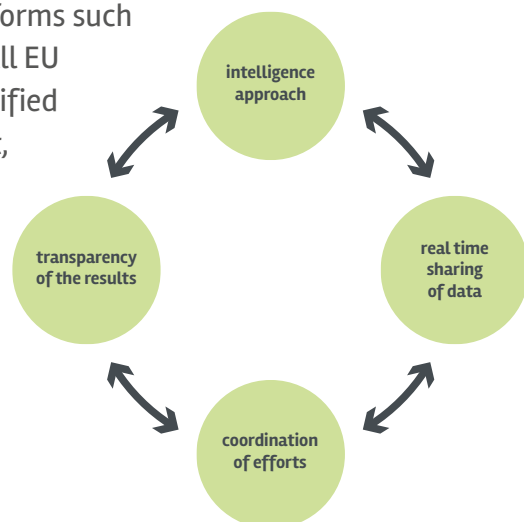
Pharmaceutical thefts occur frequently around the world, due to the high commercial value and to limited access to some medicines. Their global incidence is widely underestimated, since thefts are reported and investigated mostly at local level. Those Member States where traceability systems are in place (for example in Italy) are better positioned to investigate and respond to pharmaceutical thefts at national level.

Italy had a major **problem with thefts of medicines**: in 2012–2013, the number of assaults to hospitals was so high (up to three per week), that also the general press noticed the phenomenon. A joint intelligence/investigation activity coordinated by AIFA (national competent authority for medicines) and Carabinieri NAS (specialized police force dealing with health matters), supported by the Ministry of Health's medicines traceability systems and by private stakeholders associations (Farmindustria, ASSORAM), allowed the **eradication of the phenomenon** since April 2014.

The key point in **managing** the joint investigation was the intelligence and operative approach (AIFA gathered data about thefts, set up scenarios and fostered verifications for identifying the channels where stolen medicines were recycled), real time sharing of data between stakeholders (through web platforms such as Fakeshare), coordination of efforts in all EU Member states (infiltration of stolen/falsified medicines, having Germany as core target, involved at least 17 member states) and transparency of the results (AIFA published rapid alerts and reports on the case, allowing the sharing of data with all stakeholders, including the Italian Prosecutors).



The criminal organization managing the traffic was applying a well defined **scheme** for recycling the products for which they "commissioned" the theft: stolen medicines were paired with fake invoices, and then sold to legal Italian wholesalers exporting, mainly, to Germany. The number of directly involved wholesalers, consciously or not, is definitely low (5–10 per MS), but the quantity of products that were recycled and recalled through AIFA rapid alert is impressive (more than 3.000 transactions; more than 2000 packages of medicinal products involved; more than 100 different medicines involved; 17 countries involved).

The key **drivers** for the traffic were the different levels between Germany and other member states, in particular with respect to: prices of the products object of the transactions (higher in the German market with respect to the mediterranean countries), regulation (fostering parallel trade activities in the German market) and standards for verification of parallel trade transactions (unable to prevent infiltration, up to 2015).

The set up of tools (web platforms for sharing data, databases, blacklists for operators) and the implementation in other EU member states of existing good practices (such as the Italian cooperation scheme between authorities and stakeholders established in 2006) are aimed at **preventing** the recurrence of the cases; 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, UK, Spain, The Netherland and Austria.

After four years, on July 17 2018, following a publication by a journalist on the German media, the German authority *Landesamt für Arbeitsschutz, Verbraucherschutz und Gesundheit (LAVG)* informed the Rapid Alert network about "unconfirmed stolen products" originating from the Greek pharmacy *Ozbagdzi* (not authorised as wholesaler) and sold to the German parallel distributor (PD) *Lunapharm*.

On July 27 2018 the Greek authority EOF issued a WGEO rapid alert in which the police investigation was summarised and the main companies involved were listed. The WGEO alert stated that trades occurred between 2013 and 2016 from Ozbagdzi to companies based in Germany, Cyprus, Egypt and Switzerland.

In particular, the Greek WGEO alert reports the following: «*a criminal gang engaged in the illegal distribution of medicinal products subject to restricted medical prescription, was broken up by the police. In terms of modus operandi, the members of the gang illegally procured the products from public hospitals via over-prescription and forged medical assessment reports. Members of the gang were doctors, nurses etc who took advantage of their posts in order to leak quantities out of the hospital.*»

Further investigations performed by Greek and Italian authorities, identified that the trades of stolen products were also originating from Greece, Italy and other EU Member States. All the products were reintroduced into the legal supply chain and reached German PDs through a long chain of European operators.
In particular AIFA identified how medicinal products that according to the available traceability data were distributed only to Italian hospital, were exported to other European Member States (MMSS) in spite of the fact that they were not accessed by Italian wholesalers, and that no notification to the Italian traceability system was recorded.
An Italian pharmacy purchased Greek origin medicinal products from a number of operators, however to date no information has been achievable on the sources utilised by those companies to purchase the medicinal products provided.

The present case is very similar to the 2014 Herceptin case (the **Operation Volcano**). In particular it is becoming evident that a large number of medicinal products (in small volumes) were supplied utilising the same supply chains as was used for the first five medicinal products identified and listed in the August 2014 NUIs. It was evident that in most cases the country of final destination was Germany.

The Operation Volcano

On March 31, 2014 AIFA received a report from an English wholesaler regarding the anomalies found on some packages of Herceptin 150 mg (trastuzumab), indicated for the treatment of breast and gastric carcinomas, for which "Roche Registration Limited" owns the marketing authorization. The vials that were object of the report, with Italian package, were directed to a German operator.

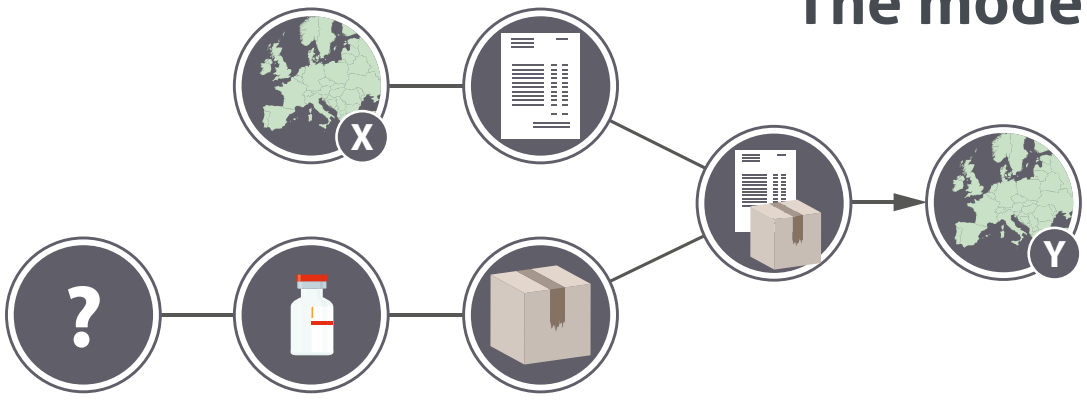
The reasons for the suspicions were based on two considerations:

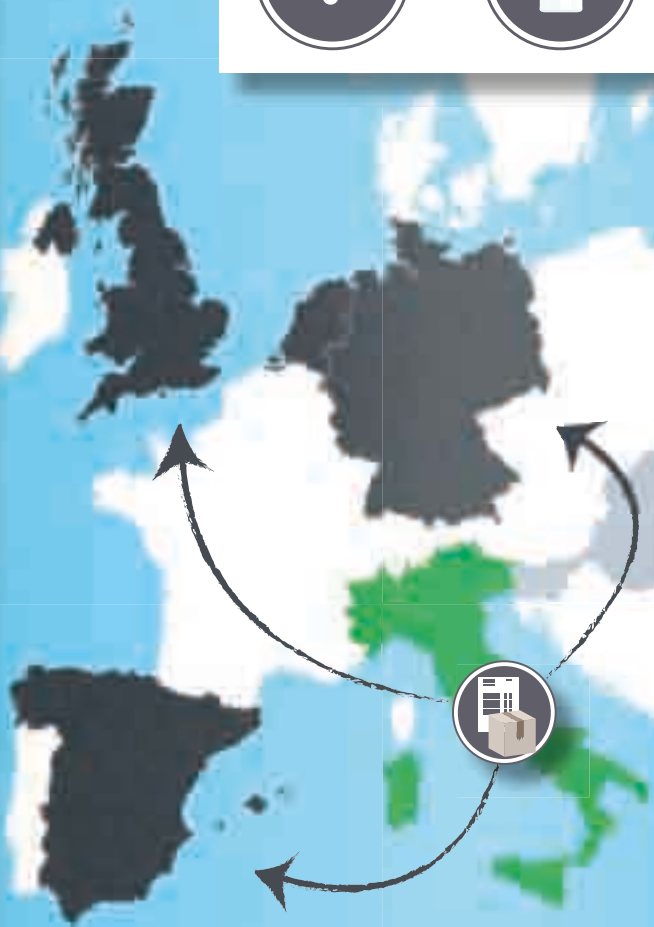
- the classification of the medicinal products involved as "hospital" medicines, which generated doubts about the availability of these with operators authorized for wholesale distribution;
- the correspondence between some batch numbers indicated in the delivery notes and those referring to medicines stolen in Italy, mostly in hospitals, between 2013 and 2014.

The in-depth analysis and investigations have quickly highlighted the nature and extent of the issue, namely the existence of an illegal traffic of medicines – not limited only to Herceptin – through which non-authorized foreign operators sold medicines, through fake invoices, to Italian wholesalers who in turn sold them to other authorized Italian and foreign operators.

Operation Volcano – The Herceptin Case
AIFA, November 2015

The model





The results of the 2014 Operation Volcano highlighted the extension of a phenomenon that until then was unknown to most Member States, and its relative dynamics:

- manipulated medicines;
- bogus wholesalers;
- fake invoices.

The criminal organization managing the traffic “ordered” a list of hospital products to burglars, acting at local level in all Italian regions.

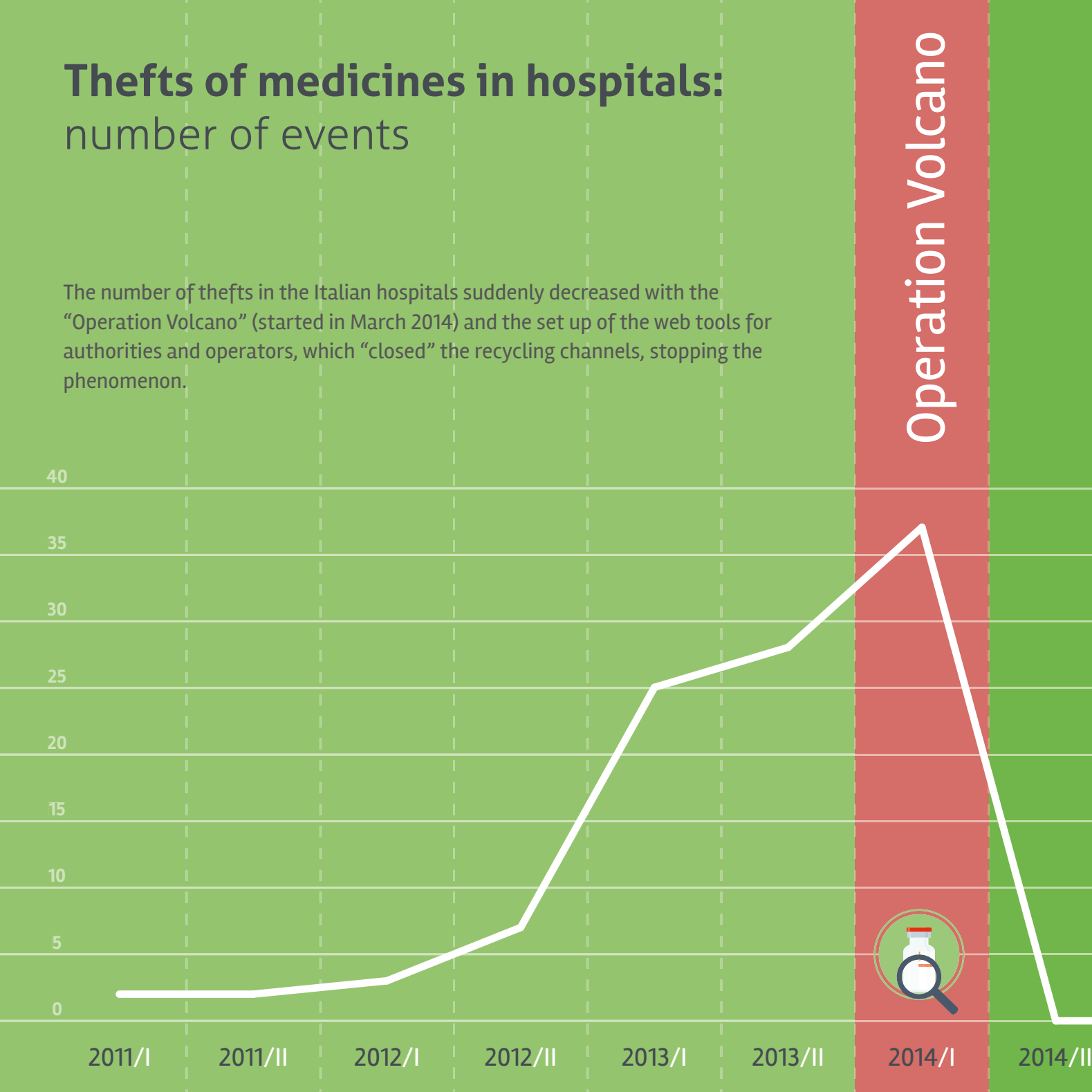
Stolen products were then sent to a central unit, sorted in order to differentiate the distribution channels, and, those relevant for export, paired with invoices issued by “bogus wholesalers” situated in other EU Member states, falsely stating a legal origin for the medicines.

Those product were then sold to legal Italian wholesalers for export, mainly to Germany (directly, or through UK, Spain, The Netherlands or other countries).

DATA

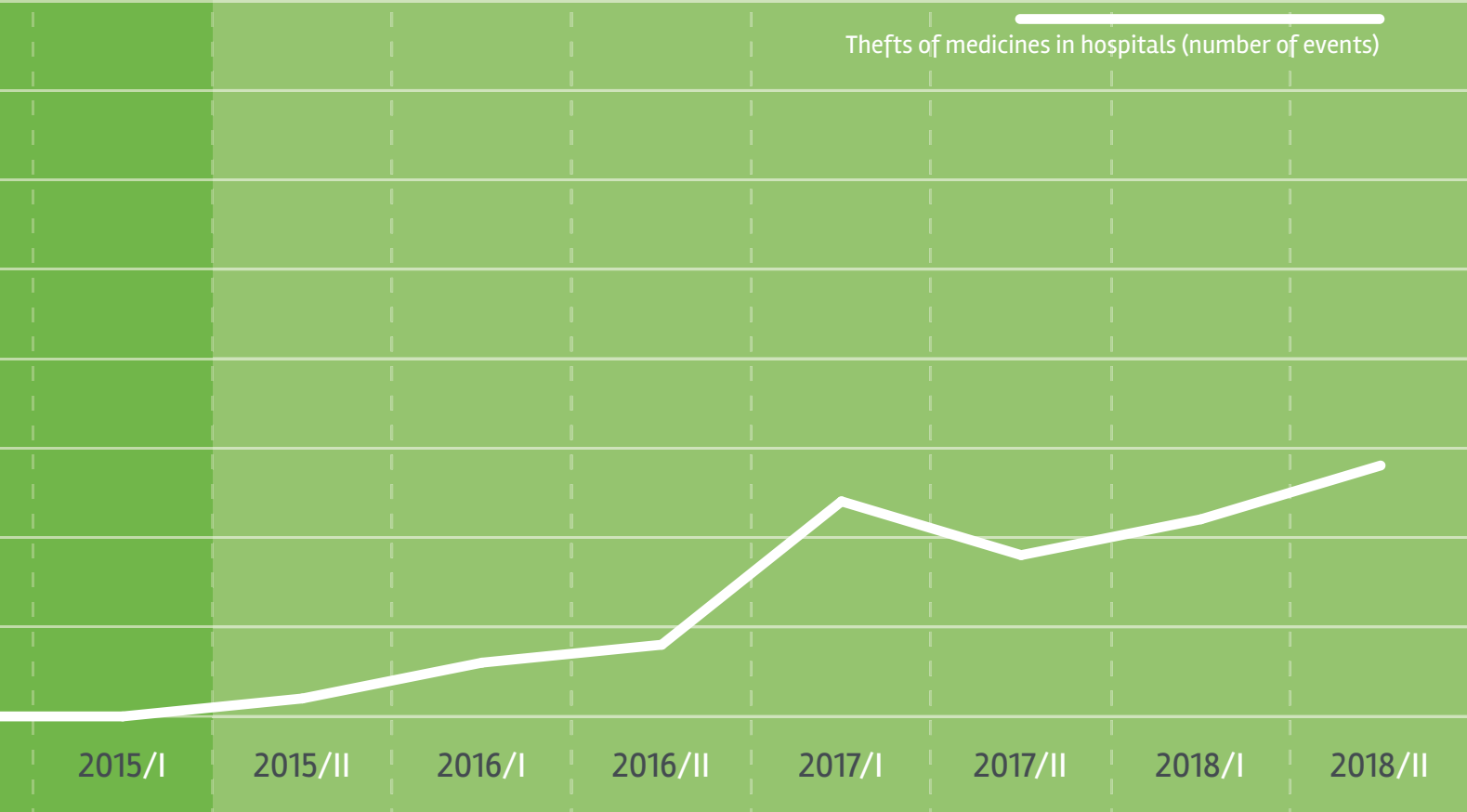
Thefts of medicines in hospitals: number of events

The number of thefts in the Italian hospitals suddenly decreased with the "Operation Volcano" (started in March 2014) and the set up of the web tools for authorities and operators, which "closed" the recycling channels, stopping the phenomenon.



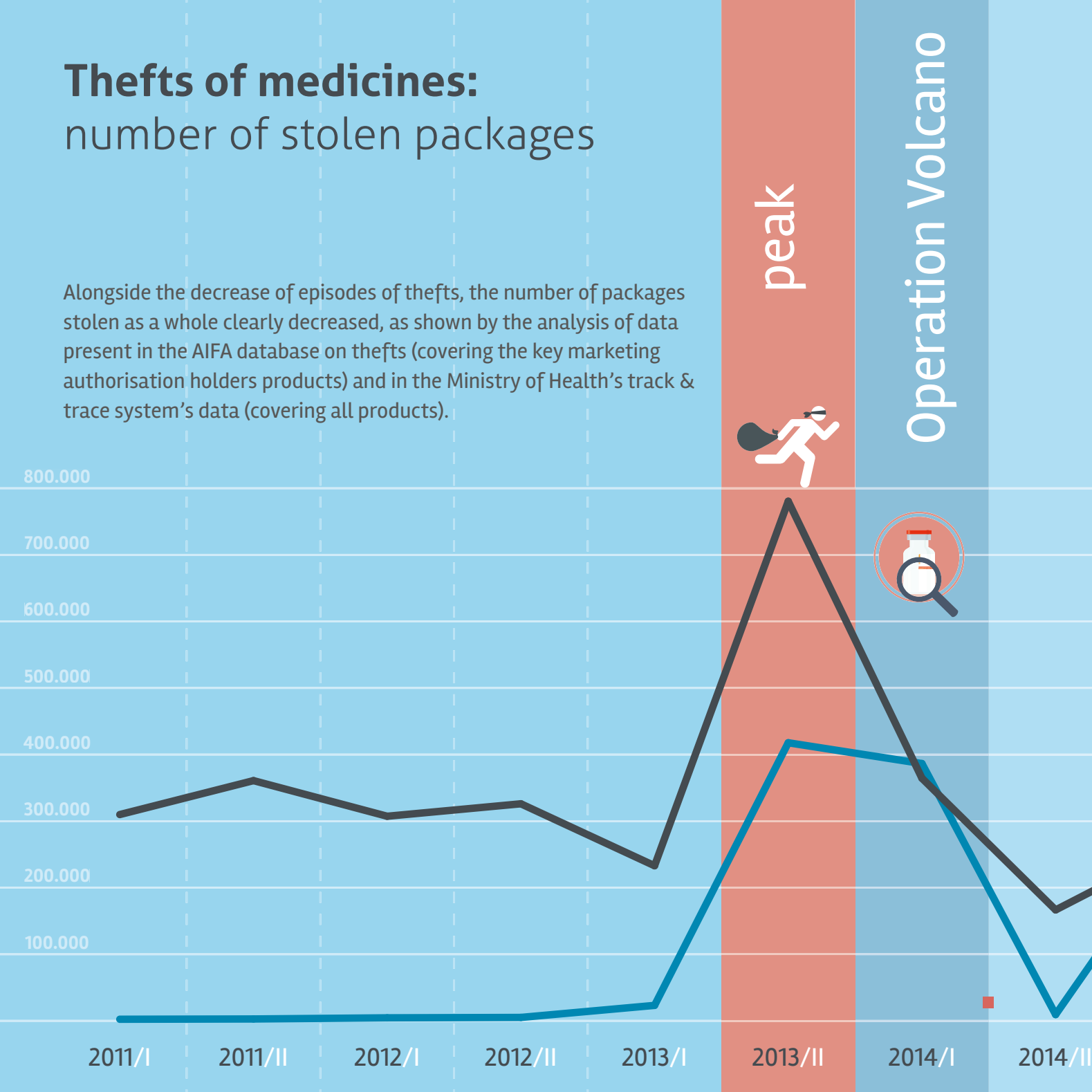
When we compare the peak years of the phenomenon (as evidenced by the data provided by Transcrime and AIFA), the few events in 2016 are mainly targeting different products (e.g. the innovative ones, barely accessible to patients even in Italy), aimed at different channels (e.g. black market, extra EU markets, patients/professionals web social network), on which authorities are now developing ad hoc intelligence, by taking the "Operation Volcano" approach.

After the Volcano Operation the criminal organizations adapted themselves to the change of framework and developed new models (see p. 22): this explais the increase in the incidence in 2017/18.



Thefts of medicines:
number of stolen packages

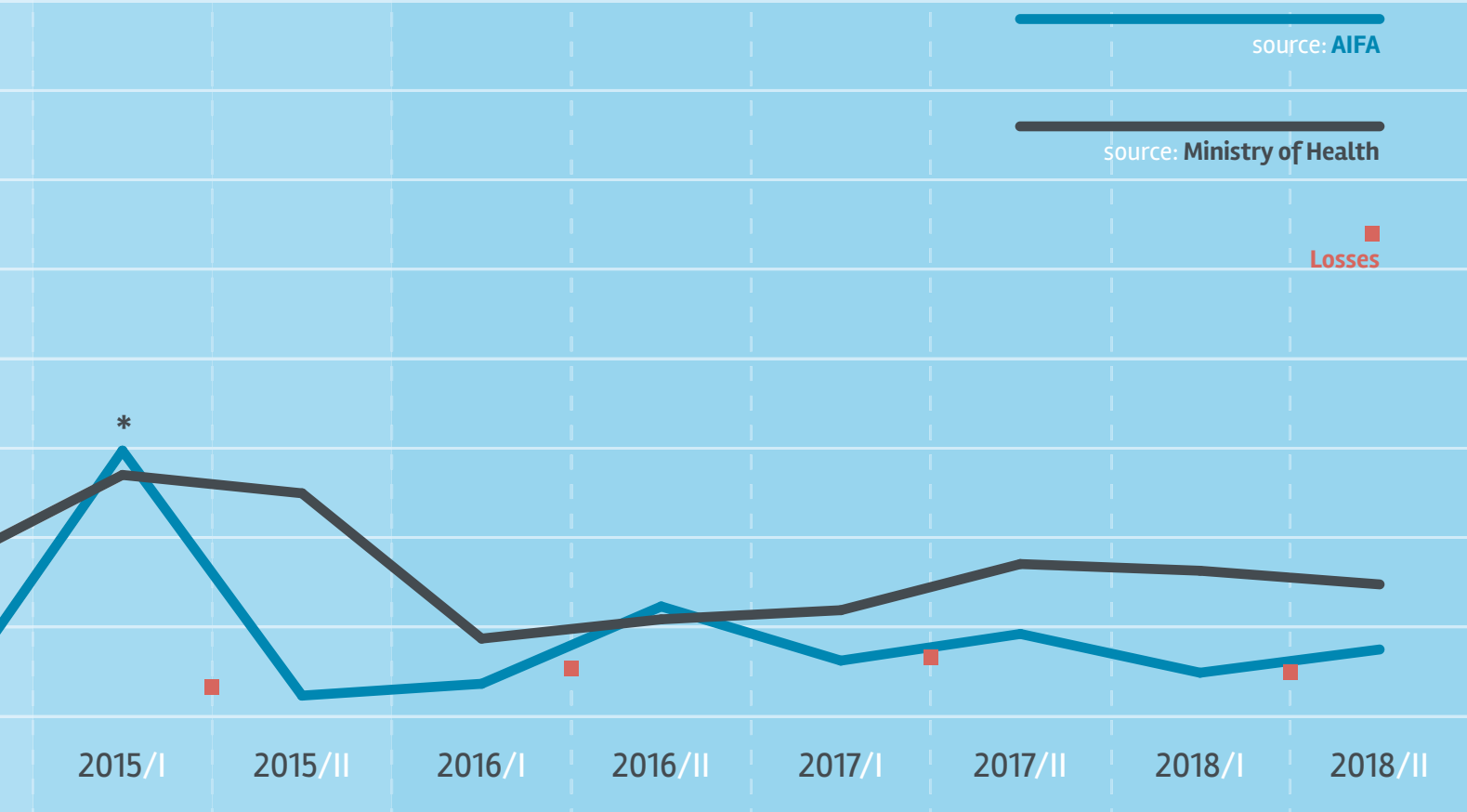
Alongside the decrease of episodes of thefts, the number of packages stolen as a whole clearly decreased, as shown by the analysis of data present in the AIFA database on thefts (covering the key marketing authorisation holders products) and in the Ministry of Health's track & trace system's data (covering all products).



As side effect the number of lost medicines reported, i.e. “non filed thefts”, slightly increased due to the investigations and tools put in place and to the increasing awareness of the Italian network.

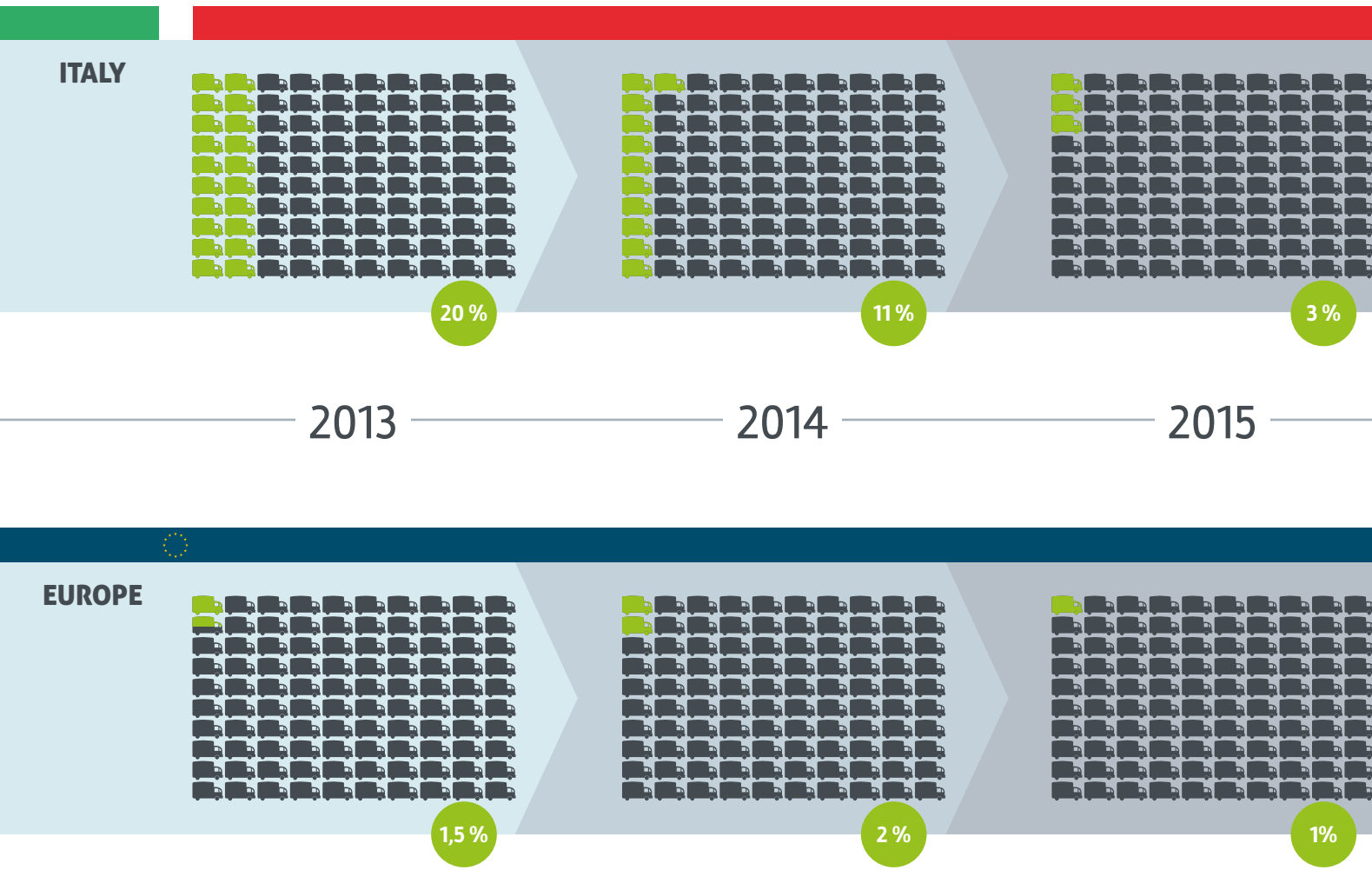
Also in this graph the increase in the incidence in 2017/18 is due to the same dynamics, namely the adaptation of the criminal organizations to the change of framework.

* The peak recorded in the first half of 2015 is due to a single theft of more than 200,000 pieces from the warehouse of a pharmaceutical company and found a few weeks later.



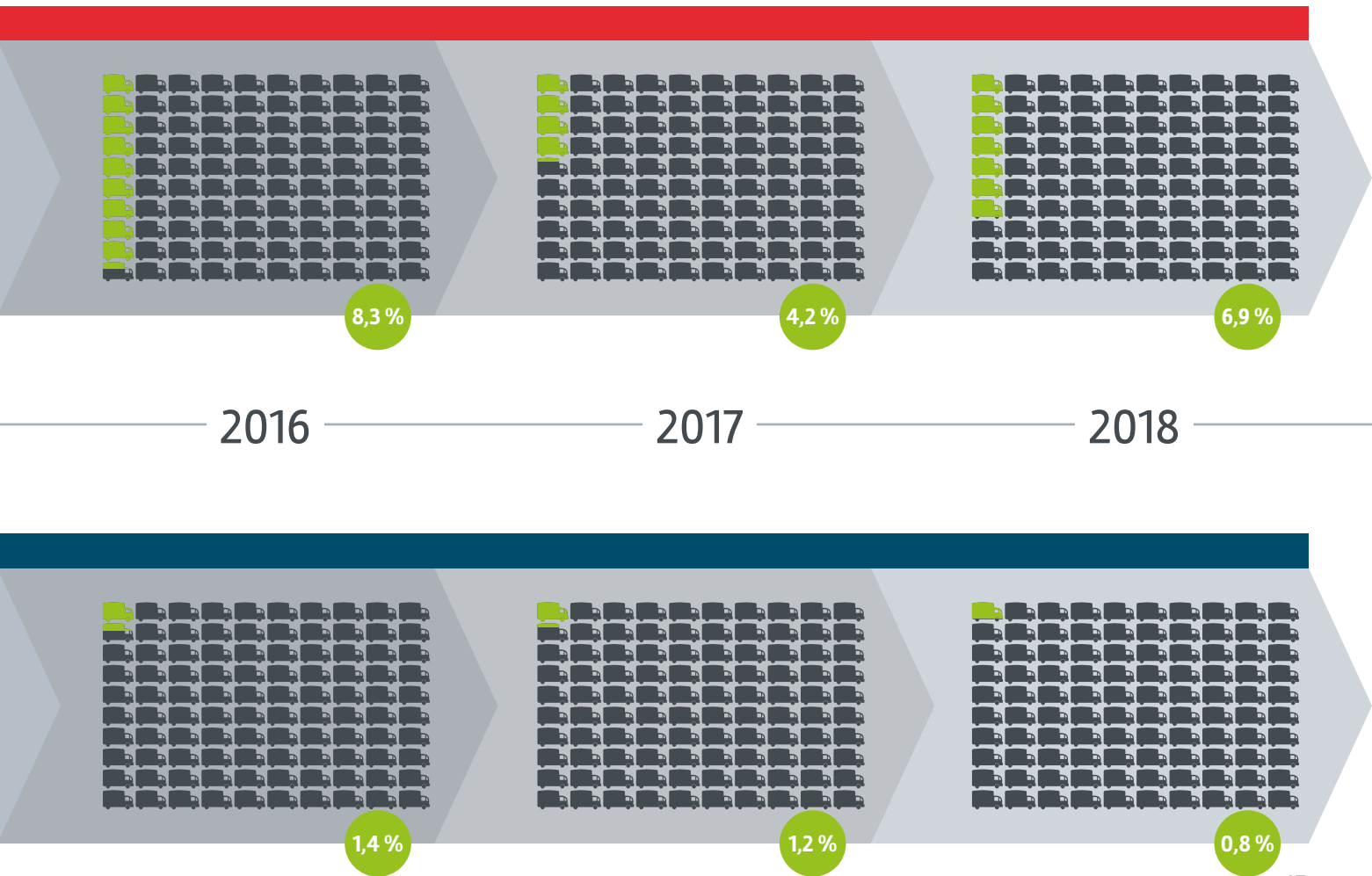
Percentage of thefts of medicines on total cargo thefts

The decrease of the number of events in Italy, since 2014, is also confirmed by the independent evaluation of TAPA (Transported Asset Protection Association).



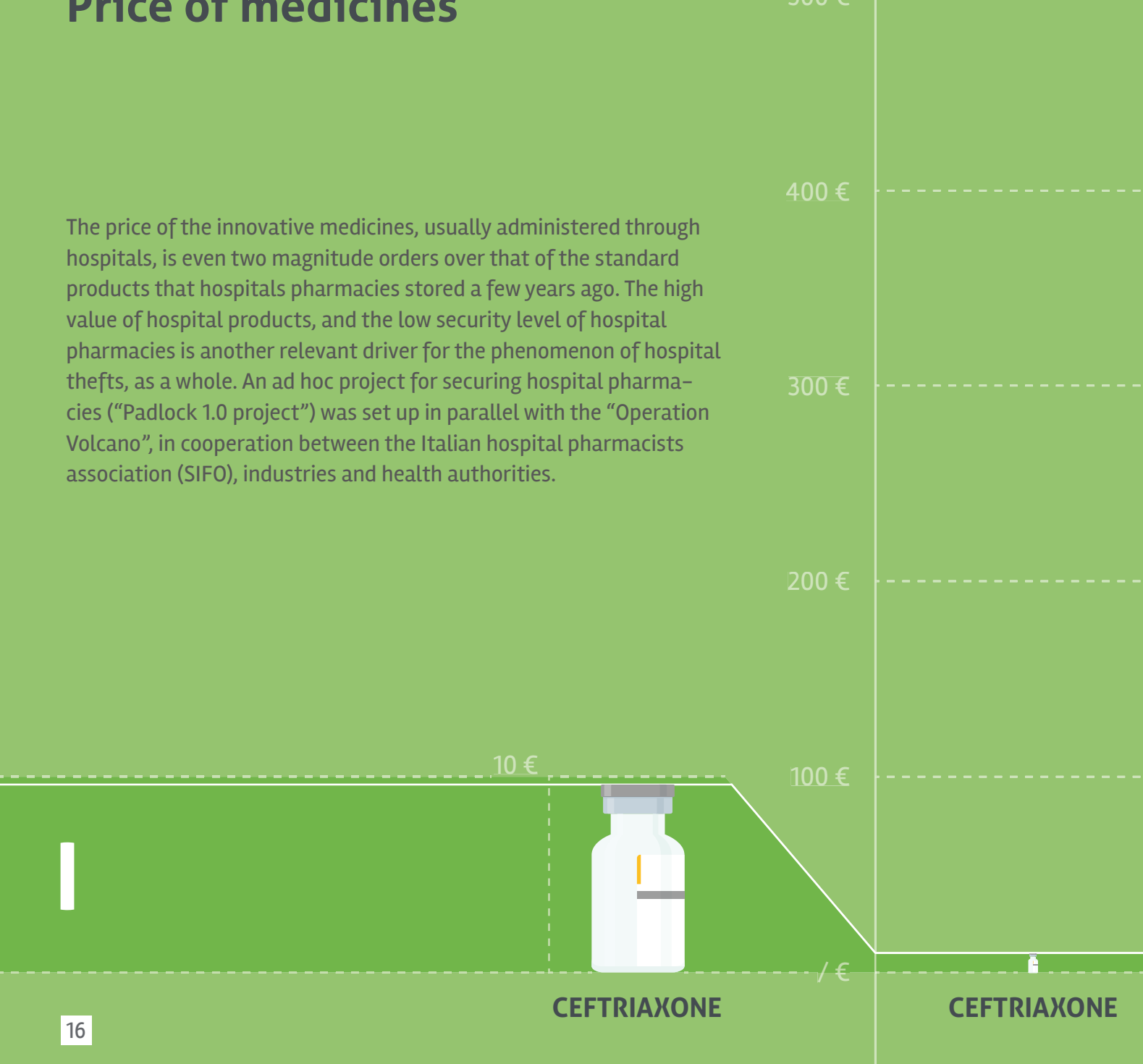
Before the “Operation Volcano”, with respect to the rest of Europe (data confirmed by Sensitech/SensiGuard), in Italy there was a clear prevalence of attacks to lorries transporting medicines; having been closed the main channels for recycling stolen medicines the situation changed, lowering the incidence of pharmaceutical thefts to the same level of other EU MMSS.

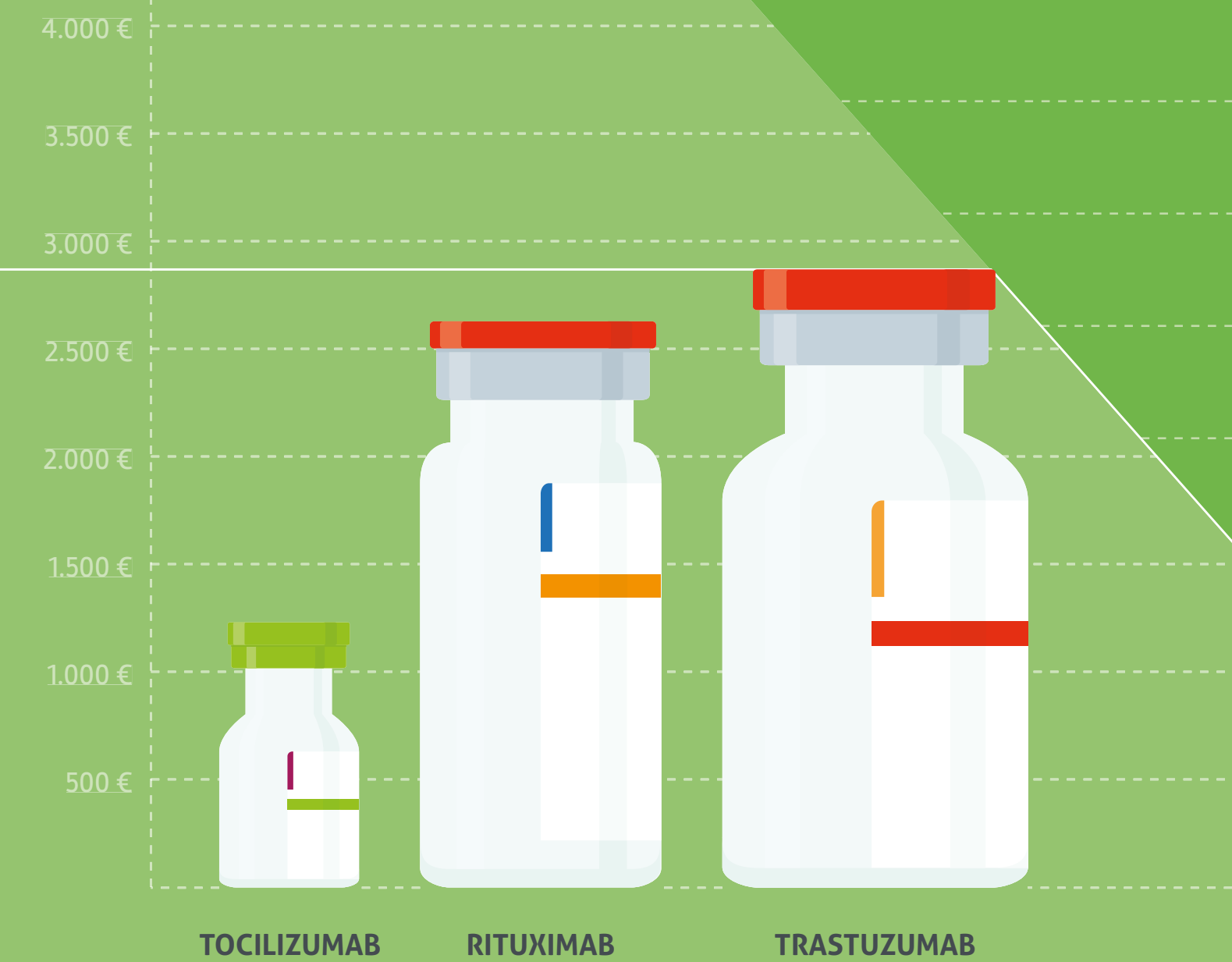
The increase since 2016 is due — again — to the adaptation to the new framework resulting in the return of the criminal organizations.



Price of medicines

The price of the innovative medicines, usually administered through hospitals, is even two magnitude orders over that of the standard products that hospitals pharmacies stored a few years ago. The high value of hospital products, and the low security level of hospital pharmacies is another relevant driver for the phenomenon of hospital thefts, as a whole. An ad hoc project for securing hospital pharmacies ("Padlock 1.0 project") was set up in parallel with the "Operation Volcano", in cooperation between the Italian hospital pharmacists association (SIFO), industries and health authorities.





Nowadays, many EU MMSS are facing major problems of price and access to new innovative medicines, such as those to treat Hepatitis C: the high value of these products is definitely attractive for criminals, and the low access for patients is creating a demand on the field, likely to be fulfilled through black market, a different channel with respect to those presented in the

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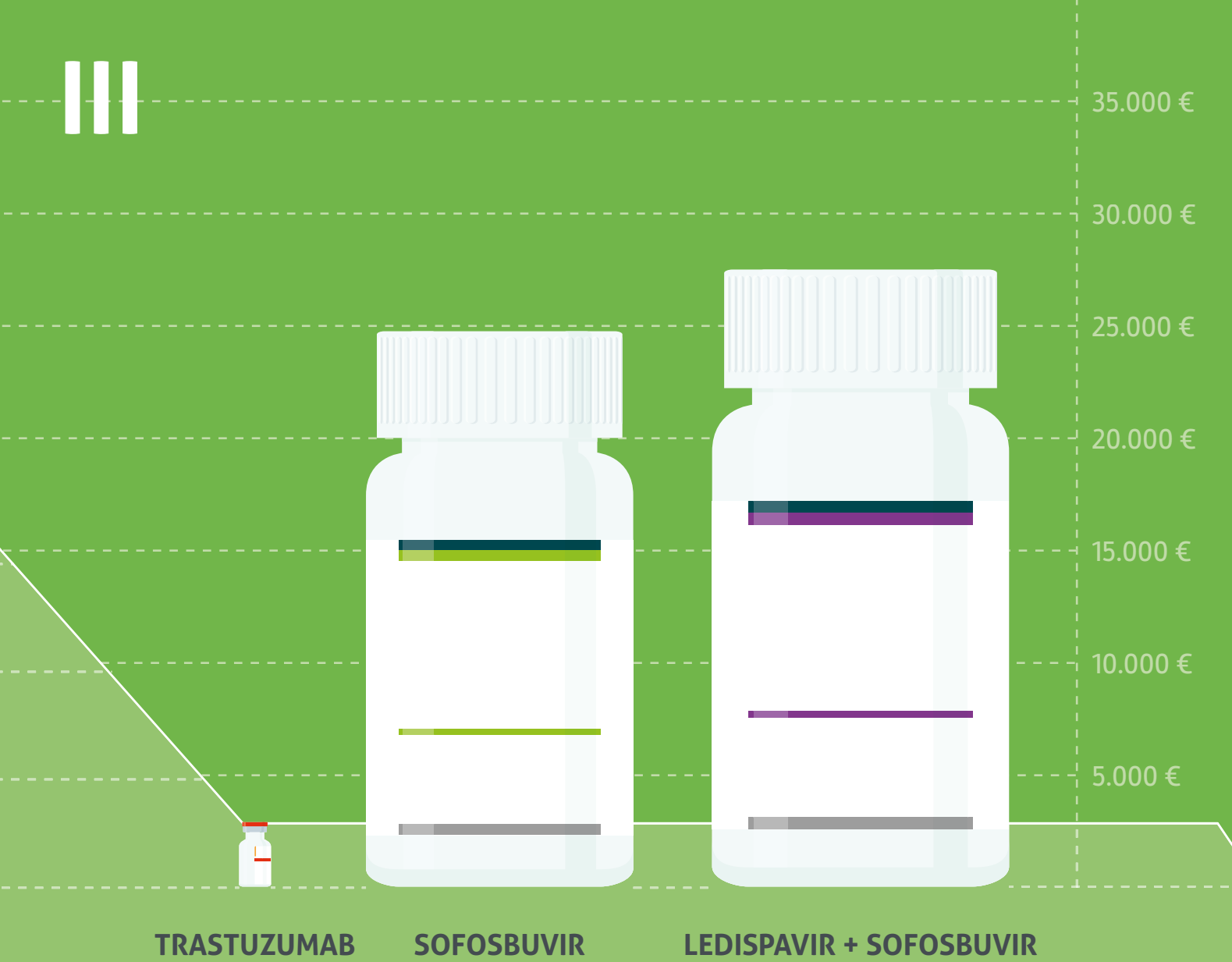


"Operation Volcano's" scenarios. In 2016, Italy has registered at least three major thefts in which products to treat Hepatitis C were the main or the only target: this trend was forecasted and evaluated in advance by Italian authorities, which are now setting up ad hoc counteracting tools.

LEDISPAVIR + SOFOSBUVIR

ONASEMNOGENE ABEPARVOVEC

IV

The American federal Food and Drug Administration has approved on may 2019 a gene therapy for a rare childhood disorder that is now the most expensive drug on the market. It costs $ 2.125 million per patient: R&D provides nowadays high cost medicines which represent extremely profitable targets for the criminal organizations' traffics.

NEW CRIMINAL MODELS

A new scenario

After the Volcano Operation the criminal organizations adapted themselves to the change of framework: due to the investigations, to the Fakeshare tools (DB/black-lists making stolen medicines difficult to sell) and to the increasing awareness of the Italian network (i.e. safer warehouses, framework investigations...), there were some changes of scenario in thefts of medicines:

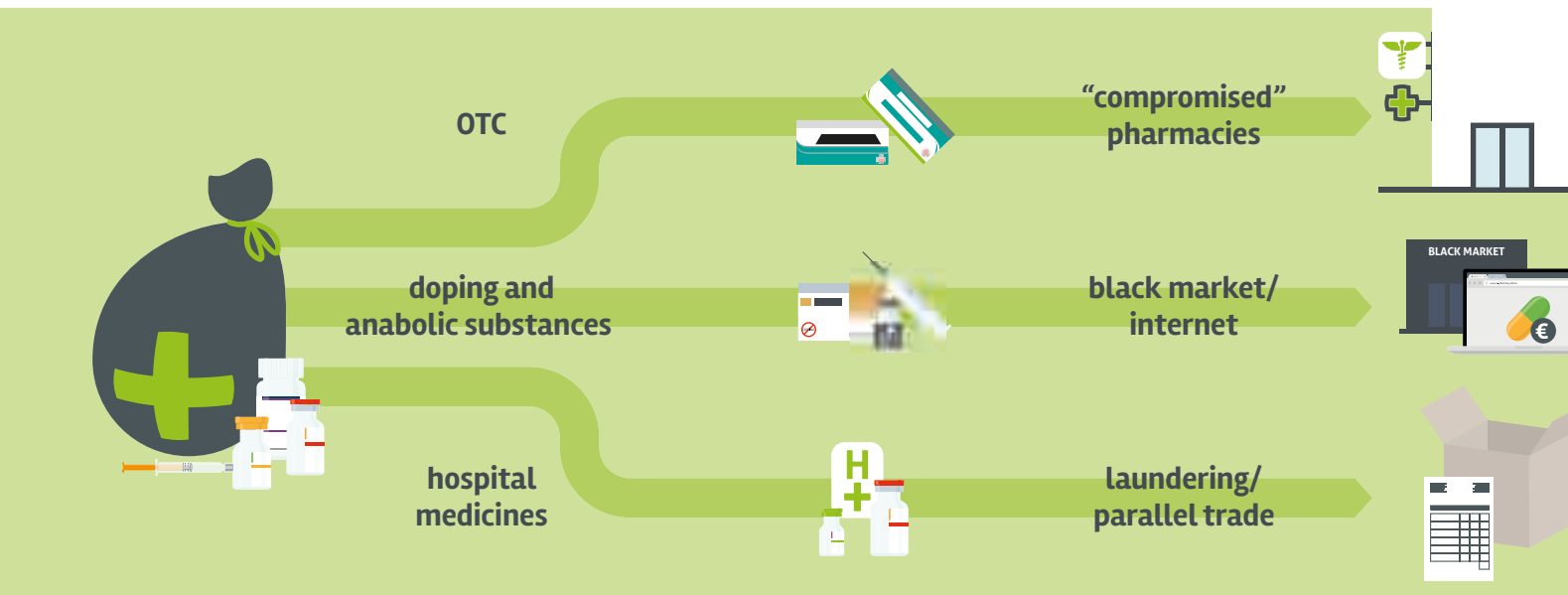
- thieves started targeting other member states (e.g. Greece);
- loss (i.e. "non filed thefts") increased (see pp. 12–13);
- new models were developed.

In general, TAPA's data confirm that the Operation Volcano reduced the incidence of thefts of medicines on total cargo thefts (see pp. 14–15), but then the phenomenon adapted to the situation: the current incidence, although not reaching the extraordinary one from previous years, returned to 4–5%, significantly higher than the average 1% recorded for Europe (data confirmed also from independent sources, such as the Sensitech/SensiGuard database).
However, a systematic evaluation defect weighs on these analyses, related to the need to survey events as such, and thus assimilating the attacks attributable to "generic criminals" to those of the "specialist circuit": a theft from a delivery van (in the so-called "last mile") is, however, certainly different, in terms of extent and operating methods, from the military attack to an armored truck, and it uses laborers and distribution channels only partially overlapping.
The limited number of cases also makes difficult context analyses such as those that Sensitech and TAPA carry out for most frequent cases: the evaluation of attack timing and type of "critical" roads are less representative for this category than for the others considered by Sensitech and TAPA.

We can summarize the approaches at present adopted by criminal organizations in three main models and related features:

- a “specialist” one, a proper professional approach;
- the organized crime’s one;
- a localized phenomenon.

The three models can intersect and their traits mix. For example, the ability of the criminal network to differentiate the **distribution channels** of the various stolen medicines was already visible since the analysis on the Herceptin case (Operation Volcano): over–the–counter drugs traceable to specific thefts had been found in “compromised” pharmacies, the products targeted by the black market left traces in sectoral investigations in Italy (such as those found by NAS investigating dop–ing in Tuscany), as well as hospital medicines had been recycled in the European parallel trade.
Even the recent evidence confirms the “flexibility” of the network: from the loot of the attack on the tractor trailer in Apulia, in July 2018, later found in the coun–tryside of Foggia by the investigators, pharmacy products for about 60,000 € were missing, probably sent to destination through the usual channels (apparently Italian), while the rest of the loot, for a value of almost 2 millions, was still await–ing buyers – reasonably foreign



The Italian context

	 SPECIALIST CIRCUIT	 ORGANIZED CRIME	 LOCAL CRIME
SUPPLY CHAIN	Assaults to specific products in protected assets: e.g. central logistic centers, armored transports, ...	Non product specific assaults to low security assets: e.g. standard cargo thefts, burglaries in hospital pharmacies.	Small quantities gathered through contacts with insiders: thefts in the wards of hospitals, thefts of samples, losses from shipments.
SUPPLY CHAIN FEATURES	Since the products are traceable (e.g. high quantities of a single batch), a "cooling period" or a non traceable third Country channel is necessary.	Since the products may be traced, criminals possibly slower data transfer, and quickly move products outside of Italy.	Non reported thefts, allowing to escape from products blacklists and verification processes.
PRODUCTS	**High cost products**, mainly hospital medicines, upon "order" by customers from abroad.	Mainly **high cost hospital medicines**, but also **B&M pharmacy products** (including OTC) are targeted.	**"Easy to sell" medicines**: e.g. black market products (doping, steroids, botox, ED drugs...), highly demanded products for export purposes.
COORDINATION UNITS	Thefts, possibly national level; no data regarding the coordination of orders/ distribution.	According to the known cases (*Lunapharm*, Calabria), an Egyptian network (wholesaler & local thieves) seems to be relevant.	Local structures. An Italian operator was apparently involved in some recurring ITA/ UK schemes.
OPERATORS	Specialized burglars arriving from other Italian Regions through public transportation, supported by local units.	Burglars from the same area or from other Italian Regions, moving via public transportation, supported by local units.	Insiders in hospitals or in logistic structures.
INSIDERS	High level insiders, sharing knowledge about the security systems.	Medium level insiders, sharing information about the presence of interesting products and the security systems.	Low level insiders, in direct contact with reference persons (*fences*) from the criminal network.

	 SPECIALIST CIRCUIT	 ORGANIZED CRIME	 LOCAL CRIME
TRANSPORTATION	Undercover, even through GDP compliant channels (e.g. hidden boxes in GDP trucks).	Small quantities in personal luggage (public transportation), and undercover shipments; laundered products shipped via GDP channels.	Very small quantities hidden by the insiders between their personal effects; laundered products usually shipped via GDP channels.
DISTRIBUTION CHANNELS	Third Countries market, and sometimes reselling via Internet.	Parallel distribution network, via operators in third Countries (Egypt), or via non authorized dealers in EU (Lunapharm case).	Local black market, EU parallel distribution network, Internet.
RECENT CASES	**Logistic centers** (DHL 01/2019, Delpharma 02/2019). **Armored trucks** (Foggia 07/2018).	**Hospital pharmacies** (Orbassano 05/2019, San Carlo MI 06/2019, Grumo BA 06/2019, Calabria 2018 – many events).	**Thefts from ward of hospitals** (Napoli 2018). **Thefts of samples** (Cialis, 12/2018). **Losses**: tenth of cases per year, sometimes for relevant quantities (Cialis, 2019).
RECENT DISCOVERIES	Units from Delpharma case found on the Internet and on some third Countries markets in Egypt, Turkey, India, Ukraine.	Units from the Orbassano hospital pharmacy found in a lost bag (personal luggage) on a train going from Milan to Rome. Units from 2018 Calabria hospital thefts offered by an Egyptian operator to the EU Parallel Distributors network (whistleblowing to EMA).	Units from the Napoli non reported theft found in Egypt, offered via Internet to the EU market. Units from non reported thefts apparently connected with an operator gathering products from many hospitals, found in a shipment from an Italian wholesaler to a UK operator.

THE SURVEY

National monitoring and reporting systems

The survey presented in these pages, promoted by the Italian Medicines Agency (Agenzia Italiana del Farmaco – AIFA) in the framework of the activities of the European Expert Group "Delegated act on safety features for medicinal products for human use", aimed to collect information about the national monitoring and reporting systems in place for pharmaceutical thefts in the EU Member States and neighboring countries, and to evaluate the possible interoperability between the Italian Fakeshare database, already available to all MS, and other similar national databases within the EU.

According to the current legislative framework, Member States should have a system in place for preventing medicinal products suspected to be falsified from reaching patients. The system should cover the reporting also of medicines with a false representation of their origin, like the ones of the Volcano Operation and of the more recent Lunapharm Case.

WGEO Rapid Alert in 2018	
Austria	1
Belgium	4
Denmark	1
Germany	1
Greece	1
Poland	1
Portugal	3
Romania	1
Sweden	1

14!

Rapid Alert (RAS) in 2018	
Germany	4
Sweden	1

5!

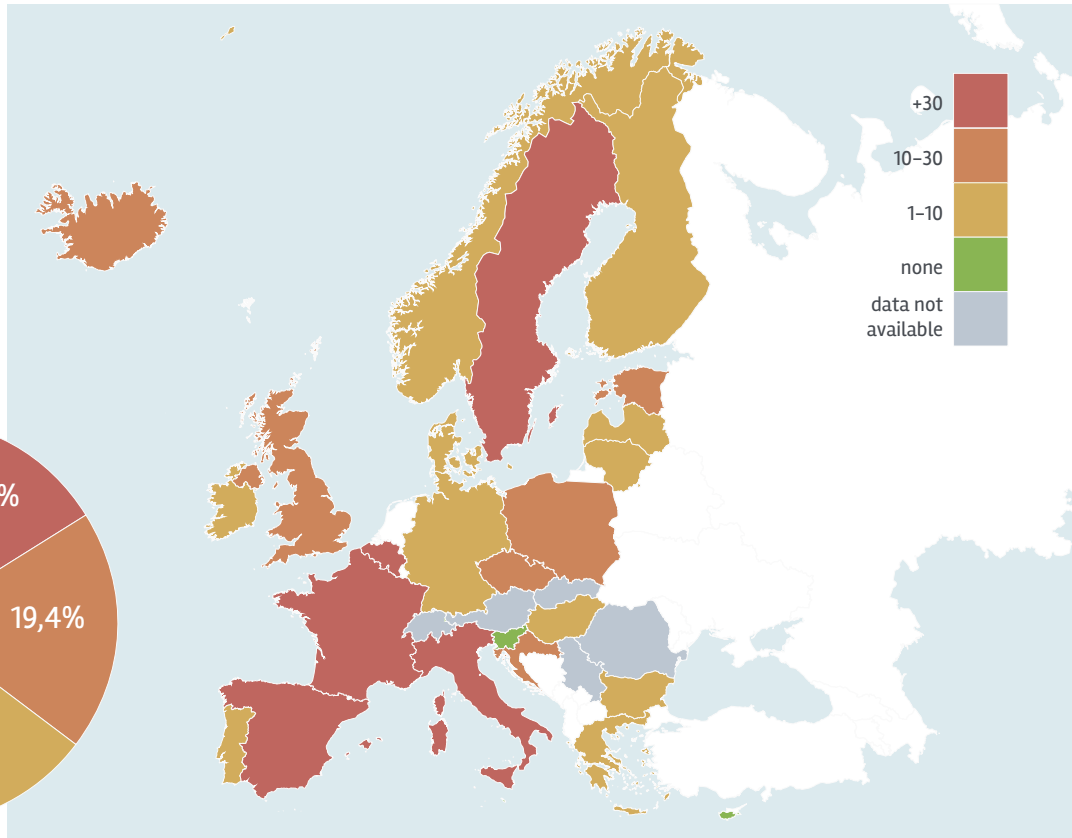
Results in a nutshell

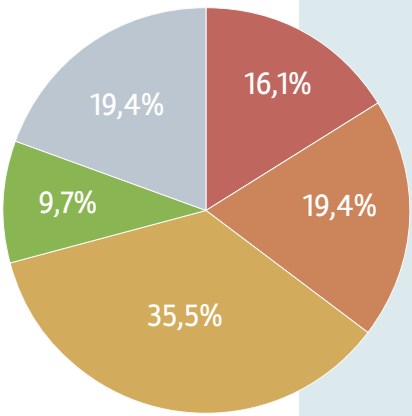
Thefts are basically not evaluated at a NCA level, then the phenomenon is underestimated: almost no ad hoc units/databases are used, and the knowledge about existing systems/tools is limited.
In spite of Dir. 2011/62, there are no signals from the field with respect to this kind of falsification, nor systems for gathering data.

Most of NCA declare that they use RAS/WGEO RAS, but there is no correspondence between the launched alerts and the actual number of filed/confirmed cases: the number of cases per year (estimate) is **over 150**, but the number of Rapid Alert (RAS, WGEO) about thefts released per year is dramatically lower: less than 20 in 2018, still no alert in 2019.

Question n.1
What is the number of pharmaceutical thefts in your country per year?

Only 5 countries indicated “more than 30” (Italy, Belgium, France, Spain and Sweden).

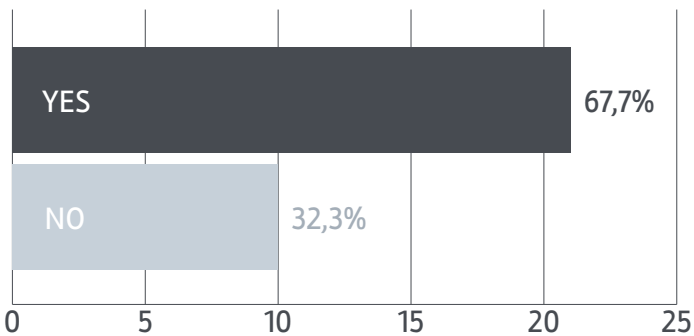




In some cases the data consider also small events related to controlled drugs (evaluated through a different regulation).

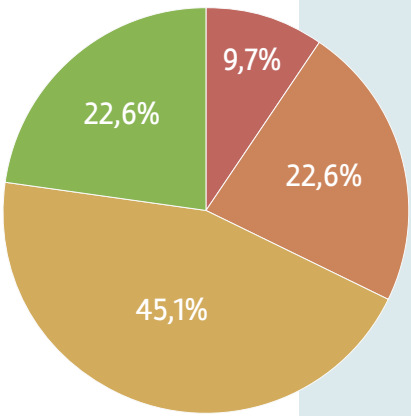
Question n.3
Is there a system in place in your country for reporting pharmaceutical theft?

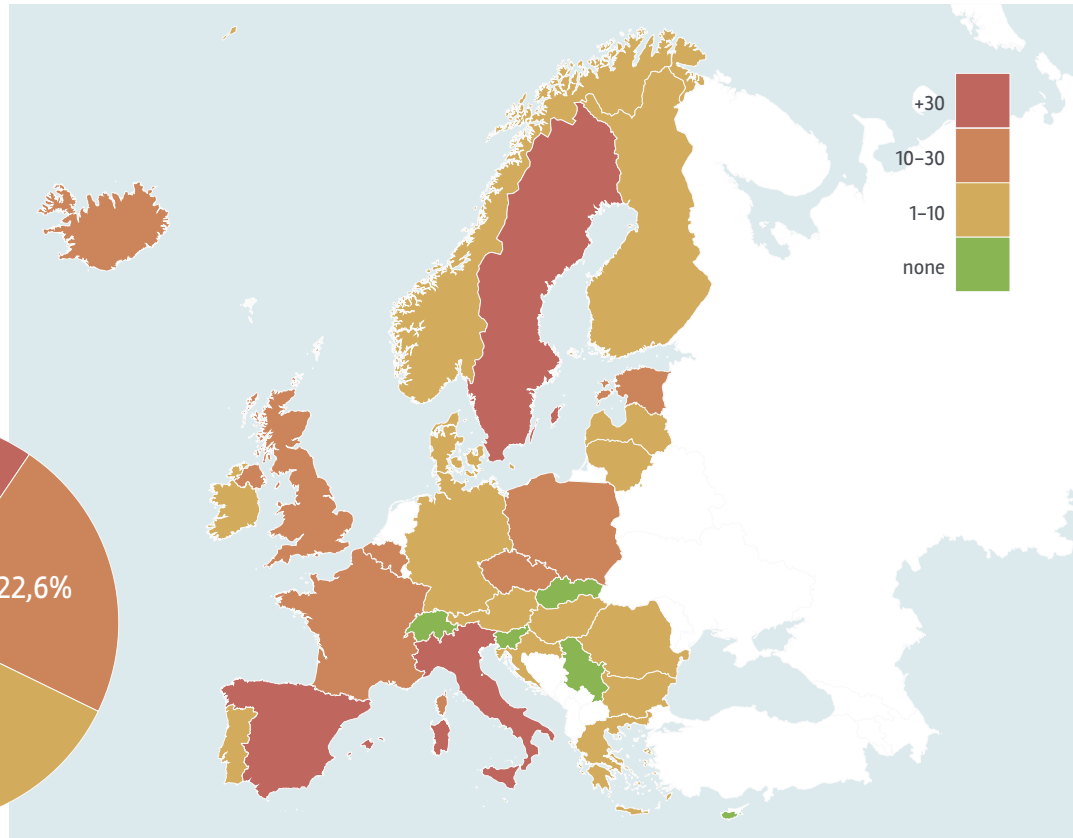
21 out of 31 countries declare to have a reporting system specific for thefts of medicines: a dedicated e-mail address, a phone number or a web page.



Question n.2
What are the number of pharmaceutical thefts reported to your administration?

Only 3 countries indicated “more than 30” (Italy, Spain and Sweden).



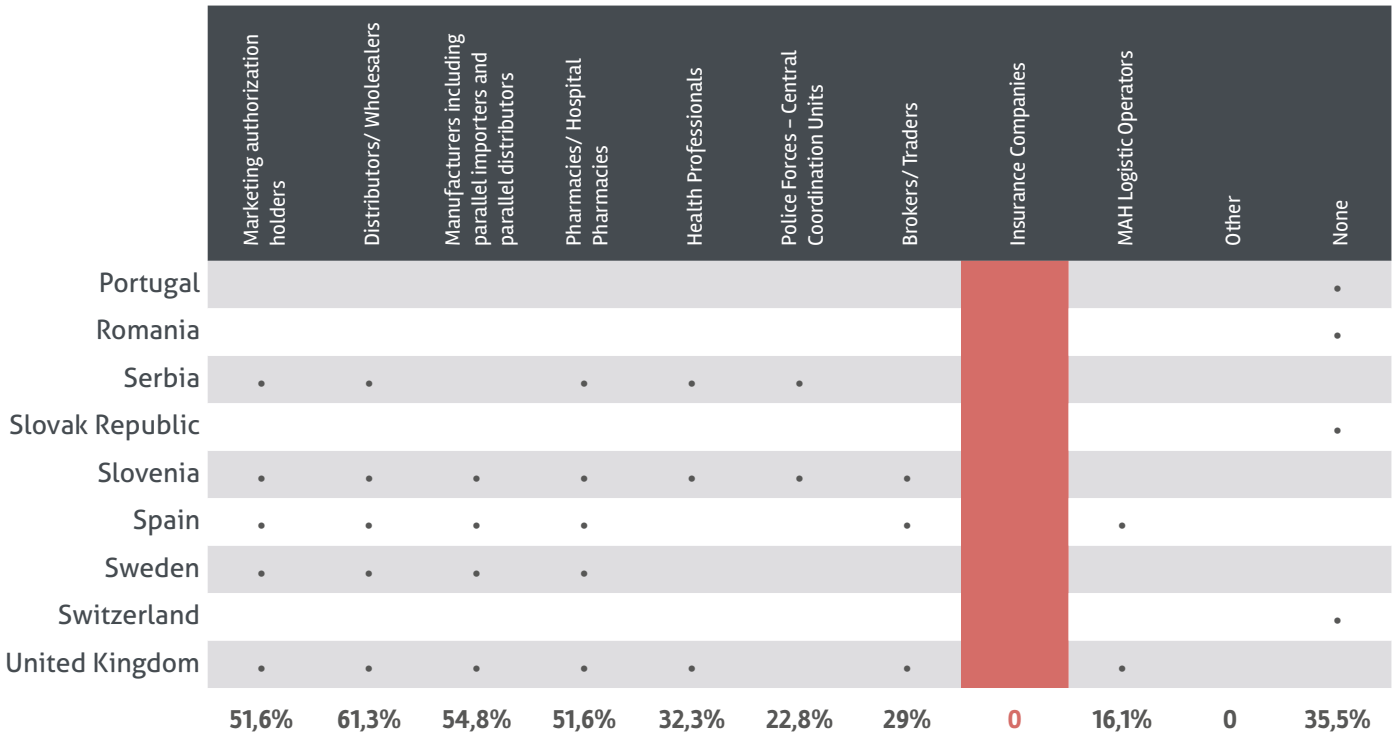


All respondents confirm that – since thefts are evaluated at local level, and there is no obligation of reporting for police/local authorities, signals to NCA are never covering the whole phenomenon.

In general, there is no specific channel for thefts – the quality defect network is the main target, even if – in the absence of a specific obligation, there are no signals from the field.

Question n.5

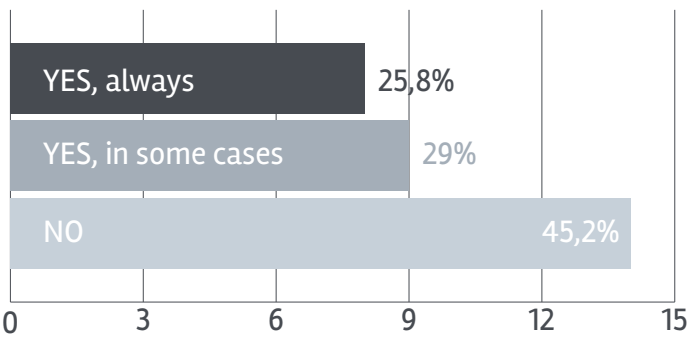
Who is legally obliged to report about pharmaceutical thefts to your administration?



It should be emphasized that no administration has activated a channel with insurance companies, which instead are in possession of important data on thefts of medicine.

Question n.4

Do parallel distributors established in your Country report to you about possible offer for suspicious medicines they receive?



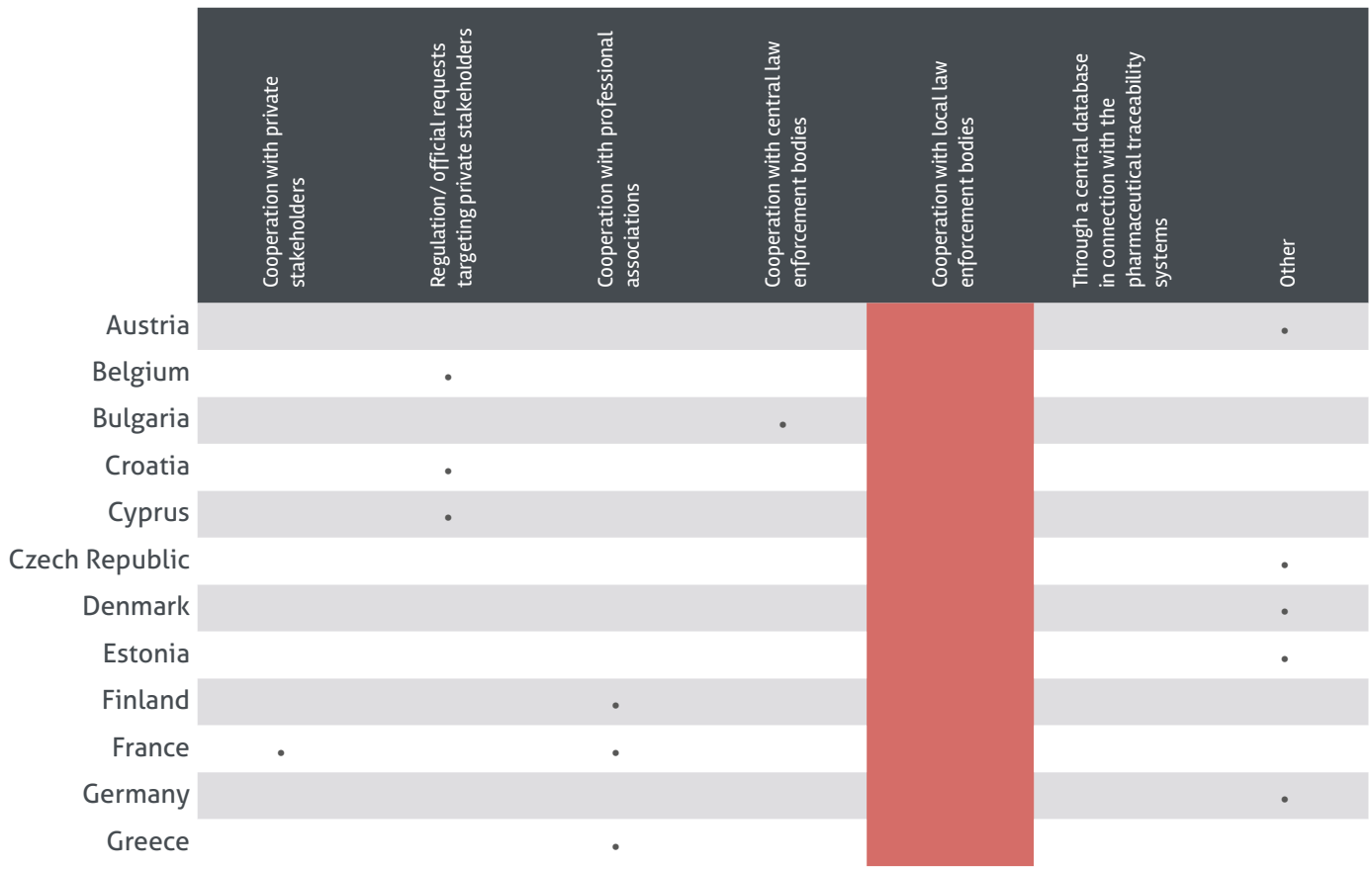
The obligation to report is already in **Dir. 2011/62/EC, Art. 80:**

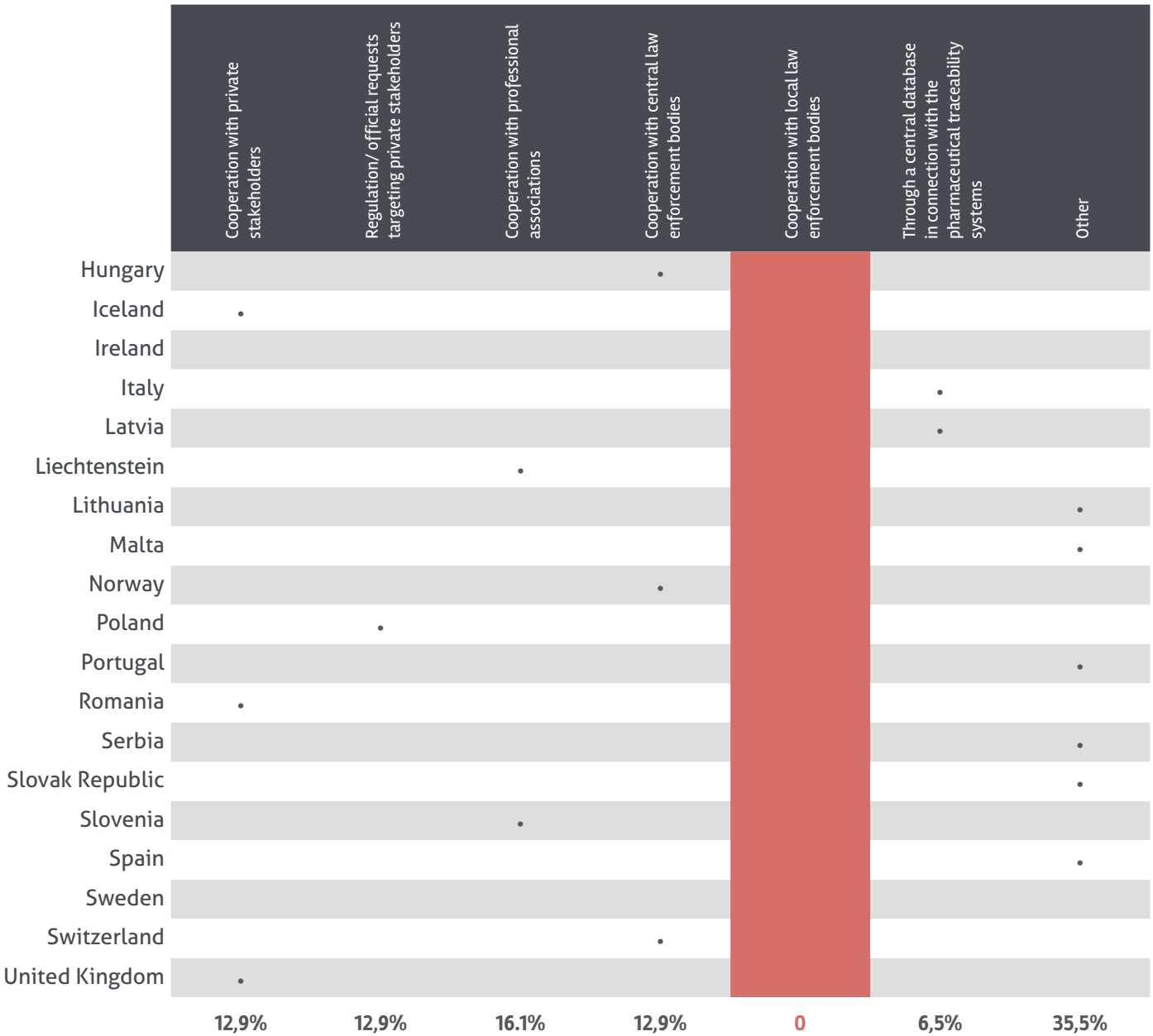
«Holders of the distribution authorization must fulfill the following minimum requirements:
they must immediately inform the competent authority and, where applicable, the marketing

authorisation holder, of medicinal products they receive or are offered which they identify as falsified or suspect to be falsified.»

But even when there is an obligation, in the absence of a specific procedure (and priority), the network is quite silent: in spite of Dir. 2011/62, there are no signals with respect to suspicious offers from Parallel Distributors, even after the issue of specific requests — such as AIFA's NUIs issued in 2019 (see Annex 2).

Question n.6
How do you inform stakeholders about medicinal product thefts and the available reporting channels?

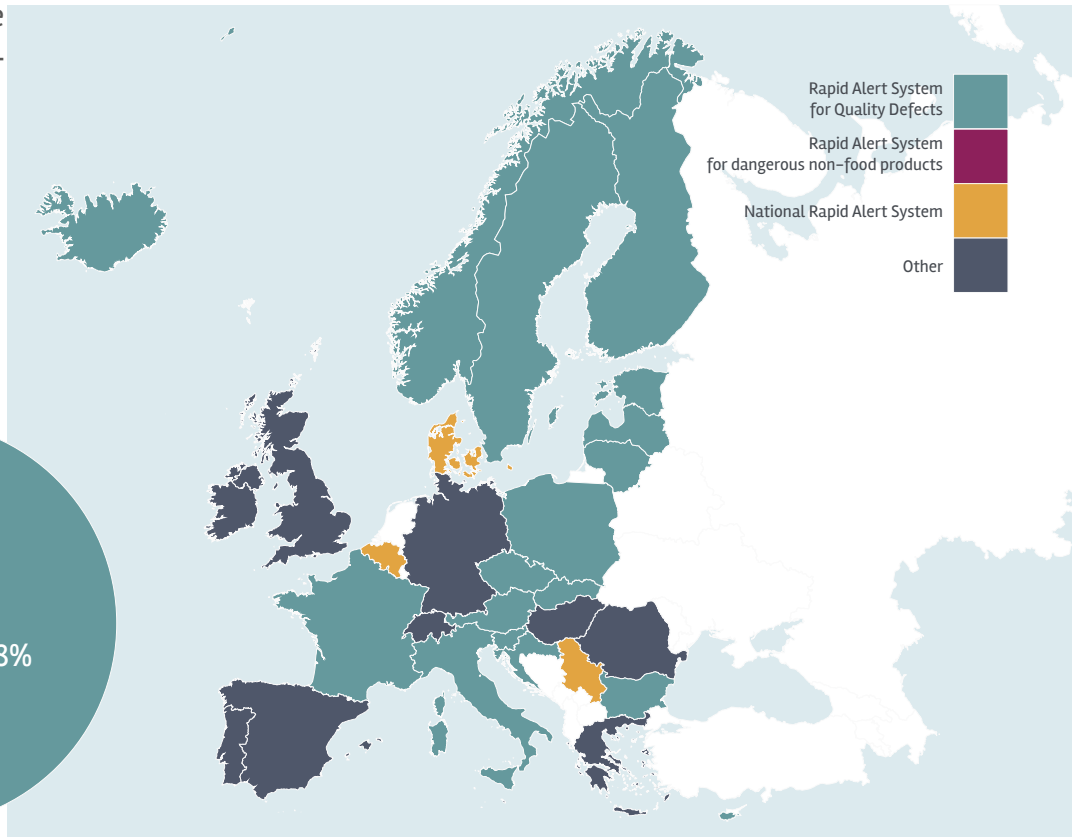


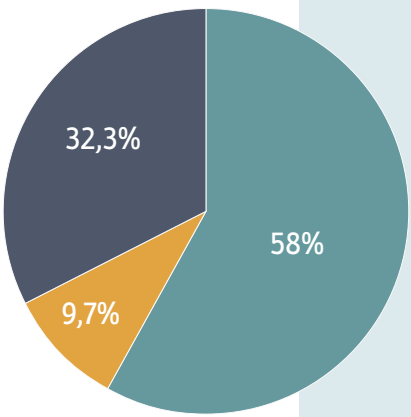


Since the complaints occur mostly at the local level the lack of involvement of the local enforcement authorities is a weakness.

Question n.7
How does the system in place in your country for reporting pharmaceutical thefts notify Member States competent authorities?

In the absence of a central Database, the RAS may be a solution; however, it is pretty clear that it is not efficient. It should be limited to relevant cases, and it may be useful only in the short term since the stolen products are distributed in about 2 weeks from the event.

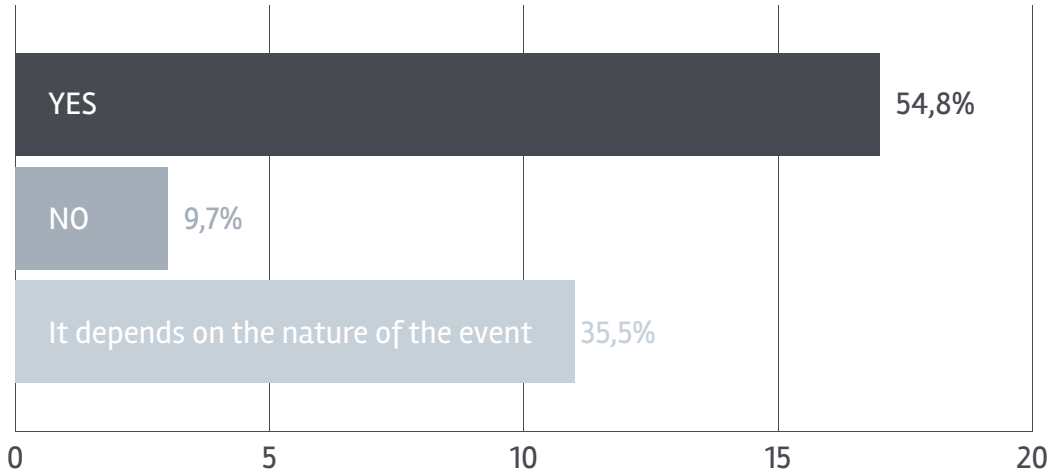




While it is evident that there is no prevalence of a specific channel for informing private parties, due to the limited experiences in the field between the MS, in the sharing of information among authorities, most member states declare instead to rely on RAS/WGEO RA, but the number of recorded alerts (less than 20 per year) is not matching the number of cases (more than 150 per year), as previously illustrated.

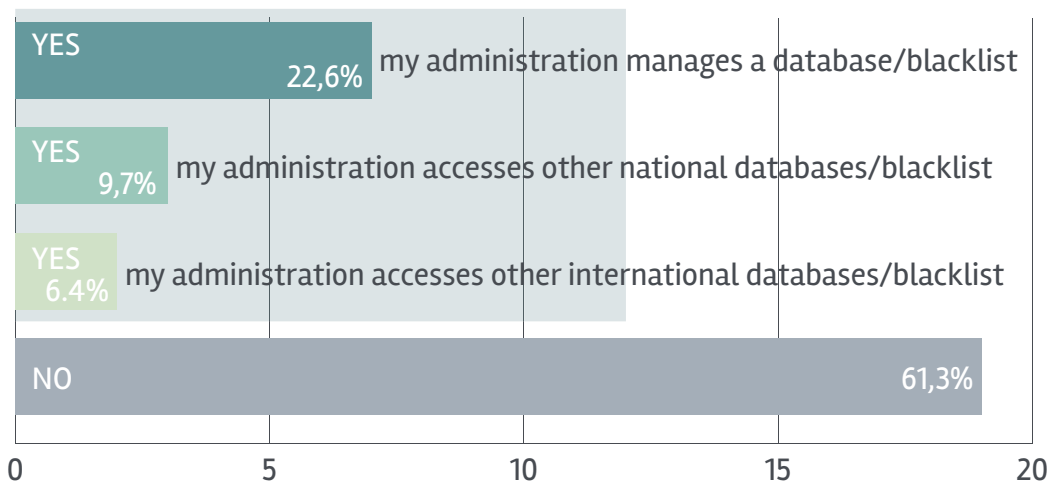
Question n.8

In case of detected pharmaceutical thefts (e.g. in the general press) does your office receive detailed information about the stolen products (i.e. brand names, batch numbers, expiry dates, quantities, ...) in order to launch a rapid alert?



Question n.9

Do you have access to any database / blacklist of medicines that have been stolen in your Country or abroad?



Only 12 countries (38,7%) have access to a database or a blacklist, either national, international or in house; in this scenario the Italian case deserves a mention apart.
In September 2013 the Italian Medicines Agency started a project with the support of the Ministry of Health and Carabinieri NAS, and in collaboration with National Associations, aiming at collecting all information available about the cases of thefts of medicines in Italy, in order to promptly share them with police forces and stakeholders. The "Database on thefts" is the tool developed at that time, which includes the data about thefts or loss of medicines provided by the companies and the authorities participating in the project. The Database was a key tool in the managing of the Operation Volcano.
In late 2014, in the framework of the European project Fakeshare II (www.fakeshare.eu), AIFA decided to open the in-house Database to the other countries participating in the project and later to all countries interested in sharing all available data on thefts.

At present UK shares regularly its national data on thefts of medicines through the AIFA/Fakeshare database: these data and all national data reported through alert systems (RAS and WGEO RA) are registered in the Italian in-house database and included in the periodic report available on a registered-only users' platform.

It is worth mentioning that those countries having put in place a reporting/data collection system (such as Italy) or investing in involving local enforcement bodies (such as UK) are aware of a higher number of events.

Conclusions

Towards a shared Database on stolen medicinal products at European level

Each medicine that is stolen has to be considered as falsified since it could be sold only through documents stating a false origin (Dir. 2011/62/EC, Art. 1). Starting from this certainty and from the lessons learned with the Operation Volcano and the following cases, it appears evident — and necessary — that existing rules (such as the obligation to report suspicious offers to parallel distributors or wholesalers in Dir. 2011/62/EC) should be better enforced; in addition an obligation for MAHs to report all thefts has to be set up, expectantly through Delegated regulation. GDP and GMP guidelines should also be reconsidered (and their implementation enforced to hospitals and pharmacies), in order to include additional provisions in relation to stolen medicinal products. Safety features regulation should eventually help solving the issue related to the limitation posed by the batch-only identification, in order to help tracing single stolen packages.

It appears clear also the need of a shared database on thefts of medicines — on the model of the AIFA/Fakeshare one — at European level and the creation of a central coordination unit to support the participating countries in cooperating, by collecting the data and dealing with specific cases, providing researches and fostering intelligence. A unit as such might also define mandatory requirements for reporting and periodically compile a list of high risk medicines.

After other countries have followed the Italian model and built a database on stolen medicinal products, sharing their data with the network, big numbers started emerging: **as for Fakeshare 2020 data, figures of events/stolen units are higher in other countries than in Italy, to show that the phenomenon doesn't exist as long as it is not investigated**.

ANNEX 1

A practical guidance on stolen medicines*

* Previously presented on October 2018 and circulated to the Italian network of stakeholders and later to the European one. The guidelines have been developed by a working group of experts.

Prevention systems, management of the events and of the possible recovery

Medicines are often characterized by a **high market value**. For this reason, **thefts of medicines** — commissioned by criminal organizations to the detriment of **pharmacies, hospitals and carriers** — subtracting products from the legal chain and then recycling them in the many different networks to which the organizations have access, became quite frequent in all European countries.
In countries such as Italy, where the pharmaceutical traceability makes possible to measure the incidence of the phenomenon, there was a significant increase in the number of events between 2012 and 2013, which was followed by a sudden stop in 2014, as a consequence of the interventions carried out by the administrations in collaboration with MAHs and industry associations. The phenomenon then resumed between 2017 and 2018, years in which in Italy the reported theft events were respectively 38 (of which 20 in hospitals) and 43 (of which 20 in hospitals).

The medicines subject to theft, from a legal and regulatory point of view, become "unusable": once they have left the legal system that guarantees their proper preservation, they can no longer be sold, and even if they are subsequently recovered, as happened in some recent cases, they should be considered as "waste", since it is **in no way possible to guarantee their safety**.

The investigations conducted in 2014 (the Operation Volcano) led to the discovery of an infiltration scheme that was targeting mainly Germany: stolen anti-cancer medicines for hospital use with packaging in Italian were sold to European Parallel Distributors through documentation falsely certifying their origin. The products were also deteriorated, because of the failure to comply with GDP (e.g. with respect to the instructions on proper storage — presumably occurred in unsuitable

environments, such as garages or improvised warehouses at temperatures higher than 30°C) or, in other cases, even diluted or tampered with, without no scruple for any damage caused to patients being treated.

Directive 2001/83/EC, art. 117a: *«if the medicinal product concerned is suspected of a serious risk to public health, the competent authority of the Member States and all actors involved in the supply chain in that member state, in case no measure has already been taken, ought to immediatly receive an alert in order to withdraw that medicinal products from the patients within 48 hours. The alerts should contain sufficient information on the suspected quality or falsification and the inherent risk.»*

Criminal organizations have implemented consolidated systems to resell stolen medicines to foreign pharmacies and hospitals, through the use of documentation that certifies — falsely — their legal origin; this form of "laundering", which is based in fact on a system of false invoices, sometimes issued by subjects without the necessary authorizations provided for in the EU for the distribution of medicines, allows the classification of the products involved in commercial transactions as **"falsified medicines"** according to the Directive 2001/83/EC and, therefore, as a danger to public health.
All regulatory agencies of the EU Member States have the **legal obligation** to issue communications that prevent these can reach patients, in accordance with the provisions of *Directive 2001/83/EC, art. 117a*.

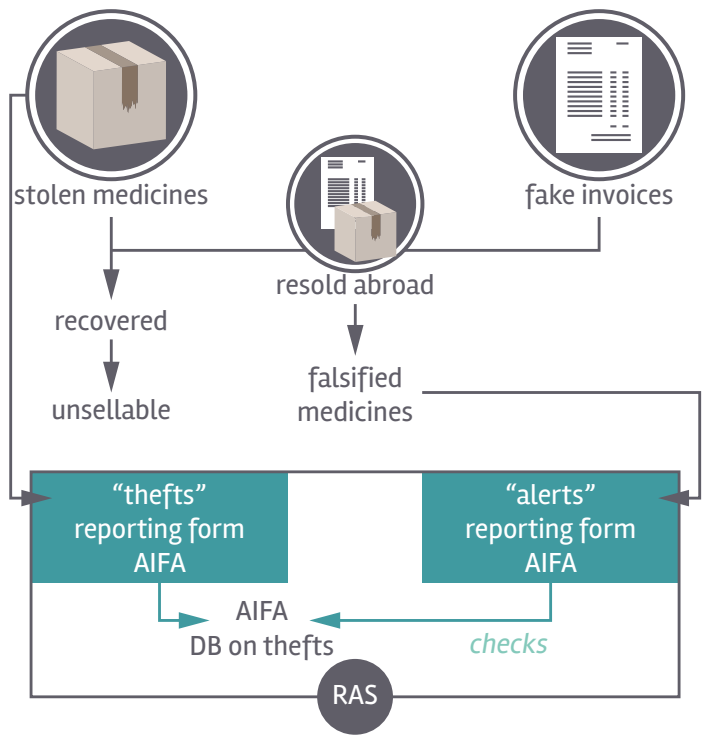
Only the timely sharing of information makes possible to send out in real time Rapid Alerts and blacklists for operators, that in turn allow the subjects to whom the offer is addressed to assess any anomalies, such as extremely discounted prices.

For the effective management of the rapid alert system, it is important for all competent authorities to promptly receive all useful information regarding the theft occurring in pharmacies, hospitals or during transportation; at the same time, this information is also very relevant for MAHs, also representing a direct contact point with health authorities — then, it may be useful to send information regarding any cases also to them.

The collaboration of all operators — **local and hospital pharmacists, wholesalers, depositaries, MAHs, concessionaires, logistic service providers, Police Forces** — is therefore essential; in order to support this process, in some countries, as in Italy, the administrations have set up an *ad hoc* system for signalling, such as

downloadable online forms (like the one available on the AIFA website) to be filled in with the requested information and sent to a dedicated e-mail address (for Italy and for countries participating in the Fakeshare platform, *medicrime@aifa.gov.it*), preferably **within 48 hours** from the event. This timing allows to inform the operators to whom these could be offered, through the timely updating of an instrument such as the Fakeshare database, and the launch of any "Rapid Alerts" to be sent to the National and International network.

In addition to the aforementioned counteracting system, which aims to prevent the reintroduction of dangerous products in the European legal chain, with regard to the aspects most closely related to the prevention of thefts and the protection of **Hospital Pharmacies and Pharmaceutical Services of Healthcare Companies**, Italy also developed a **guideline** that collects the organic set of best practices to refer to in order to design and verify the correct implementation of a management



system to guarantee the safety of the medicines (*http://www.sifoweb.it/images/pdf/attivita/attivita-scientifica/aree_scientifiche/Logistica/SIFO_LINEE_GUIDA_def.pdf*); also as regards the transport of medicines, associations such as **TAPA** (*https://www.tapaemea.org/about-tapa/chi-tapa.html*) provide operators with operational indications and intelligence data to minimize the risks of assaults and robberies

It is also advisable to communicate to the administrations, always through dedicated e-mail addresses (such as *medicrime@aifa.gov.it*) and appropriate reporting forms, information on the discovery of suspected medicines, including photographic findings, which are certainly useful during the initial evaluation of the report.

Reporting cases is extremely important: the availability of information and the comparison of data on shared cases allows the health authorities to support the investigative activities carried out by Police Forces and Prosecutors.

The administrations and the MA holders can have data on the traceability of the products, on the basis of which it is possible to unequivocally identify the products found as "stolen".

To find out more

Forms (thefts and alerts):
http://www.aifa.gov.it/sites/default/files/Mod_Segnalazione_furti.xls, *http://www.aifa.gov.it/sites/default/files/Mod_336_01_segnalazione.doc*

Thefts of medicines:
http://www.agenziafarmaco.gov.it/sites/default/files/AIFA_Volume_Furti_2017_EN.pdf, *http://www.agenziafarmaco.gov.it/sites/default/files/OperationVolcano.pdf*

Security in hospital pharmacies:
http://www.sifoweb.it/images/pdf/attivita/attivita-scientifica/aree_scientifiche/Logistica/SIFO_LINEE_GUIDA_def.pdf

Publications and data on pharmaceutical crime and thefts:
http://www.aifa.gov.it/content/crimine-farmaceutico,
http://www.agenziafarmaco.gov.it/content/contrasto-al-crimine-farmaceutico

The Fakeshare project:
http://www.fakeshare.eu/

ANNEX 2

Italian 2019 NUIs:
a sample signal to the network

Follow-up and Non-urgent Information for Quality Defects

The 2014 "Herceptin Case" and the 2018 "Lunapharm Case"

	ITALIAN MEDICINES AGENCY (AIFA)		
1.	To: (see list attached, if more than one)		
2.	Recall Number Assigned: German RA of 17.07.2018	3.	National reference Number
4.	Product: Herceptin 150 MG and other products supplied by unauthorized operators indicated in point no. 17	5.	Marketing Authorisation number: For use in Humans
6.	Brand/Trade name: Herceptin 150 MG and other products supplied by unauthorized operators indicated in point no. 14	7.	INN or Generic Name:
8.	Dosage form:	9.	Strength:
10.	Batch number (and bulk, if different): NA		
14.	Marketing Authorisation holder: NA		
15.	Manufacturer: NA	16.	Contact Person: NA
17.	SUBJECT: The 2014 "Herceptin Case" and the 2018 "Lunapharm Case"		

Background information

On the 17 July 2018, following a publication by a journalist on the German media, the German authority Landesamt für Arbeitsschutz, Verbraucherschutz und Gesundheit (LAVG) informed the Rapid Alert network about "unconfirmed stolen products" originating from the Greek pharmacy Ozbagdzi (not authorised as wholesaler) and sold to the German parallel distributor (PD) Lunapharm.
On the 27th of July 2018 the Greek authority EOF issued a WGEO rapid alert in which the police investigation was summarised and the main companies involved

were listed. The WGEO alert stated that trades occurred between 2013 and 2016 from Ozbagdzi to companies based in Germany, Cyprus, Egypt and Switzerland.
[...]
In particular, the Greek WGEO alert reports the following: "a criminal gang engaged in the illegal distribution of medicinal products subject to restricted medical prescription, was broken up by the police. In terms of modus operandi, the members of the gang illegally procured the products from public hospitals via overprescription and forged medical assessment reports. Members of the gang were doctors, nurses etc who took advantage of their posts in order to leak quantities out of the hospital."

Investigations of the 2018 Lunapharm case

Further investigations performed by Greek and Italian authorities, identified that the trades of stolen products were also originating from Greece, Italy and other EU Member States. All the products were reintroduced into the legal supply chain and reached German PDs through a long chain of European operators.
In particular AIFA identified how medicinal products that according to the available traceability data were distributed only to Italian hospital, were exported to other European Member States (MSs) in spite of the fact that they were not accessed by Italian wholesalers, and that no notification to the Italian traceability system was recorded.
[...]
AIFA's investigations also highlight how the present case is similar to the 2014 Herceptin case (described in the report Operation Volcano – http://www.aifa.gov.it/sites/default/files/OperationVolcano_0.pdf). In particular it is becoming evident that a large number of medicinal products (in small volumes) were supplied utilising the same supply chains as was used for the first five medicinal products identified and listed in the August 2014 NUIs. It was evident that in most cases the country of final destination was Germany.

One of the key lessons learned during this phase of the investigation is that as the legal supply chain was impacted by "a criminal gang" it is impossible to fully rely

on the information from the paperwork retrieved. In addition, some of the information related to the illegal channels emerged only after repeated police inspections and in depth verifications.
[...]
For the above reasons AIFA is seeking to obtain more information on the trades which occurred between the operators listed in the Greek WGEO alert and the operators identified during the inspections at Farmacia San Vito, the Italian operator listed in the same WGEO alert. AIFA is also interested in understanding whether any trade concerning Italian origin hospital only medicinal products occurred in the EEA.

Proposed action

In order to further continue the current investigations, we ask to all operators to provide to medicrime@aifa.gov.it, or to their national competent authorities (NCAs) for forwarding to AIFA, any information regarding the following:

1.
Trades with any of the below listed operators :

- OZBAGDZI HARALAMPIDIS STILIANOS (Greece)
- AXXON PHARNA (Cyprus)
- PHARMAGEN (FYROM)
- PRINTEMPS HOSPITAL SUPPLIES (Germany/Egypt)
- RHEINGOLD PHARMA MEDICA (Germany)
- SAN VITO (Italy)
- GNOMON PHARMA LDT* (Cyprus)

AIFA was also informed about other traders from Egypt, offering Italian hospital drugs such as the ones mentioned in the previous section: since the ongoing verifications on these offers already confirmed that all the identifiable products/

* The involvement of this operator is under scrutiny, since according to the verifications it seems that the name of the Cyprus operator was used as a mere reference over completely fake invoices.

batches have references in the list of medicines stolen from Italian hospitals in 2018, we ask all EU PD to report to AIFA for verification any offer for the above mentioned Italian hospital drugs from traders from Egypt or other non EU MS.

2.
Trades of the following products which occurred in 2017–2018: any signal (even if not related to the above mentioned operators) will be evaluated (through tracea–bility data and verification with MAH) and, if confirmed as "suspect", forwarded to police/prosecutor for follow up activities (EG inspections and seizures).

AVASTIN	Italian and French packaging
HERCEPTIN	Any packaging
MABTHERA	Any packaging
REBIF	Italian packaging
ROACTEMRA	Any packaging

Moreover, all operators are invited to check the list of stolen products published every 2 weeks by AIFA (see as a reference the list in annex, dated February 6th) in the Fakeshare web platform, when receiving offers for products that are cause suspicion (in terms of origin, price, channels for distribution, nature/quality of the goods): the Fakeshare list of stolen products covers not only the events which occurred in Italy, but also the ones reported by other Fakeshare partners (such as UK – MHRA) and the main events which occurred in Europe, reported via WGEO.

Any suspicious offer that may seem related to products in the list may be reported to national competent authorities (NCAs) and medicrime@aifa.gov.it for further evaluation.

February 6th, 2019

Follow-up and Non-urgent Information for Quality Defects

Falsified "bollino"* stickers

	ITALIAN MEDICINES AGENCY (AIFA)		
1.	To: (see list attached, if more than one)		
2.	Recall Number Assigned: German RAs of 08.10.2018 and 21.11.2018	3.	National reference Number: DE_BW_01_FD Pharma_2018_001 DE_BW_01_Allomedic_2018_001 DE_BW_01_Allomedic_2018_002
4.	Product: Seebri Breezehaler; Abstral; Palexia	5.	Marketing Authorisation number: 042306035; 038736031; 040422661 For use in Humans
6.	Brand/Trade name: Seebri Breezehaler; Abstral; Palexia	7.	INN or Generic Name: Glycopyrronium–bromid; Fentanyl; Tapentadol
8.	Dosage form: capsule with powder for inhalation; sub-lingual tablets; modified release tablet	9.	Strength: 44 mcg; 150 mg; 150 mg
10.	Batch number (and bulk, if different): BCE98 – BCJ73; 607717701; 681N01		Expiry Date: 12/2019 – 11/2019; 01/2020; 12/2020
14.	Marketing Authorisation holder: Novartis Europe Limited (UK) Kyowa Kirin Services Ltd, EC3M 6BN, London, GB Grunenthal Italia Srl (Italy)		
15.	Manufacturer: Novartis Aescia Queenborough Ltd, GB Grunenthal GmbH (Aachen, D)	16.	Contact Person: NA
17.	SUBJECT: Falsified "bollino" stickers		

* See p. 51

Background information

Following the reports issued by Germany (October 08 and November 21, 2018), where bollini labels have been suspected to be manipulated and then confirmed as falsified, upon further investigation, the Italian authorities detected addition–al cases of bollini labels falsification related to hospital medicinal products, in particular:

a. Standard pharmacy medicines bought by wholesalers in "hospital package", and sold to pharmacies or exported after having substituted the stamped bollino with a fake one bearing the same unique code, but no indication regarding the hospital use;
b. Anti–cancer drugs, sold without bollini stickers on the outer box/carton:

In both cases, the products should be considered as possibly falsified medicines, as for the EU definition:

a. Products bearing a falsified "bollino" bear a counterfeit component in the packaging;
b. Products with no "bollino" could have been sourced via theft, and sold via fake credentials.

A number of **security checks** can be carried out in order to verify the authenticity of a "bollino" sticker:

1. **UV lamp exposal**:
   - security fibers reaction to UV light;
   - paper surface reaction to UV light (UV Dull security element).

2. **Watermark shapes** visible when the upper layer is held against the light.

3. **Barcode check**: using a general purpose *code scanner App for smartphone* scan the barcodes and check:
   - the AIC number in code 39 form;
   - the UID (correspondent to the two clear versions printed on the lower and the upper layer);
   - the combination of the UID and AIC number in code 39 form.

Proposed action

In order to prevent the distribution of falsified med–icines through the parallel distribution channel, it is considered useful to widespread the guide attached to this NUI, describing the essential characteristics of genuine Bollini labels which should and could be checked by the parallel importers within their incoming goods inspection.

It is also considered useful to underline that the Italian bollino label has always to be present on the outer carton of exported medicines of Italian origin. Furthermore, the exported packages should bear a

"bollino" with a nullification mark (e.g., an **"annullato"** stamp or a cross over the barcode).

For medicines classified as hospital product (class H), the packs distributed should have the bollino with the specific wording **"Confezione Ospedaliera/ Ambulatoriale"** stamped on the label, in order to invalidate reimbursement out of the hospital channel.

If there be any anomalies with regard to the offer of medicinal products with bollini labels showing different features from those described, please contact the writing office at the e-mail address medicrime@aifa.gov.it, to allow any check to ascertain the legitimacy of the products.

February 6th, 2019

Bollino

The Italian Security Label for Pharmaceutical Products

The Italian Security label for Pharmaceutical products (Bollino) is a two-layer paper label:

The upper layer shows the following information:

- The AIC code in both clear ① and code 39 barcode ② form;
- The name of the medicine with pharmaceutical form, dosage indication and number of dose units ③;
- The company that holds the AIC in the Italian regulation system ④;
- The unique serial number (UID) in both clear ⑤ and barcode form ⑥.

Technical features:

- Size: 35 mm X 25 mm;
- Watermarked paper with rhombus shape;
- UV dull paper treatment;
- Security fibers in light blue and yellow colours.

The lower layer shows the unique serial number (UID). It will remain attached to the pack for the entire period of validity of the pharmaceutical product and in case of attempts of removal it acts as anti-tampering device;

Technical features:

- Size: 40 mm X 25 mm;
- Printed text “SICUREZZA” and symbol of the caduceus, red ink.

Information provided by:

POLIGRAFICO E ZECCA DELLO STATO ITALIANO

Table of contents

In recent years, thefts of medicines have become a European challenge. Through the Italian Database on Thefts (IDT), AIFA, in the absence of such a tool at EU level, started collecting also data provided by other Member States, demonstrating the spread of a phenomenon that until then was perceived only as a national issue. AIFA's IDT tool, enriched by information from other countries, has made it possible to extend the intelligence/investigation Agency's activities on a larger scale and to counter cross-border trafficking of stolen medicines.

Italy has rapidly become a reference point for all those Countries that decided to put in place similar systems, showing that such a phenomenon doesn't exist as long as it is not investigated. A year after the first publication of this report (2017), a positive trend showing a reduction in the reported thefts seems to have started. We have therefore decided to develop an update to give a boost to this positive change, confident that collaboration among all stakeholders, sharing and knowledge of good practices, together with effective investigative tools and data sharing represent the best response to these criminal phenomena that pose a threat to our NHS and patients.

Nicola Magrini
AIFA Director General

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