



The fight against falsified medical products in Italy, and the activities of the Council of Europe in this domain

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The world together against falsified and substandard medical products

Belgrade, Serbia – 14 October 2025

Public Declaration of transparency/interests*

The view and opinions expressed are those of the individual presenter and should not be attributed to AIFA

Interests in pharmaceutical industry	NO	Current	From 0 to 3 previous years	Over 3 previous years
<i>DIRECT INTERESTS:</i>				
1.1 Employment with a company: pharmaceutical company in an executive role	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> mandatory
1.2 Employment with a company: in a lead role in the development of a medicinal product	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> mandatory
1.3 Employment with a company: other activities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
2. Consultancy for a company	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
3. Strategic advisory role for a company	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
4. Financial interests	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
5. Ownership of a patent	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
<i>INDIRECT INTERESTS:</i>				
6. Principal investigator	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
7. Investigator	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
8. Grant or other funding	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
9. Family members interests	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
10. Serious reasons of convenience	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional

*Domenico Di Giorgio, in accordance with the Regulation for the prevention and handling of conflicts of interest of the Italian Medicines Agency, approved by AIFA Board of Directors (Resolution no. 9 - 12 February 2025).

N.B. I am not receiving any compensation

Pharmaceutical crime

The definition of pharmaceutical crime includes all those phenomena, in the pharmaceutical sector, characterized by different profiles of illegality:

- production and distribution of illegal or falsified medicines;
- thefts and recycling/laundering of medicines;
- promotion and sale of medicines through non authorized websites.

Falsified medicinal product (Dir. 2011/62/EU)

Any medicinal product with a false representation of:

- a) its **identity**, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients;
- b) its **source**, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or
- c) its **history** (traceability), including the records and documents relating to the distribution channels used.

This definition does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights.

Illegal and falsified medicines: the Italian framework

To outline the activities carried out by AIFA in the sector, it is usual to use the definition of pharmaceutical crime, which includes all those phenomena, in the pharmaceutical sector, characterized by different profiles of illegality.

- In the Italian experience, these phenomena can be traced back to some specific typologies/categories:
- Production and distribution of illegal and/or falsified medicines
- Theft of medicines and laundering in the legal supply chain of other countries
- Promotion and sale of medicines through websites not authorized by the competent authorities

Activities/Initiatives

- Analysis of the reports on suspected cases
- Participation in international working groups, also for regulatory review at EU level
- Coordination of projects co-financed by the EU for the promotion of specific activities in the sector
- Communication and information initiatives
- Training initiatives aimed at sector operators

Analysis of reports on suspected cases

The reports mainly concern:

- Products found in shops not authorized to sell medicines (gyms, ethnic shops)
- Products found at customs
- Products advertised and sold through websites

Illegal medicines found in not authorized shops

Regarding the reports relating to illegal medicines discovery in unauthorized sales points, these are the result of control activities carried out periodically by the different police forces.

The police force involved requests the Agency's support:

- before formalizing the seizure
- after the formalization of the seizure

The Judicial Authority also requests the Agency's official view on the correct classification of products

Illegal medicines found in not authorized shops: examples

- Chinese medicines
- Whitening action creams
- Antibiotics authorized in foreign markets
- Aesthetic medicine products

Illegal medicines seized at Customs level: examples

As evidenced by the results of control activities carried out during Operation PANGAEA, the most frequently intercepted products are:

- erectile dysfunction medicines
- performance-enhancing medicines
- weight-loss medicines

Medicines sold through the Internet

AIFA receives reports from private citizens, companies and associations regarding prescription medicines sold online.

Italian regulation, in relation to online sales, states that only pharmacies and authorized shops may sell OTC medicines through their websites (RX medicines e-commerce is not allowed in Italy).

The intervention on illegal websites is managed via Ministry of Health and Carabinieri NAS.

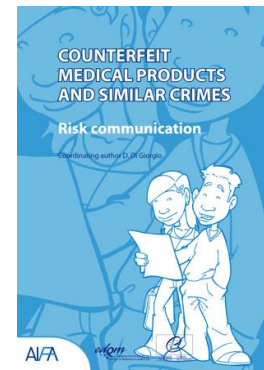
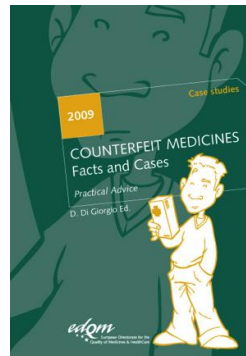
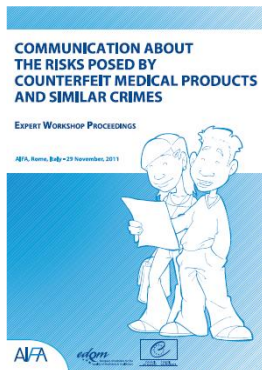
Doubtful cases, are evaluated within the Stakeholders conference (Directive 2011/62 implementation)

Poor quality



Publications

Publications



Publications



EU-Funded projects

EU-Funded projects



2013 - Fakeshare project (I)

Goal: ensuring a coordination in investigation activities and polices forces initiatives targeting the illegal web distribution of medicines, through an efficient sharing of information between countries with similar frameworks (scenarios), allowing the development of coordinated initiatives.

- The project allowed the set up of a shared web system between administration of different countries, in order to manage the data related to the illegal sale at the distance of medicines.
- The IT structure supported LEAs in the blocking/shutdown of non-authorized websites

2014 - Fakeshare project (II)

Goal: sharing best practices among the countries participating in the project. The AIFA Database on Thefts has been proposed as model for the Fakeshare Database on Thefts.

- The ultimate goal is to share on the platform also data on thefts and reported products, documents and information related to the pharmaceutical crime in general, not only with the countries participating in the project but also with those wishing to join.

EU-Funded projects

2021 - MEDI-THEFT project

Objective: counteract the organised theft 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 that will allow to:

- collect, share and analyze data related to the theft of medicines in view of identifying and preventing criminals modi operandi;
- produce early warnings and alerts to prevent stolen medicines to re-enter the legal market;
- improve joint transnational investigations teams and public-private partnerships in this field.

Awareness campaigns

Awareness initiatives

Communication campaign (Fakeshare/2016)

- Communication campaign of the European Fakeshare project (I and II) - **'Online medicines: do you really know what you are buying?'**
- Falsified medicines represent to date one of the main threats to safety and public health.
- Dangerous medicines are sold through various distribution channels and, in particular, through the Internet, which is currently used by both private individuals and unauthorized "intermediaries" who buy drugs online and then resell them in the local area (sex shops or gyms).



Communication campaign (Fakeshare/2016)

Lynda

compra le pillole per dimagrire online perché non le trova in farmacia. È convinta che siano assolutamente naturali. In realtà non lo sono affatto.

UNA STORIA VERA

Domenica 12 aprile Aimee Eloise Parry, una ragazza di 21 anni, ha assunto delle compresse dimagranti acquistate su internet. Più tardi, quello stesso giorno, è stata trovata morta. La polizia ha dichiarato che le compresse probabilmente contenevano diidrofenolo - una sostanza chimica altamente tossica.

21 aprile 2015
BBC

Paolo

compra nel sexy shop i farmaci per migliorare le prestazioni sessuali, perché si vergogna di andare in farmacia. Il proprietario del sexy shop, però, li acquista online.

UNA STORIA VERA

«Muore dopo aver preso Viagra sudamericano»

La sostanza acquistata oltrevalsa dalla sorella della fidanzata

29 ottobre 2013
IL GAZZETTINO

Luca

compra online i medicinali di cui ha bisogno perché, non avendo la prescrizione medica, non può acquistarli in farmacia.

UNA STORIA VERA

«Mike ha comprato la sua morte su internet»

DOPING Una donna di Jura (Francia) piange suo figlio, morto per un attacco di cuore dopo aver assunto degli anabolizzanti acquistati online.

30 giugno 2014
L'Espresso

Tony

su consiglio dei colleghi, compra online dei farmaci "miracolosi" che non sono in vendita nel suo Paese.

UNA STORIA VERA

Dong Hui e Silvia Fink si sono incontrati a tangenziali su una strada [...] il giorno seguente, ancora nella loro, Silvia ha preso una soluzione Miracolo Miracolo - MMS, un composto che aveva comprato da due compagni di scuola, un belga e un olandese, i quali la avevano assicurato che così avrebbe curato le malattie nelle loro famiglie, prevenendo l'insorgenza di tumori [...] Fink, "E' molto male, ma da subito [...] E' diventato un terrore [...] non hai che stare sempre pigro, [...] Fink non è sopravvissuto molto tempo [...] Silvia è morta a Windischhof intorno alle 21, appena dodici ore dopo aver bevuto quella fida dose di MMS.

9 gennaio 2010
The Sydney Morning Herald

Il distributore (DIT) è una sostanza industriale non destinata all'uso umano che tuttavia è facilmente acquistabile e commercializzata su Internet come "Tonic grasso" sicuro ed efficace. Inoltre, può anche essere presente, senza essere dichiarato in etichetta, in vari dimagranti farmacia e viene così assunto in modo del tutto inconsueto dai consumatori.

Il DIT è un veleno metabolico che altera le funzioni delle cellule endocrine e disperde energia come calore invece di immagazzinarla in loro interno. Questo effetto induce causa una perdita di peso ma è così variabile e imprevedibile da rendere minima la differenza tra una dose minima e una dose letale. La pericolosità propria del DIT inoltre, è ulteriormente amplificata dai rischi collegati alle condizioni incontrollate in cui vengono fabbricati i prodotti illegali che lo contengono.

La tossicità del DIT si manifesta con innalzamento della temperatura corporea, sudorazione profusa e aumento della frequenza cardiaca e respiratoria. Questo classico complesso di sintomi può aggravarsi fino a condurre al decesso prima del quale il più delle volte, il soggetto presenta una febbre altissima. La morte di solito avviene a seguito di un collasso cardiovascolare.

Rammenta che anche i farmaci per la disfunzione erettile regolarmente autorizzati possono causare gravi effetti indesiderati. Rivolgiti al tuo medico prima di iniziare ad assumerli. Non decidere da solo, potresti mettere in pericolo la tua salute!

I farmaci per la disfunzione erettile (FDE), per le loro proprietà sono spesso oggetto di contraffazione e di commercio illecito. Inoltre, sul mercato illegale sono compresi anche prodotti che vengono presentati come integratori di origine vegetale e spesso come alternative "naturali" alla cura di cui si malintende nella loro composizione l'uso e l'azione dei principi attivi (ad esempio i derivati di origine vegetale). In questi casi, i rischi per la salute sono particolarmente elevati, dovuti alla presenza nella confezione di sostanze tossiche, di una quantità di principio attivo superiore a quella consentita e questo frequentemente provoca gravi effetti nocivi da sovradosaggio. Questi rischi, intrinseci al prodotto falsificato, sono accresciuti dal fatto che i pazienti, seguendo il mercato illegale, evitano di rivolgersi al servizio sanitario pubblico così come possibilità di intervenire e curare quella patologia, come il diabete e le malattie cardiovascolari, che spesso si associano alla disfunzione erettile.

Secondo il Codice Europeo dei medicinali per uso umano, questi possono essere venduti soltanto dietro prescrizione medica quando:

- possono presentare un pericolo, anche in condizioni normali di utilizzazione, se usati senza controllo medico;
- sono normalmente somministrati per via parenterale (ad esempio per iniezione, infusione, ecc.);
- gli effetti avversi (ad esempio gli effetti collaterali) sono preparazioni di sintesi che mimano gli effetti dell'ormone sessuale maschile testosterone e sono illegalmente usati in ambito sportivo per aumentare la massa muscolare, la forza e la resistenza alla fatica, e rendono inoltre gli atleti più aggressivi e competitivi sia in allenamento che in gara. La medicina da DIT si manifesta a carico di numerosi organi e apparati e provoca gravi effetti indesiderati: quali acne, perdita dei capelli, eruzione del testicolo, impotenza, cancro del fegato, ipertensione, trombosi, insufficienza renale acuta, polmoni e dipendenza farmacologica.

Gli effetti sull'apparato cardiovascolare possono contribuire a spiegare i casi di morte improvvisa in atleti e dilettanti che si autosomministrano DIT. Un recente studio ha dimostrato un più elevato indice di mortalità in coloro che abusavano di DIT rispetto ai soggetti di pari età che non ne facevano uso.

Il prodotto "Miracolo Miracolo Solution", conosciuto anche come "Miracolo Miracolo Solution" o "MMS", è una soluzione per uso orale che viene venduta vantandone le proprietà curative nei confronti di molte malattie infettive tra le quali AIDS, epatite, influenza, polmonite, tubercolosi, meningite, ecc. e viene distribuita in Italia. La MMS è venduta su Internet da vari distributori indipendenti e, sebbene i nomi siano gli stessi, l'aspetto dell'etichetta può variare.

Questo prodotto mette a grave rischio la salute dei consumatori che seguono una cura fadista invece di ricorrere ai trattamenti regolarmente autorizzati.

La soluzione del prodotto indicato di risultare la soluzione al 20% di clorato di sodio contenuta nel flacone incluso nella confezione con un acido debole, quale ad esempio il succo di limone. Dopo questa miscelazione il prodotto è identico al clorato di sodio, un composto tossico, utilizzato solo a livello industriale per la decolorazione dei tessuti e per il trattamento delle acque. La pericolosità di questa "soluzione miracolosa", di clorato di sodio al 20%, è immediatamente percepibile tenendo presente che la comune "sancru" (ipoclorito di sodio) normalmente non supera una concentrazione del 25%.

Una dose elevata di questo veleno, quel che è quello che la soluzione del prodotto raccomandato di assumere, può causare nausea, vomito, diarrea e, per la disidratazione che ne consegue, una ipotensione tanto grave da mettere in pericolo la vita.

Communication campaign (December 2022)

Campagna AIFA per acquisto farmaci attraverso canali sicuri ▶ Riproduci tutti



Come avere fisico scolpito in pochi giorni - Campagna AIF...

AIFA - Agenzia Italiana del Farma...
83.712 visualizzazioni • 2 anni fa

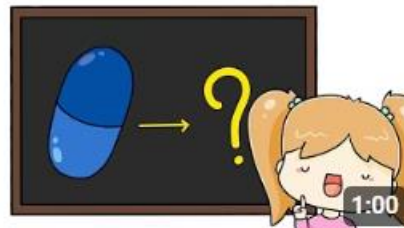
Sottotitoli



Come tornare in forma in tempi record - Campagna...

AIFA - Agenzia Italiana del Farma...
75.502 visualizzazioni • 2 anni fa

Sottotitoli



Anche i giovani lo usano! - Campagna AIFA per...

AIFA - Agenzia Italiana del Farma...
81.758 visualizzazioni • 2 anni fa

Sottotitoli



Aims of the communication campaign

The initiative takes the form of the creation of 3 mini videos which make use of the contribution of the talent Cesca, published on AIFA's Facebook, Youtube, Twitter and LinkedIn channels.

- inform citizens in a simple way about the dangers associated with the purchase of counterfeit medicines, encouraging a correct perception of the risk;
- discourage the purchase of drugs outside legal channels, such as websites, e-commerce platforms, gyms, sex shops and/or beauty centres;
- reach the target through the channels most used by the target.

Case studies

CASE 1 | Non authorized OTC medicines from China

Discovery both in customs and in the territory (in commercial establishments not authorized to sell medicines) of a Chinese product claiming therapeutic properties for the treatment of COVID-19

Verifications made by AIFA

- Verification of the product status with the China Pharmaceutical Industries Association and request for documentation
- Verification of therapeutic properties reported in the package leaflet and product composition

CASE 1 | Non authorized OTC medicines from China

Outcome of the findings

- Product classified as a drug, authorized by the Chinese Regulatory Authority for trade in China.
- The product information document states typical therapeutic properties: treatment of flu, fever, muscle soreness, nasal discharge, cough, sore throat.

Regulatory framework

- From a regulatory point of view, it could be considered an herbal medicine product; however, in the composition the presence of menthol is declared (herbal or synthetic), an isolated chemical compound not provided in the definition of herbal medicine product according to the provisions of Directive 2001/83 and ss.mm.ii. Even leaving out the presence of menthol, the medicine could not fall under the simplified registration procedures according to traditional or established medical use, because it does not meet the requirements for such procedures, including, mainly, medical use in the EU.

CASE 2 | Product of Chinese origin

Outcome of the findings

Based on currently available documents, it is not possible to infer:

- certain information about the origin of the product, or the manufacturing processes used and the application of Good Manufacturing Practice (GMP)
- certain data on the trials conducted, the methods of conducting them and the outcomes, which in Italy, as in the member states of the Union, must instead comply with Good Clinical Practice (GCP) standards;
- information on the procedures applied for verification when granting marketing authorization.

Regulatory framework

- Legislative Decree 219/2006, in Article 6, paragraph 1 (Title III, Chapter I), provides that “No medicinal product may be placed on the market in the national territory without having obtained an authorization from AIFA or a Community authorization in accordance with Regulation (EC) No 726/2004 in conjunction with Regulation (EC) No 1394/2007.”

CASE 3 | Parvulan

Report, from the Ministry of Health garrison at the Bologna airport, regarding the request to import 2000 vials of the drug Parvulan (origin Brazil)

Findings made by AIFA

- Verification of reasons for import request (treatment of patients with shingles)
- Verification of product status with the Regulatory Agency of Brazil
- Verification of therapeutic indications in the package leaflet
- Verification with AIFA Offices with respect to products authorized and marketed in Italy for the treatment of shingles
- Verification of information on open sources (Parvulan use as a replacement for Covid-19 vaccines)
- Request for verification to Carabinieri NAS
- CTS AIFA opinion request

CASE 3 | Parvulan

Outcome of the findings

- Product classified as a medicinal product, duly licensed in Brazil (not as a COVID-19 vaccine)
- Use of Parvulan as an unlicensed alternative to COVID-19 vaccines
- Unfavorable opinions expressed by CTS AIFA for compassionate use and clinical trials of the said medicinal product
- Negative opinion CTS AIFA on product use as an alternative to licensed vaccines
- Sanctioning measures for the applicant physician

CASE 4 | Online sale of medicines presented as cosmetics

Report received from a pharmaceutical company and private citizens regarding the online sale of a product presented as a cosmetic based on natural substances, and actually containing several pharmacologically active substances

Investigations made by AIFA

- Verification of product status
- Verification of the composition declared on the label
- Request for information from the Ministry of Health as the competent authority for cosmetics
- Evaluation in the Services Conference

CASE 4 | Online sale of medicines presented as cosmetics

Outcome of the findings

- Product classifiable as a medicinal product, as it contains Clobetasol (0.018%), Procaine, Benzocaine and Lidocaine (anesthetics, 2.5%), manufactured in Romania. Sold through e-Bay, Amazon and the “aurderm.com” website
- Notified under the current Regulation (1223/2009) to the European Cosmetics Portal
- Active substances found as a result of analysis are not declared on the portal
- The product is no longer manufactured
- The product is not present in Europe
- Notice published on the AIFA website

CASE 5 | Illegal Online Sales of Aesthetic and Diabetes Treatments

Increase in reports of counterfeit medicines sold via unauthorized websites and social media (2023)

- Aesthetic products: botulinum toxin and hyaluronic acid fillers used by unqualified practitioners in unauthorized clinics
- Antidiabetic medicines: falsified semaglutide (Ozempic®) sold online, often misused for weight loss

Response: AIFA–NAS investigations, alerts, and public informative note

CASE 6 | Illegal GLP-1 Medicines in the EU (2025)

- Promoted online for weight loss or diabetes treatment
- Sold via unauthorized websites and social media platforms
- No infiltration detected in Italy's legal supply chain

Response: coordination with EMA/HMA, alerts, and ongoing surveillance

CASE 7 | Online sale of GLP-1 supplement Using AIFA Logo

- Facebook Promotion: Supplement marketed with AIFA logo to suggest legitimacy, referencing effects of Ozempic and GLP-1 medicines.
- Amazon Sales: Product sold online without AIFA logo, but still misleading.
- Customer report being scammed, leaving negative reviews on Amazon and Facebook groups.



Sharing and use of information

Example A

This 150 Kb image submitted by a Dutch wholesaler triggered a very quick investigation, allowing to discover a chain of distribution of falsified medicines:

- the Dutch wholesaler bought this product from an Italian operator, that was inspected: his Italian supplier purchased the illegal product on the web;
- the supplier authorization was cancelled;
- other similar operators were also suspended;
- the regional authority revised its procedures.



Example B

Outcome of the findings

After the distribution of this operative guideline to operators in EU, many signals were received (and verified according to our procedures), regarding:

- Italian medicines with no bollino sticker
- Italian medicines with suspicious bollino sticker

MHRA and NAS/AIFA investigations led to the disruption of other diversion schemes.



Example C

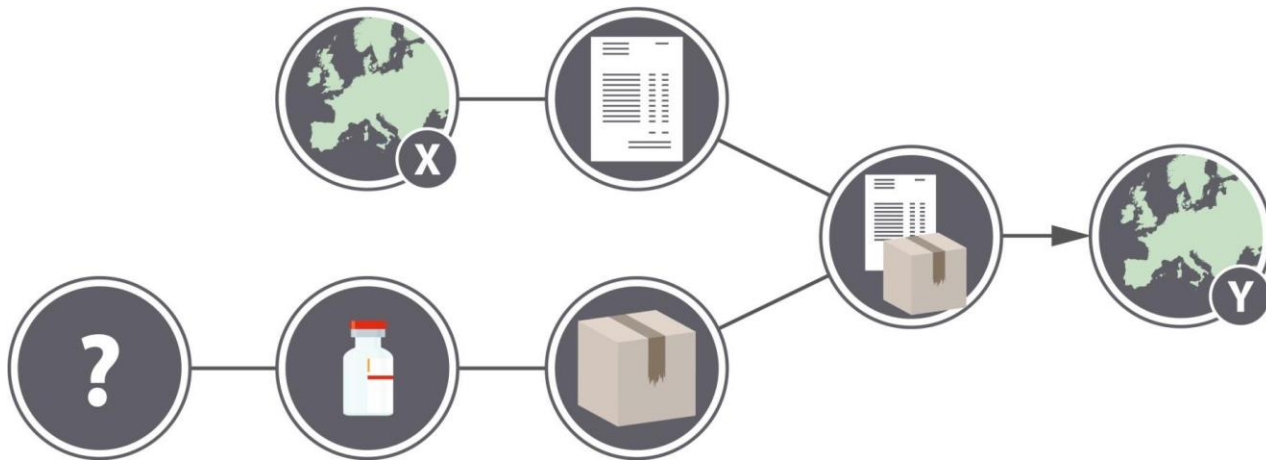
Similar schemes of verification were developed against pharmacrime and shortages (eg “raking prevention” in 2017, “export ban verification” in 2023), always considering:

- signals evaluation, leading to a possible scenario for diversion or falsification;
- data analysis (traceability) and field verification (inspections with NAS or local authorities);
- structured activities in the field.



Example D | Operation Volcano (2014)

- 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, paired with invoices issued by “bogus wholesalers” situated in other EU MMSS, falsely stating a legal origin for the medicines, and then sold to legal Italian wholesalers for export, mainly to Germany (directly, or through UK, Spain, The Netherlands or other countries).



Example D | Operation Volcano (2014)

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

- manipulated medicines;
- fake operators;
- fake invoices.



Example D | Lunapharm case (2014)

- Although in the period immediately following the Operation Volcano the phenomenon seemed eradicated, the **Lunapharm case** confirmed that criminal organizations never stopped infiltrating the Parallel Distribution network – they simply changed “suppliers”, moving to other Member State.



Example E

Outcome of the findings

Same kind of signals (eg, single units detected in third countries) gathered through informal forum (on thefts – TTF, shortages – TTI, or at international level) may lead to different evaluation:

- (2018) Units in Egypt, no cases/data in MEDI-THEFT/FAKESHARE (thefts) db: internal thefts in hospital.
- (2019) Units in UK, no cases/data in thefts db, no export in traceability: fake prescriptions.
- (2024) Units in Lebanon, Egypt, Turkey + increase of cases in thefts db: new “Volcano style” model targeting third countries (via Egypt/Turkey, probably)



Thank you!

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