



# PHARMACEUTICAL CRIME



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# PHARMACEUTICAL CRIME

# Table of Contents

Abstract _____	5	Q&A on the counterfeiting of medicines __	10
Warnings recently launched by AIFA on falsified medicinal products distributed in Italy through illegal networks _____	6	Report EUCOJUST 2014 _____	14
Falsified Viagra (26/06/2015).....	6	Organised crime.....	14
Counterfeit copies of the medicinal product Cialis (05/12/2014).....	6	Internet .....	14
Counterfeiting of high-cost hospital medicinal products: new alert in Europe ____	7	Law enforcement .....	14
White Paper on "Operation Volcano" - Introduction _____	8	Legislation.....	14
Interpol Report on pharmaceutical crime (2014) - Introduction _____	9	Medicrime Convention against counterfeiting of medicinal products _____	15
		On line sale of medicinal products: the situation in Italy _____	16

## Abstract

Pharmaceutical Crime is a major public health concern which jeopardises human lives and causes direct damage to patients and to the pharmaceutical supply chain – consisting of manufacturers, distributors, pharmacists, doctors, private organisations and public bodies.

The counterfeiting of healthcare products is a growing phenomenon and difficult to quantify with precision; however, data provided by the investigators of the Pharmaceutical Security Institute (PSI) show that in 2013 more than 2.000 cases were reported, which means an average of more than 5 cases per day and a resulting tenfold increase compared to the cases registered in 2000.

The [international organisations](#) combating pharmaceutical crimes have long considered such problem as one of the most serious emergencies to be tackled.

[Frequently, information on this phenomenon](#) is not sufficiently known to the public, despite the efforts of the authorities in the initiatives related to [communication on risks](#) to health.

In the past 5 years remarkable events have been reported with [numerous victims](#) all over the world and in some cases the ensuing investigations have led to several arrests – in Italy as well. Even so, illegal medicinal products, which are very difficult to infiltrate into the legal supply chain and into pharmacies – at least in so far as Italy is concerned (\*Tracking system) – find alternative distribution channels, such as [sex shops](#), gyms and beauty centres.

Trafficking of falsified medicinal products is managed by international criminal organisations, which can structure and consolidate ad hoc distribution networks

to infiltrate stolen and counterfeit products into the European pharmaceutical network – as highlighted in 2014 through the operation called “[Operation Volcano](#)”, or create a wide online sales system, with thousands of unauthorised websites promoting and selling uncontrolled products targeted at final consumers who may not be aware of the dangers and the potentially serious – and sometimes fatal – adverse reactions caused by intake of such products.

However, [current applicable legislation is still not sufficient](#) to efficiently counter the criminal activities carried out by individuals or international criminal organisations; full implementation of the [Medicrime Convention of the Council of Europe](#) (signed by Italy in October 2011, and presently in the process of ratification), could allow to adopt appropriate measures as well as deterrent sanctions, proportional to the gravity of the criminal behaviours.

It is likewise necessary to improve the existing rules through fostering international cooperation, as exemplified for instance by the [European project Fakeshare](#), which AIFA has led in cooperation with other public and private partners, as well as national cooperation (as for instance in the [Inter-departmental conference on e-pharmacies](#) established by AIFA with an aim to examine alerts on websites selling medicinal products, which has also allowed to enforce not specifically sectoral rules and legislation to block illegal websites). It is also desirable to strengthen cooperation between health authorities and the judiciary for a timely identification of offences and related criminal penalties, in order to appropriately prosecute criminals.

*AIFA Directorate General*

*In the following pages recent cases of counterfeiting are described, which AIFA has managed and published on the Agency website for the purposes of information sharing with citizens and other public authorities.*

# Warnings recently launched by AIFA on falsified medicinal products distributed in Italy through illegal networks

## Falsified Viagra (26/06/2015)

On June 26th 2015 AIFA's Product Quality and Counterfeiting Office notified that Customs in Bari discovered some counterfeit blisters of the medicinal product **Viagra 100 mg**, in the context of the Operation Pangea VIII (9th–16th June 2015).

Each blister, containing 4 tablets of 100 mg, reported the batch no. **B714830238** (which was confirmed as non-original by the marketing authorisation holder Pfizer) and expiry date **04/2017**; the blisters confiscated came without outer wrapping (secondary packaging) and package leaflet.

Packages of this illegal product could be present in Italy on the illegal market.

It should be underlined that the medicinal products distributed illegally through unauthorised channels, as for instance sex shops, are generally counterfeit copies of medicinal products regularly on sale in pharmacies. Some specific batch numbers (as Cialis 05668 and AC066018) recur periodically on the counterfeit copies, often with different expiry dates; therefore also Viagra B714830238 may have been illegally marketed, with the indication of different expiry dates.

Should any professional be in possession of packages of Viagra 100 mg, with the above-mentioned characteristics, they are required to not distribute the product and to contact AIFA at the following email address: [medicrime@aifa.gov.it](mailto:medicrime@aifa.gov.it).

## Counterfeit copies of the medicinal product Cialis (05/12/2014)

On 5th December 2014 AIFA's Product Quality and Counterfeiting Office notified the discovery on the EU market of some counterfeit packages (in Italian) of the medicinal product Cialis 20mg 4 film-coated tablets, batch no. **C251489**, expiry **08/2016** and (falsified) label no. **009746984**.

The counterfeit packages did not show the anti-counterfeiting hologram, unlike the original product.

Further packages of the illegal product may be present in Italy on the illegal market, in retail outlets not authorised to distribute medicinal products.

Should any professional be in possession of packages of Cialis 20mg, with the above-mentioned features, they are required to not distribute the product and to contact AIFA at the following email address: [medicrime@aifa.gov.it](mailto:medicrime@aifa.gov.it).

## Counterfeiting of high-cost hospital medicinal products: new alert in Europe (AIFA article, August 7<sup>th</sup> 2015)

The new targets of pharmaceutical crime, subject to theft and counterfeiting, are not only monoclonal antibodies, whose market values range between two and twenty million Euro per kg (with an average of eight million/kg against 3.6000 €/kg for gold), but also many other high-cost medicinal products.

On 3rd August 2015 the Czech regulatory authority launched a rapid alert on the counterfeiting of Exjade (a product for treatment of chronic iron overload due to frequent blood transfusion in patients with Beta Thalassaemia Major of 6 years of age or more, whose MAH is Novartis Pharma); the blisters detected during checks by the company which was importing the product to Germany through Parallel Import(\*) reported batch numbers corresponding to the original ones, but date of production and expiry had been counterfeited; moreover, the content proved to be contaminated with non-pharmaceutical material, not matching with the composition of the original product.

This is just an example of the many [Rapid Alerts](#) launched in the past few months by the European authorities (especially by the German authority), referring to cases of counterfeiting of high-cost hospital products or other pharmaceuticals – such as Herceptin, Humira, Viread – which were not falsified until a few years ago – or Botox.

The European cooperation in the context of the “[Operation Volcano](#)” has brought about the development of new verification procedures shared between healthcare professionals and national bodies, as well as the strengthening of controls, so allowing to timely detect and block any infiltration – as in the cases which had affected the European market in the last few years.

Furthermore, such activities have helped to eradicate theft of medicinal products in hospitals, a growing

phenomenon until May 2014, which has been dramatically declining after the “[Operation Volcano](#)”. However, this does not mean that the illegal trafficking of medicinal products has stopped: the criminal groups managing such commercial transactions have developed different distribution strategies. For instance, the past few months saw a significant increase in the offers dealing with some kinds of medicinal products also on illegal websites; actually, the internet and the organisations which are supplied by the internet have become a risk source not only for now well-known medicinal products – such as those used for sex (distributed through [e-pharmacies and sex shops](#)), but also for life-saving medicines or products with critical profiles, which are illegally made available to patients, healthcare facilities and [beauty centres](#). “Pirate” e-pharmacies sell potentially hazardous medicines by presenting them as “Asian” medicinal products (that is, products by way of derogation from [patent rights for humanitarian reasons](#) for developing countries, which can be legally produced and distributed within their borders); however, in the vast majority of cases such products are [counterfeit, ineffective or toxic copies](#) and in some cases hospitals or healthcare facilities for deprived patients are supplied with those products, as it happened in 2012 in [Pakistan](#), where such phenomenon caused a humanitarian tragedy of catastrophic proportions.

Medicinal products provided illegally through uncontrolled channels, such as unauthorised online pharmacies or facilities not subject to investigation by national healthcare authorities are a major risk for purchasers: this is why AIFA and the partners of the [Fakeshare](#) project are about to launch on the internet an awareness campaign which employs fictional characters to refer to real cases of fatal events due to intake of hazardous products.

# White Paper on “Operation Volcano”

## Introduction

### *AIFA/Working Group of Enforcement Officers, 2015*

The so-called “Operation Volcano”, also known as “Herceptin case”, originates upon receipt of an alert by a German parallel distributor, soon followed by further investigations in respect of which emerged that vials of the cancer medicine Herceptin (trastuzumab), stolen from Italian hospitals, have been manipulated and falsified and re-introduced under false credentials by unauthorized wholesalers into the legal supply chain. Seizures of falsified vials have been carried out by authorities in Germany, Finland and United Kingdom (UK). The distribution of the falsified vials to other European Union (EU) Member States (MS) was also proved.

Upon further investigation by the Italian authorities, additional medicinal products have been identified as stolen in Italy and, subsequently, re-introduced under false credentials by a criminal organization connected to Italy.

This has been facilitated through unauthorized wholesalers connected with the Italian criminal organization, formally based in Cyprus, Hungary, Latvia, Romania, Slovak Republic, Slovenia and Greece issuing fake invoices to sell the stolen medicines to authorised Italian and Maltese operators. These authorised operators have subsequently exported these to other EU markets.

A similar scheme, involving operators from other countries, was also discovered.

The vulnerability of the parallel import channel to this kind of attack and the lack of enforcement actions with respect to Good Distribution Practice (GDP) (e.g. inspections to wholesalers) were major causes for the case; strong protection of the network via strict importing rules for parallel distribution and traceability systems for medicines, cooperation between enforcement and health authorities, sharing of information and intelligence knowledge (also via web tools such as the AIFA/Fakeshare ones) allowed Italy to counteract criminals and to avoid the infiltration of illegal medicines and up to July 2015 led to the arrest of more than 60 people in 8 different police operations in Italy, and to the eradication of the hospital thefts in Italy (passing from 3 cases per week, until May 2014, to zero, from June 2014), but were not enough for preventing further possible theft/falsification/exporting criminal plot, as demonstrated by the recent RA issued by Germany and other MS with respect to the possible infiltration of counterfeit medicines in the same channels targeted in this case.

By explaining the case in detail, summarising the key lessons learned and the possible preventive actions, the White Paper calls for a stronger enforcement effort against pharmacrime, with more resources at MS level and an ad hoc coordination at EU level.

The following table is an update on police operations related to the “Operation Volcano” criminal network in Italy:

Investigation period	Enforcement unit	Arrested people	Seized products
November 2013	Police (Lodi)	20	236 boxes
December 2013	Carabinieri (Caserta)	0	52.251 packages
February 2014	Carabinieri (Naples)	2	404 boxes
April 2014	Police (Bari)	4	680.00 euros
February 2015	Carabinieri (Siena)	9	Not declared (tons)
April 2015	Carabinieri NAS (Milan)	19	16.000 packages
June 2015	Guardia di Finanza (Rome, Naples)	10	68.000 packages

# Interpol Report on pharmaceutical crime (2014)

## Introduction

Pharmaceutical crime involves the manufacture, trade and distribution of fake, stolen or illicit medicines and medical devices. It encompasses the counterfeiting and falsification of medical products, their packaging and associated documentation, as well as theft, fraud, illicit diversion, smuggling, trafficking, the illegal trade of medical products and the money laundering associated with it.

Illicit drugs can contain the wrong dose of active ingredient, or none at all, or a different ingredient. They are associated with a number of dangers and, at worst, can result in heart attack, coma or death.

The fight against counterfeit medicines is crucial in order to ensure the quality of products in circulation and to protect public health on a global scale.

The increasing prevalence of counterfeit and illicit goods has been compounded by the rise in internet trade,

where they can be bought easily, cheaply and without a prescription. It is impossible to quantify the extent of the problem, but in some areas of Asia, Africa and Latin America counterfeit medical goods can form up to 30% of the market.

Organized criminal networks are attracted by the huge profits to be made through pharmaceutical crime. They operate across national borders in activities that include the import, export, manufacture and distribution of counterfeit and illicit medicines. Coordinated and cross-sector action on an international level is therefore vital in order to identify, investigate and prosecute the criminals behind these crimes.

*(Report Interpol 2014)*

<http://www.interpol.int/Crime-areas/Pharmaceutical-crime/Pharmaceutical-crime>

# Q&A on the counterfeiting of medicines

## “Counterfeit Medicines – Facts and practical advice”, AIFA/EDQM, 2011

### What are counterfeit medicines?

Counterfeit medicines are products which are labelled with false information with regard to the content and origin of the medicine. They may be medicines without active ingredients, with active ingredients present in a quantity different from that declared or even with the correct active ingredient in fake packaging. There is a wide range of examples, varying from cough syrup containing a toxic solvent instead of the more expensive glycerine, to stolen medicines which have been relabelled and put on the market with a larger labelled dosage with respect to the content of the original medicine. In all cases it is the patient who takes the medicine who will be adversely affected both due the lack of therapeutic effect and due to possible adverse effects which can sometimes be harmful or lethal.

Falsified medicines usually do not contain the correct active ingredient (assuming they contain active ingredients), or they contain a lower amount than the genuine medicine; They are not usually manufactured in authorised sites and are often handled without any warranty with respect to proper storage. The definition of “falsified medicinal product”, introduced by Directive 2011/62 (implemented in Italy in Legislative Decree no. 17/2014) and reported below, provides a comprehensive description of these problems:

- (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, including the records and documents relating to the distribution channels used.*

### Is the counterfeiting of medicines exclusively an economic problem related to copyrights and patents?

The seriousness of the crime of counterfeiting medicines is not limited to economic damage to a commercial brand but also has wider consequences in terms of the risks to public health.

Recent and well-known episodes reported in the media have shown how counterfeiting medicine (which may or may not be a lifesaving product) can lead to numerous deaths.

If the counterfeit medicine is used to treat a life threatening condition, the inefficacy of the counterfeit medicine can cause tragic events, but also medicines which are much less critical, as for example a cough syrup, can become very dangerous in the case that the active ingredient is “substituted” with a toxic substance.

The present regulations on counterfeit medicines appear to pose the problem in terms of damage to commercial brands instead of the relevance to the risk to public health.

### Is counterfeiting only relevant for branded and costly medicines?

Counterfeiting is important both for branded and generic medicines. The production of fake medicinal products is performed with the aim of making a profit and the counterfeiters therefore concentrate on the products most easily sold in their supply chains and on those which guarantee the highest profit.

As a result, counterfeiting affects a wide range of medicinal products. The panorama of illegal manufacturing varies with the changes in the market and is modified by unpredictable events, such as a sudden lack of a product which can increase the demand for that medicine in a specific market, as happened recently for certain vaccines during the swine-flu crisis.

The criminal groups dedicated to these activities do not use controlled lines of production and the ingredients used are generally not legal in order to produce packages which imitate the most successful medicines that have extensive distribution chains capable of absorbing large quantities.

These products may be fake steroids for athletes or medicines with a huge demand in a certain market for example due to an epidemic. Therefore counterfeit medicines can be extremely varied but have in common the threat to public health.

### Does the problem of pharmaceutical counterfeiting also affect developed countries?

Counterfeiting is common across the globe but with varying characteristics. While in developing countries the affected medicines are of the lifesaving kind (vaccines, antibiotics and other lifesaving products), in developed countries counterfeiting was originally encountered

in the market of lifestyle medicines such as slimming medicines which are often sold outside legal supply chains but more recently has been extended to medicines distributed through authorised pharmacies.

### **What kind of distribution channels are used for selling counterfeit medicines?**

In general, criminal organisations look for their revenues where the market is; IE, as soon as there is demand for a certain product, or as soon as they find loopholes in a distribution chain, they try to make their business, offering the right illegal medicine for the targeted channel. In developing countries, it means that every time there is need for medicines, to be provided through emergency procedures that reduce the control on the products, criminals will propose their counterfeit medicines, using also corruption as a possible tool; in 2012, more than 100 people died in Pakistan because of a counterfeit medicine distributed via an unaware Non Governmental Organisation, which was victim of a fraud; but in recent years, vaccination or antibiotic campaigns in African countries were disrupted by the infiltration of counterfeit medicines.

In Europe, the infiltration of the legal chain is possible, but not frequent; patients may buy their medicines through authorised pharmacies, taking no risk. But as soon as they decide to use “alternative suppliers”, such as “rogue” e-pharmacies, “experienced friends” or “reliable trainers” offering mysterious preparations, like the “100% natural products” claiming to guarantee miracle slimming effects, they fall into the criminal organisations hands.

### **In developed countries does counterfeiting affect life-saving medicines or is limited only to lifestyle medicines?**

As shown by some recent cases in the United Kingdom, counterfeiting does not only affect medicines classified in the “lifestyle” medicine category but has been encountered more often in commonly used and life-saving medicines.

In technological terms, counterfeiting does not always require a particularly advanced and technological process. For example, in the United States a case study was encountered in which a criminal group bought high-dose life-saving medicines, then diluted these down to a minimum dose and finally repackaged the products in bottles with labels indicating a different dosage with respect to the true one. The activity of the counterfeiters was therefore quite simply limited to a label change but the consequences were tragic for the patients

who bought these seriously under-dosed life-saving medicines.

Recent case histories can give an idea of the complexity of the problem:

- Counterfeit anti-cholesterol life-saving medicines were recently seized from pharmacies in the United Kingdom. The medicines were imported and sold by an authorised distributor who had been misled by one of his suppliers. The distributor was convinced to sell a legal product. Investigators in the United Kingdom have also found production sites of counterfeit and illegal pharmaceutical products for human and veterinary use.
- The Swiss pharmaceutical regulatory agency, SwissMedic, has seized numerous confections of Carcinonate. This product, which does not contain any pharmacologically active ingredient, is claimed to have antitumoral properties but is sold as a food supplement. Carcinonate does not violate any intellectual property rights, and therefore is not considered as counterfeit by the active regulations even though it clearly represents a risk to public health.
- In 2012–2015, counterfeit copies of highly priced hospital drugs (such as anticancer treatments) were found in different incidents all around EU; an in depth investigation coordinated by the Italian authorities in 2014–2015 unveiled a huge plot for infiltrating illegal medicines (stolen, falsified, counterfeit) in the legal parallel trade chains of Germany and other EU Member States.
- The crises related to the pandemic alarms (for example the bird and swine flus) have demonstrated other counterfeiting risks. In the case of the bird flu, the origin of the infections has been traced back to the treatment of the first infected animals with counterfeit antiviral drugs and, in both cases, the growth in the demand for antiviral medicines following the alarms launched by the press has given rise to the arrival of counterfeit copies of medicines on the European market.
- In 2008, lifesaving medicines based on counterfeit heparin caused tens of deaths in the United States. The medicines were produced and marketed by an American multinational which, however, used Chinese starting materials that had been counterfeited in a manner not detectable by the usual tests. In this case, the product was counterfeited in that it contained counterfeit ingredients. Those who produced and legally marketed the product were not aware of the danger.
- In 2011, in Kenya, nearly 3.000 patients were affected by falsified batch of their antiretroviral therapy (Zidolam-N) for HIV/AIDS.

- Falsified Avastin, a drug for cancer treatment affected 19 medical practices in the USA in 2012. The drug lacked active ingredient.

Finally, it is estimated that every year 100.000 people, mostly children die after taking fake malaria drugs in Africa.

### **Are all counterfeit medicines really dangerous?**

All counterfeit medicines are dangerous because of the common denominator of the low and unverifiable quality of the product. Those who prepare an illegal product are obviously not interested in certifying its quality.

In certain cases, the investigators have discovered that the illegal products contained all of the right ingredients, but that a homogeneous distribution of the substances between the different doses was not guaranteed. It was therefore possible to find in one tablet a negligible and inefficient dose of the active ingredient and in another a double and potentially lethal dose.

### **Is it possible to determine the percentage of counterfeit medicines on the market?**

Although the statistics on the level of counterfeit medicines are variable, there is general agreement on the fact that the percentage varies between approximately 1 and 10% of the global pharmaceutical industry.

More importantly than the statistics one should consider the case histories: the possibility that a single batch of counterfeit medicines could arrive on the market may be converted into a enormous damage to public health, such as in the case of the counterfeit syrup that killed 100 people. All available indicators, even if clearly indirect, show a clear indication that the incidence of the problem is increasing: the high margins (one single vial of an anticancer product could cost more than 1.000 euros) and the low penalties, in comparison with other illegal activities, are attracting criminal organisations into the pharmaceutical market.

### **Why does the problem affect Italy less than other EU MS?**

Thanks to the system of pharmaceutical product traceability only medicines which are controlled throughout their entire journey from the manufacturer to the pharmacy circulate in the Italian legal distribution chain. As a result, the phenomenon of counterfeit medicines is limited only to uncontrolled channels such as illegal pharmacies which are organised in certain specific environments (such as gyms) and pharmacies operating by internet which are often managed directly by criminal organisations.

### **How much counterfeit medicines are imported into Italy by the internet?**

Given the characteristics of the Italian pharmaceutical market (with reimbursement for all essential medicines, the widespread presence of pharmacies and authorised sales outlets throughout the country and a limited recourse to e-commerce) the phenomenon in Italy would seem to be limited, at least in appearance, to certain well defined types of medicines, such as erectile dysfunction medicines and steroids illegally used in sporting environments.

### **Of all the pharmaceutical products bought online what is the percentage of counterfeit medicines?**

The figures on this subject are principally drawn from studies of unlicensed or suspect pharmacies and are therefore not entirely reliable for defining the exact percentage of counterfeit medicines sold online.

On the internet it is possible to find legal, illegal and even fake medicines, connected to websites dedicated to computer fraud (digital identity theft, credit card cloning, etc.).

In any case, recent research has demonstrated that medicines bought from illegal pharmacies are in most cases counterfeit or of poor quality. The "Fact Sheet" on counterfeit medicines published by WHO in 2012 stated that more than 50% of medicines bought from internet websites which hide their email addresses are counterfeit, and furthermore, all verification exercises on rogue e-pharmacies performed by EU authorities led to percentages of counterfeit products always greater than 50%.

### **Are identity theft and credit card cloning associated with pharmaceutical fraud?**

An interesting overall picture emerges from the studies performed by a number of European agencies (among whom AIFA by means of the Italian national task force, IMPACT Italia). This overall picture is formed by the presence of legal, illegal and fake medicines which are difficult to distinguish for a patient without expertise in the matter. These products are sold via spam (undesired messages received by email) which also contain links to websites dedicated to computer fraud such as identity theft and credit card cloning.

### **What are the most common fake medicines bought online?**

Any medicine which can give rise to significant commercial gain may become the object of interest of criminal organisations. The reasons which may induce a patient

to purchase medicines online can be mainly of a financial nature, related to the possibility to buy medicines not available via the usual channels, or due to the privacy of the purchase of certain types of medicines such as those dedicated to “embarrassing” dysfunctions.

The result is that, at the present time, the most common “brands” available through these channels are medicines for erectile dysfunction and those which have restricted use in many markets such as anorectic medicines. However, crises such as that related to the swine flu generate temporary markets for various medicines, such as for example the vaccines cited above.

Fake dietary supplements are a new trend in this area, meaning, the criminals use these less regulated products as carriers for active ingredients from medicines, or as alternatives for medicines that are more expensive. Such was the case of Green coffee products, found in Serbia in 2012, that contained a hidden active ingredient sibutramine, from a drug Reductil, that was banned due to serious adverse reactions. The green coffee worked, but not based on its natural ingredients, and it posed a threat to health too.

#### **What about the internet?**

From 2015, European Union countries will allow the internet distribution of medicines: authorised pharmacies and stores will be able to open their website and to sell authorised medicines – mainly, Over the Counter medicines, needing no prescription from a physician. Patients will recognise the good websites through a quality logo and other features; but even without the logo, it is not so difficult to recognise a legal website from a “rogue” one! Legal e-pharmacies represent less than 1% of the web offer: but the most part of websites offering medicines propose prescription products of some specific categories (slimming products, sexual enhancers, doping and steroids...), at unbelievably low prices.

#### **Are the illegal websites a real danger for public health?**

Buying medicines from these illegal websites is DANGEROUS: even an expert could find difficulties in

distinguishing a bad imitation from an original product, without a lab analysis... that’s the reason why in some web communities, such as the one of body builders, there are web forums where people shows the pictures of the products they bought on line, explaining the effects they experimented; a service to the community – basically, the adolescents participating to these forums act as “laboratory rats” for checking the effect of the products, signalling any lack of effect or bad side effect to other possible customers of the supplier they are testing.

Since people harmed through products supplied via illegal channels avoid to report the source of their diseases, it is not usual that these side effects are properly reported in the general press: but it is easy to see the connection between these websites and some recent cases signalled also in EU, such as the 80 years old man died in 2012 for a stroke related to the pills he assumed for a “party”, that no physician prescribed him, or the body builder deceased in 2014 due to a critical mix of medicines used for non-therapeutical reasons, or the young woman damaged by a miracle slimming medicine...

#### **What should a patient who has encountered a suspect medicine through uncontrolled channels do?**

Contact the authorities: all countries have contact points for this kind of incidents, allowing the patients to send signals about dangerous products under a privacy protection policy, related to the prevalence of the public health protection with respect to any consideration about the possible infringements to the regulation that could be charged on the ones buying medicines from illegal sources.

In Italy, Italian Medicines Agency – AIFA, is in charge of fight against falsified medicines, and it cooperates closely with police, customs, Ministry of Health and other government institutions as well as other stakeholders in the healthcare system.

In order to report a case, or even just a suspicion for a product or situation, use the official AIFA email [medicrime@aifa.gov.it](mailto:medicrime@aifa.gov.it).

# Report EUCOJUST 2014

(<http://www.eucojust.org/pharmaceuticalcrime.html>)

## Organised crime

Both Organised Crime Groups [1] and individual criminals are involved at any point in the supply chain of falsified medicines. Organise Crime Groups (OCGs) are playing an growing role in pharmaceutical crime by taking advantages of the changes that have characterised the last decade: intensified international commerce, expansion of internet, widespread use of “free zones” in international trade, and e=easier access to printing and manufacturing technologies.

Usually OCGs involved in pharmaceutical crime are small, with between three and 10 members. Their activities include illicit production of medicines, repacking and relabeling packages and distribution at marketplaces, to dealers or street hawkers, and/or directly to pharmacies and medical centres. For more specialized medicines, such as doping substances, groups target specific locations to sell the medicines, such as gyms and sports clubs. Some group specialize in the robbery of medicines (from hospital, pharmacy or transport companies) which are then resold to secondary distributors and wholesalers, or, directly to pharmacists as illustrated by a recent case in Europe.

OCGs involved in pharmaceutical crime often do not resort to external violence – unlike OCGs which deal exclusively with illegal drugs such as heroin and cocaine –which allows these OCGs to keep a low profile and avoid law enforcement authorities. The comparatively low level of violence might also lower the threshold for individuals to join the pharmaceutical crime arena and become part of the supply chain.

## Internet

Criminal elements are increasingly turning to the internet to sell illicit products as it offers a high degree of security and anonymity for their actions. The profits earned from illicit online pharmacies are substantial. Online pharmacy networks are predominantly not involved in the production of counterfeit or illicit medicines themselves. Instead, medicines are bought from the original manufacturing countries, resold over the internet through both their own and affiliate websites, and distributed through regular mail or courier services. Those working within this network structure often

do not know each other. This compartmentalization is a contributing factor to the difficult task of establishing the full extent of the workings of such networks.

## Law enforcement

The degree of resources allocated to fighting pharmaceutical crime varies greatly from country to country. Some countries have large and well-established units dedicated to fighting pharmaceutical crime, while others proactively target criminal elements utilizing non-dedicated officers from various other units. The inadequacy of enforcement is found to be chiefly caused by a lack of officers dedicated to working on pharmaceutical crime, or too few dedicated officers to cover the entire country. This is especially true with regards to the lack of dedicated IT crime units in many national police administrations.

## Legislation

Most countries do not possess legislation directly addressing pharmaceutical crime. Rather than examining pharmaceutical crime as a specific type of crime requiring specialized legislation, many countries continue to place it under the category of intellectual property crime or use existing criminal law on narcotics or fraud. As a result, several countries do not possess the necessary legal apparatus to effectively target the issue. In addition usually penalties are far too low to create effective deterrent impact. Stronger legislation clearly addressing pharmaceutical crime would help to make the action of police, customs, regulatory enforcement and the court systems more effective.

The Council of Europe’s Medicrime Convention is a step in the direction of creating an international criminal law framework to specifically and primarily address the public health threats of pharmaceutical crime. The Convention has provisions for protecting victims and for international cooperation in investigation, extradition and mutual assistance. However, the process of adoption of this Convention is still at its early stages: as of November 2014, 23 countries had signed the convention and three had already ratified it (to enter into force the Convention requires the ratification of five countries).

# Medicrime Convention against counterfeiting of medicinal products

## (AIFA press release no. 212, 28/10/2011)

*AIFA Director-General Guido Rasi: "The signing of the MediCrime is the result of two years' work and AIFA concretely committed to defining the text. This is an essential instrument from both a juridical and operational viewpoint, as it will finally allow to prosecute under criminal law illegal activities which represent a serious threat to the health of all citizens. By recommending an investigation approach against pharmaceutical crimes, it will also affect criminal law governing transactions on the internet, and will also help, for instance, to indict the "cyber pushers" maintaining the websites selling counterfeit pharmaceuticals".*

The Medicrime Convention was signed today in Moscow by the Italian Ambassador Antonio Zanardi Landi on behalf of the Foreign Minister Franco Frattini and by 12 of the 47 countries belonging to the Council of Europe, with the aim of prosecuting pharmaceutical counterfeiting. The text was signed in the presence of Dr. Domenico Di Giorgio and General Cosimo Piccinno, representing respectively AIFA and the Italian anti-adulteration units (NAS), the two organisations which made a major contribution to drafting the document.

*"The cooperation between AIFA and the Italian anti-adulteration units (NAS) has proven successful also at an international level – said General Piccinno – and I hope for greater cooperation under the auspices of such new Convention".*

The Convention resulted from the cooperation between the EDQM (European Directorate for the Quality of Medicines) and the Directorate General Human Rights and Rule of Law of the Council of Europe; it will allow the introduction of criminal laws whereby police forces, medicines agencies and customs of the 47 countries of the Council of Europe will be able to exchange information and cooperate through INTERPOL and EUROPOL.

In particular, the following crimes shall be introduced:

- manufacturing of counterfeit medicinal products;
- supplying or promotion (also via the internet) and trafficking of counterfeit medicinal products;
- falsification of paper-based or online documents relating to medicinal products.

The event was preceded by a two-day meeting which also addressed the implementation of the rules included in the Convention. Dr. Di Giorgio, on behalf of AIFA and of the EDQM pharmaceutical committees, hoped for awareness initiatives based on reliable scientific criteria, relating to the risks arising from internet and counterfeiting, in line with the measures taken by EDQM to train healthcare professionals.

General Piccinno proposed the creation of a Medicrime network within which each subscribing country shall appoint a contact person to provide information on existing pharmaceutical law, progress of subscription procedures and new legislation.

# On line sale of medicinal products: the situation in Italy (AIFA article, 26/06/2015)

Online sale and purchase of non-prescription medicinal products shall be shortly allowed also in Italy, pursuant to the provisions of the [Legislative decree no. 17 of 19 February 2014](#), transposing [Directive 2011/62/EU](#) on counterfeit medicinal products. This is a first for Italy, which will align our market with other EU countries.

In a first stage, distance selling in Italy shall only be granted to pharmacies and stores already entitled to drug selling (as the business trades under the [Decree Law of 4 July 2006 no. 223](#)), meeting the requirements laid down by legislation on distance selling.

Legal online pharmacies shall be recognisable – and therefore discernible from the illegal ones – through the “[common logo](#)” a safety label issued by the Ministry of Health.

The Ministry of Health – according to a [note](#) available on the portal – is about to issue a decree defining the national identification logo (in compliance with the EU directions) for the operators already authorised to sell medicinal products to the public who wish to sell those products online. The note explains that “...at a later time it shall be possible to set up the procedures for the on-line selling of only non-prescription medicinal products, including over-the-counter (OTC) pharmaceuticals – which are self-medication medicinal products. In particular, the authorisation for such activity shall be issued by the Region or the Autonomous Province or by other competent authorities, identified by local legislation at a specific request containing the identification elements of the pharmacy or other business trade, as well as the website address used for the online sales. Once the authorisation is granted, the person concerned may ask the Ministry for the abovementioned logo through the procedure which will be soon available on the Ministry website.”

The logo was designed with specific technical characteristics in order to ensure the highest safety standards and to avoid any fraudulent use. Moreover, the European Commission has contemplated further protective measures, such as patent status for the logo, whereby appropriate measures and sanctions may be taken in case of non-compliant and illegal uses.

Therefore, before purchasing any non-prescription medicinal product on the internet, it shall be necessary

to verify in advance the presence of the common logo, which will be linked to the list of all the legal online pharmacies, registered with the Ministry of Health.

Also the European Medicines Agency shall provide the links to the NCAs of any member State, with the official list of all the pharmacies entitled to online selling or the implementation status of the directive in every country.

It shall be important to raise awareness on the risks of purchasing pharmaceuticals online, just as AIFA has long been doing through the fight against pharmaceutical counterfeiting. It is noteworthy that in Italy checks and shutdown/block of illegal online pharmacies have been in force for a long time now, well before transposal of the recent European legislation, as shown by the results of the investigations carried out in cooperation with the other public bodies involved.

Since 2011 AIFA has launched shutdown campaigns against illegal sites through a cooperation agreement signed with [Legitscript](#), the US intelligence agency which also supports Google.

In the past few months, through the abovementioned Legislative decree 17/2014, AIFA has strengthened law enforcement in wider projects: the [Impact Italia](#) task-force has been changed into a national anticounterfeiting task-force, and an interdepartmental “Conference of Stakeholders” on [e-pharmacies](#) has been established, so formalising intersectorial cooperation on *e-pharmacies* involving Carabinieri NAS, Ministry of Health, Competition authority, IT Registry and Ministry of Economic Development.

The task of such new working group is to receive and analyse all the alerts on suspect websites selling medicinal products and to identify any infringement to the legislation on distance selling to the public; after verification, the information material on the reported website is forwarded to the Ministry of Health, which is the competent authority responsible for issuing provisions to prevent access to internet addresses that were deemed illegal by the aforementioned interdepartmental conference.

AIFA will continue its surveillance activity on illegal online sales of medicinal products, also by participating in international operations as the recent “[Pangea VIII](#)”

(whereby from 9th to 16th June 2015 more than 90.000 packages of falsified or illegal medicinal products were seized at the main Italian ports and airports), as well as through training and update activities for health-care professionals.

However, law enforcement should be supported by comprehensive consumer awareness campaigns on the risks of illegal websites; unfortunately, such awareness

is still rather limited, as proven by [research](#) published in the context of the Fakeshare project.

This is why AIFA and the partners of the [Fakeshare](#) project will shortly launch an international awareness campaign, underlining the risks of uncontrolled online purchase of pharmaceuticals, along with the advantages of the new safety systems, such as the common logo.



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