



THEFT OF MEDICINES

Trend of the phenomenon over the years



Agenzia Italiana del Farmaco

AIFA

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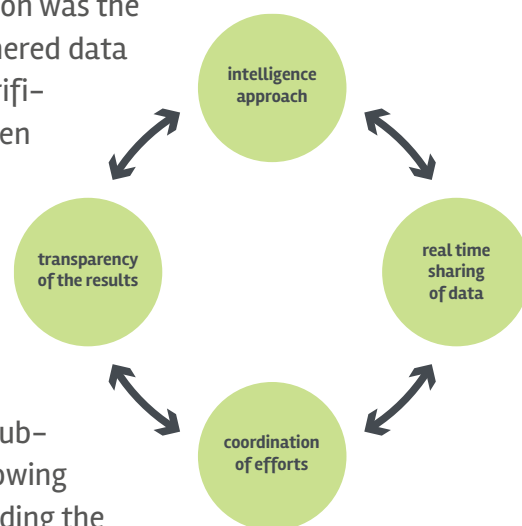


Agenzia Italiana del Farmaco

AIFA

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 MMSS (infiltration of stolen/falsified medicines, having Germany as core target, involved at least 17 MMSS) 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).

The key **drivers** for the traffic were the different levels between Germany and other MMSS, in particular with respect to: prices (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 MMSS 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.

DATA

Thefts of medicines in hospitals: number of events

2011/I

2011/II

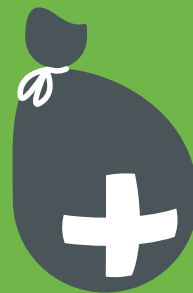
2012/I

2012/II

2013/I

2013/II

2014/I



2

2

3

7

25

28

37

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.

2014/II

2015/I

2015/III

2016/I

2016/III

0

0

1

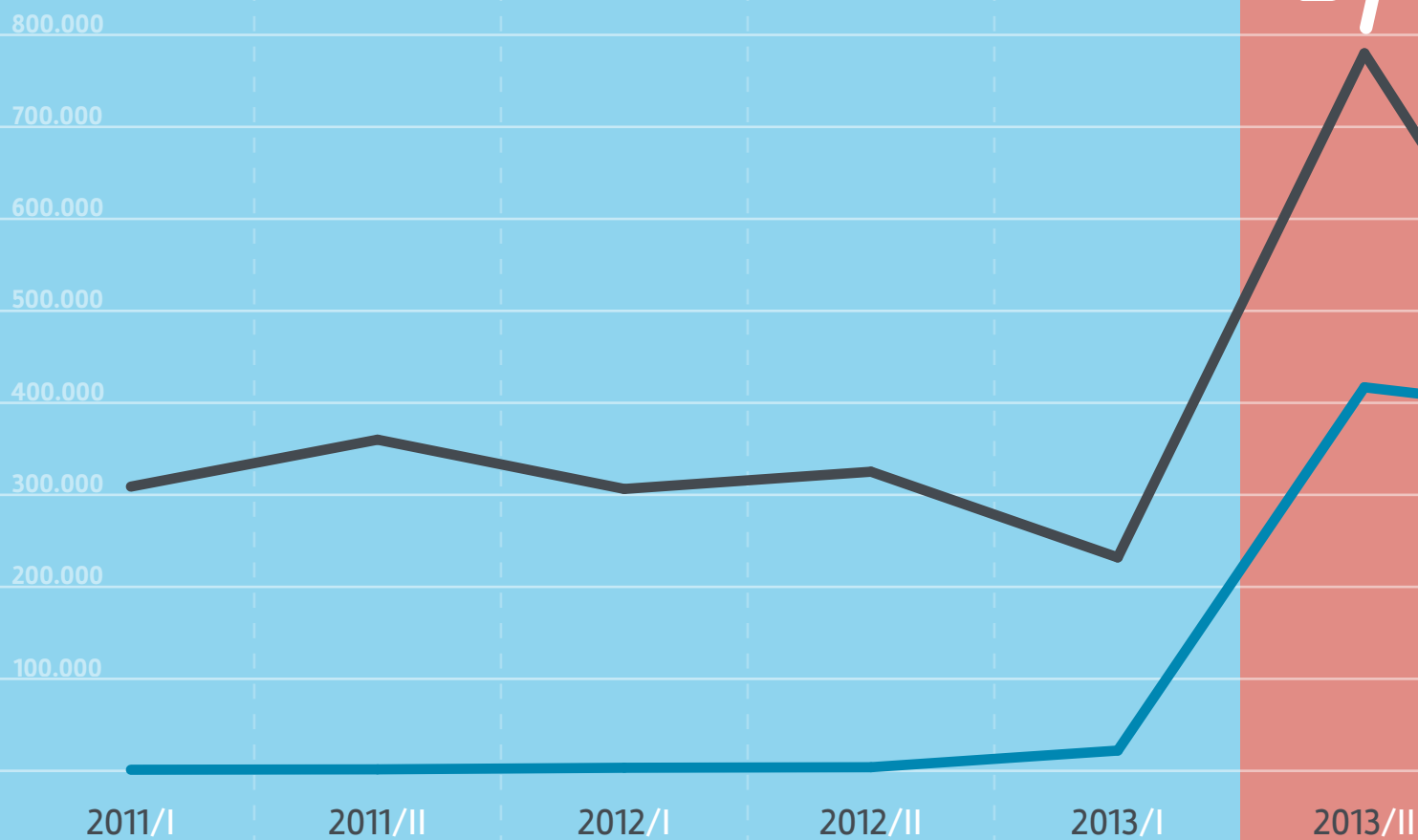
3

4

9



Thefts of medicines: number of stolen packages

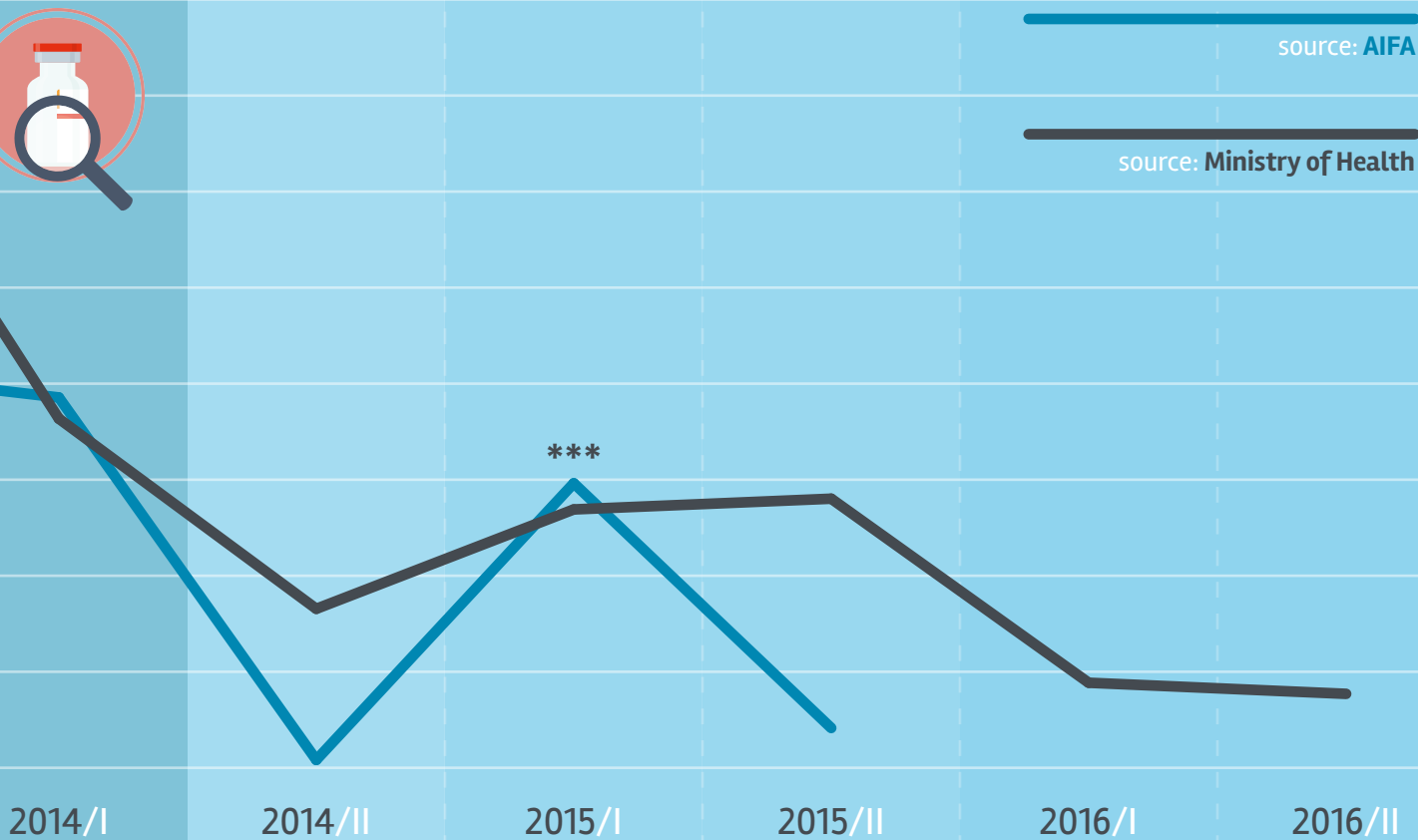


Operation Volcano



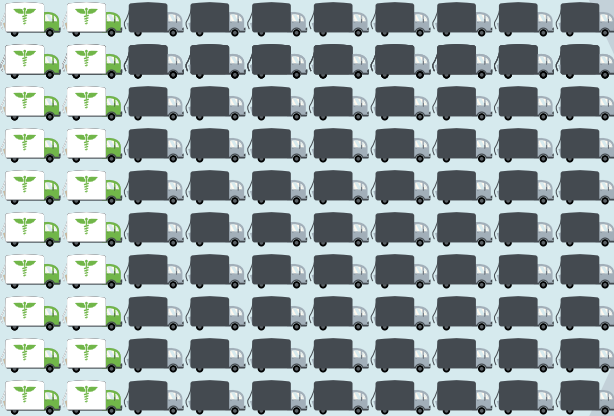
Alongside the decrease of episodes of thefts, the number of packages stolen as a whole clearly decreased, as shown by the analysis of data present in the AIFA database on thefts (covering the key marketing authorisation holders products) and in the Ministry of Health's track & trace system's data (covering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

*** 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.

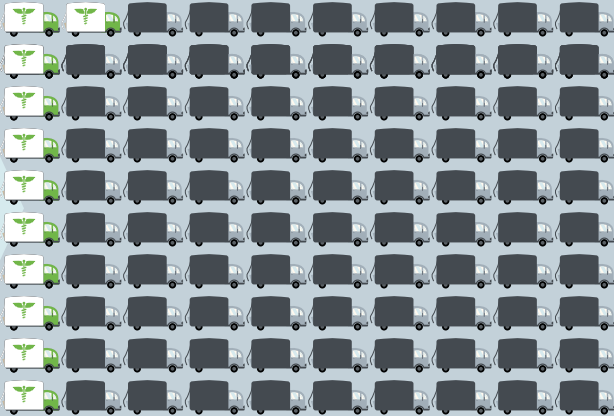


Percentage of thefts of medicines on total cargo theft

ITALY



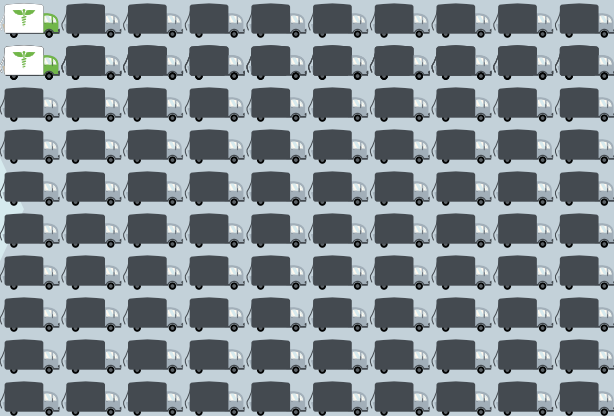
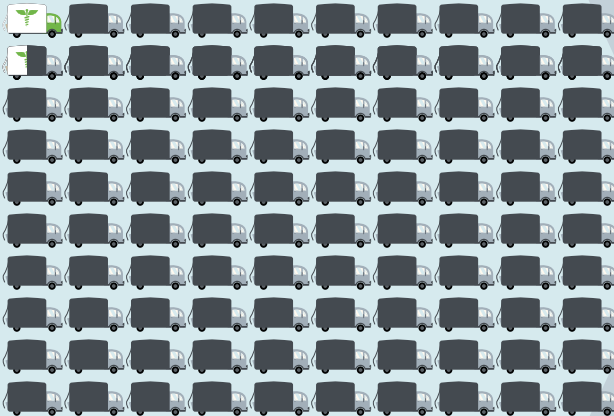
2013

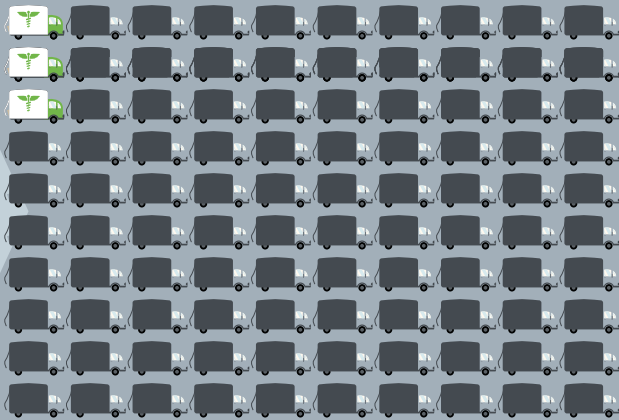


2014

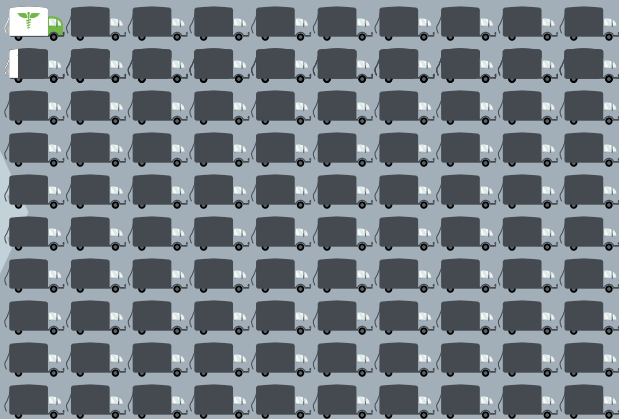


EUROPE





2015



The decrease of the number of events is also confirmed by the independent evaluation of TAPA (Transported Asset Protection Association). Before the “Operation Volcano”, with respect to the rest of Europe, 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.

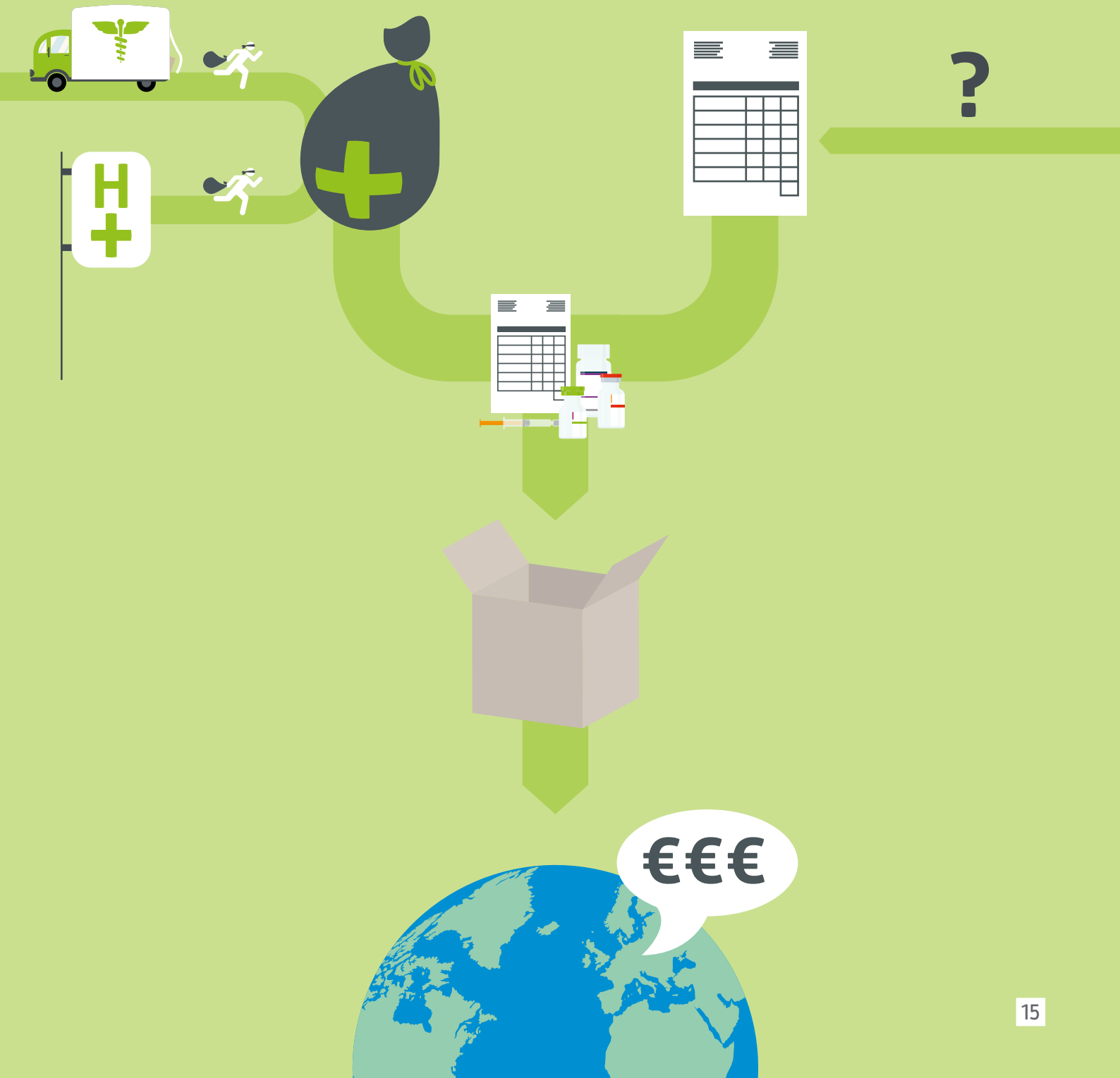
Scenarios: the parallel trade

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).

UPDATE OCTOBER 2016:

police operations related to the “Operation Volcano” criminal network in Italy.





Price of medicines: Italy VS Germany

The structure of the German pharmaceutical market attracts products from all other EU MMSS, and in particular from Italy, Greece and Romania. Parallel trade is fostered through ad hoc regulation aimed at saving on pharmaceutical expenditures; differences in price between Germany and other EU MMSS is a key driver for the process. Due to this situation, the level of verifications on trades should be as high as possible, since undetected infiltration of illegal products was proven possible: after the “Operation Volcano”, Germany set up a cooperation scheme between authorities, similar to the one established in Italy since 2006, that allows to identify other dangerous infiltration channels.



KEPPRA® - tablets 500mg



~0,75 €



~1,97 €



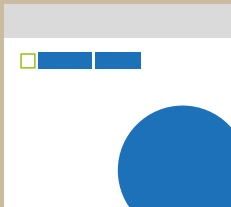
VIMPAT® - tablets 200mg



~3,82 €



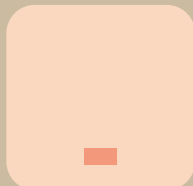
~4,75 €



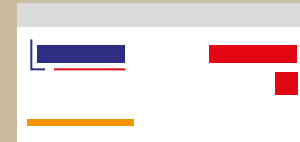
NEUPRO® - patches 8mg/24h



~6,04 €



~11,79 €



CLEXANE® - syringes 0,6ml



~6,70 €

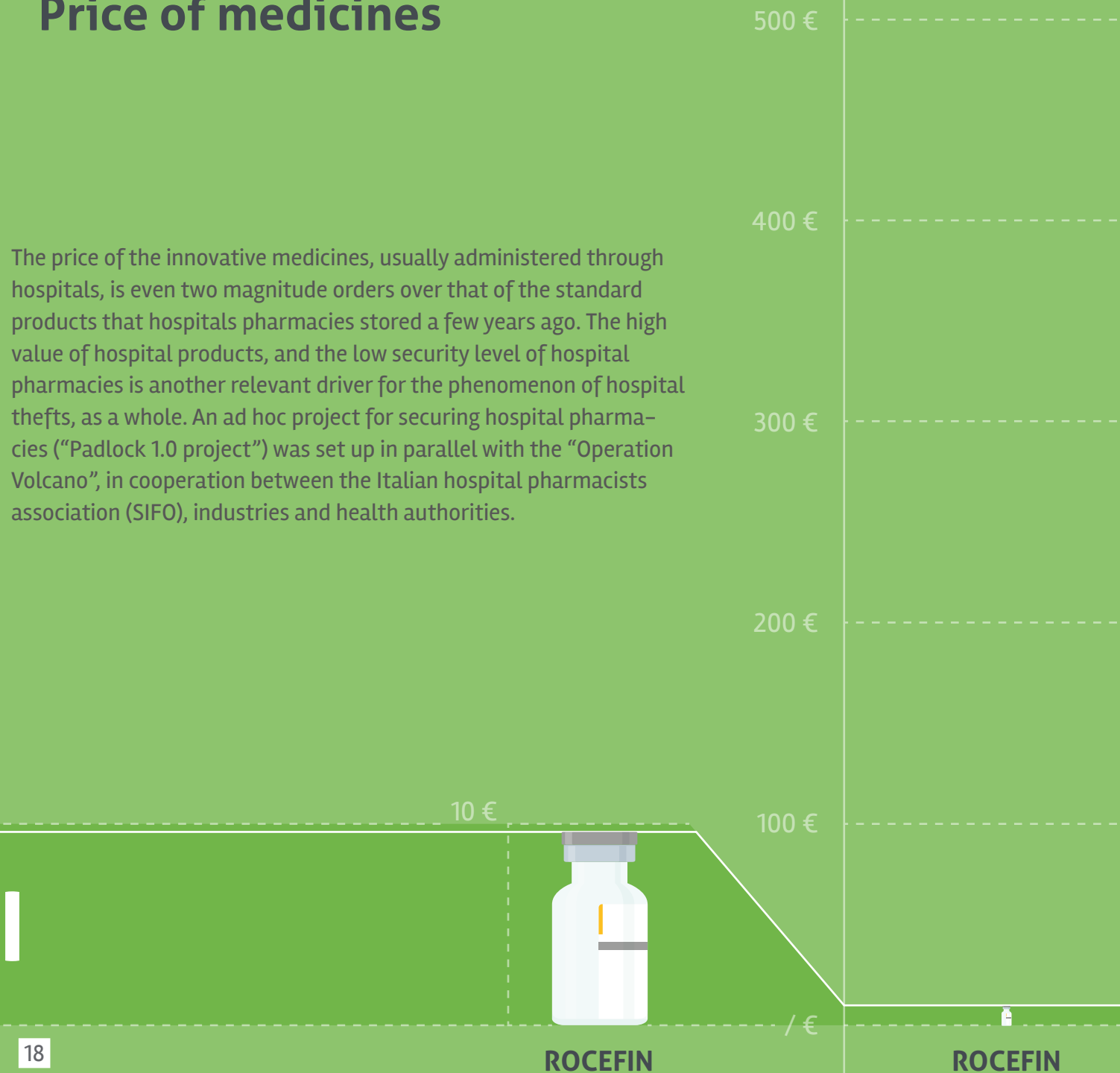


~7,69 €



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.



4.000 €

3.500 €

3.000 €

2.500 €

2.000 €

1.500 €

1.000 €

500 €



ROACTEMRA



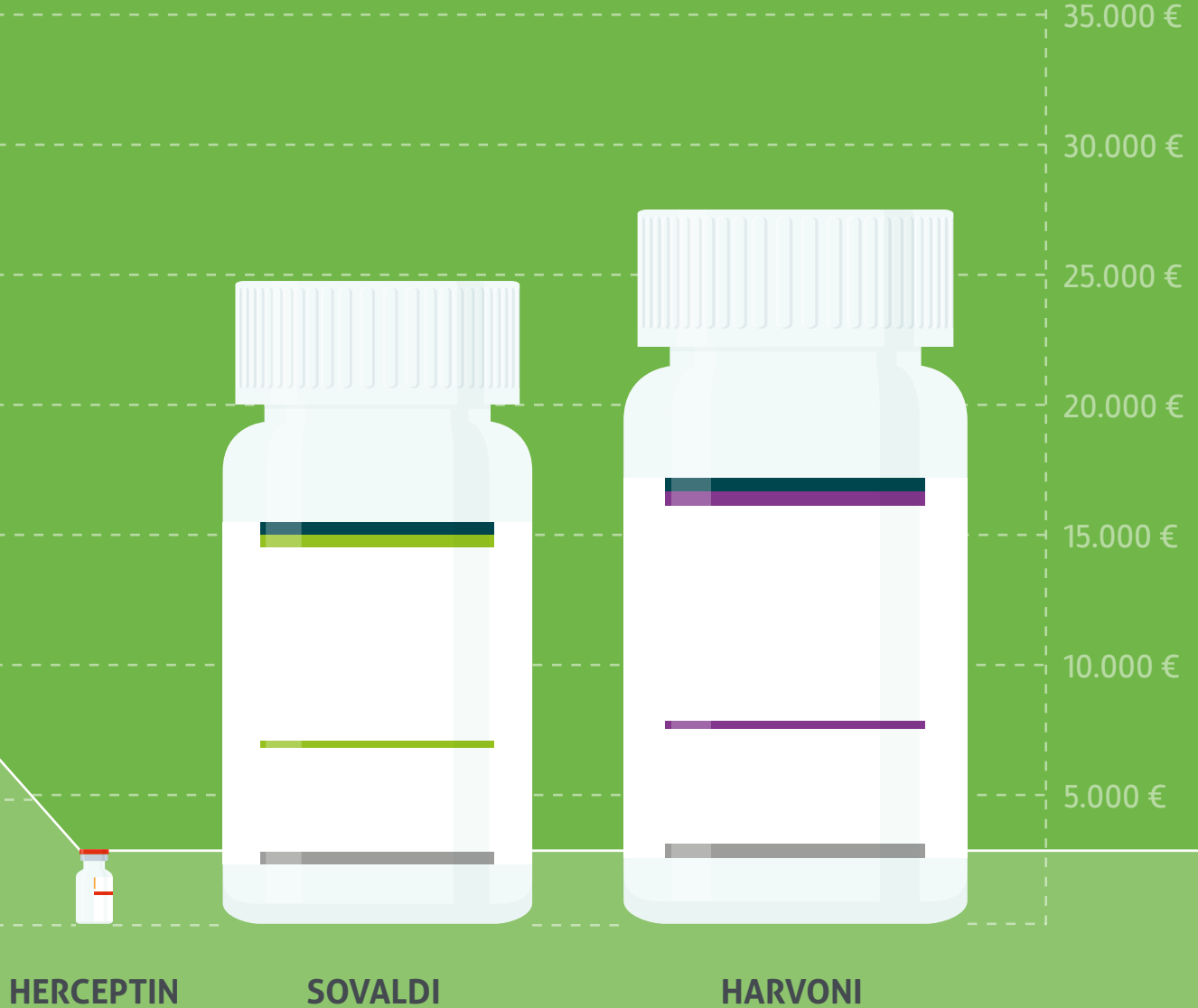
MABTHERA



HERCEPTIN



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



“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.

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