

# THEFTS OF MEDICINES

## Practical guidance: implementation of prevention systems, management of the events and of the possible recovery of stolen medicines

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 (“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.

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*:

**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 immediately 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.**

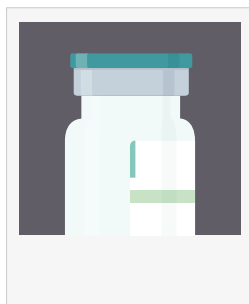
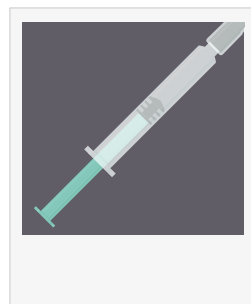
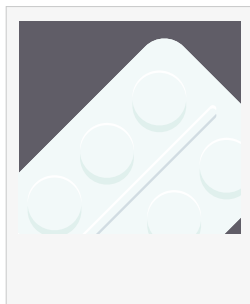
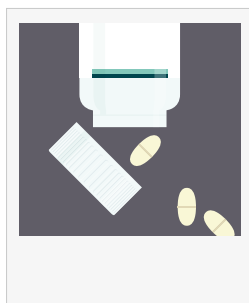
For the effective management of the rapid alert system, it is important for all competent authorities to promptly receive all useful information regarding the theft occurring in pharmacies, hospitals or during transportation; at the same time, this information is also very relevant for MAHs, also representing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

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.



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](mailto: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 Fake-share database, and the launch of any “Rapid Alerts” to be sent to the National and International network.

In addition to the aforementioned counter-acting system, which aims to prevent the re-introduction 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 manage-



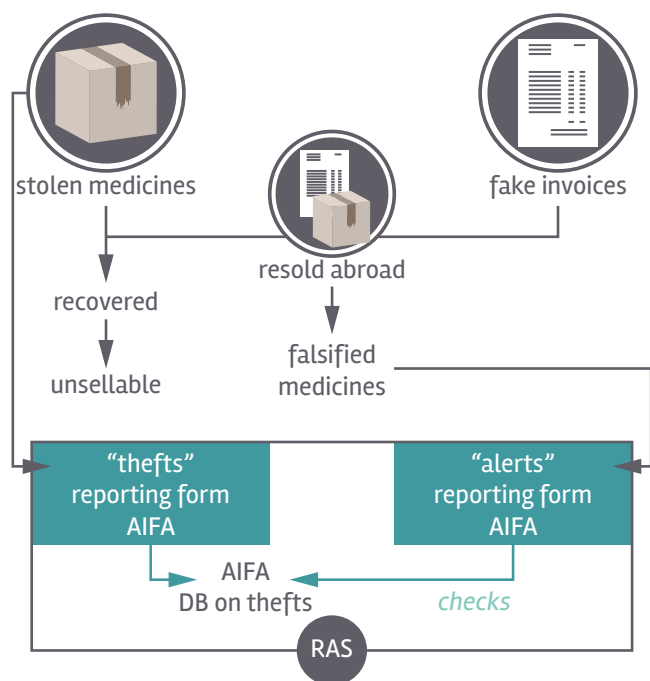
ment system to guarantee the safety of the medicines ([http://www.sifoweb.it/images/pdf/attivita/attivita-scientifica/aree\\_scientifiche/Logistica/SIFO\\_LINEE\\_GUIDA\\_def.pdf](http://www.sifoweb.it/images/pdf/attivita/attivita-scientifica/aree_scientifiche/Logistica/SIFO_LINEE_GUIDA_def.pdf)); also 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](mailto: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.

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”.

**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.**

## HELM



### To find out more

- Forms (thefts and alerts): [http://www.aifa.gov.it/sites/default/files/Mod\\_Segnala-zione\\_furti.xls](http://www.aifa.gov.it/sites/default/files/Mod_Segnala-zione_furti.xls), [http://www.aifa.gov.it/sites/default/files/Mod\\_336\\_01\\_segna-lazione.doc](http://www.aifa.gov.it/sites/default/files/Mod_336_01_segna-lazione.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/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](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/>