

# Trick or Treat(ment)?

## Guidelines for safe online purchases of medicinal products in the EU



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Rome, April 2015

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# The online purchase of medicinal products and the associated risks

The falsification of medicinal products and the online trade in medicines are two closely intertwined phenomena reaching alarming proportions and having an increasingly detrimental impact on public health. Without the Internet, the trafficking in falsified medicinal products would not have expanded to the extent it has in recent years, particularly in developed countries.

Internet usage enables criminals to sell potentially dangerous products on a large scale, directly to buyers, whilst circumventing the legal supply chain. This has largely been facilitated by the emergence of so-called online pharmacies since the 1990s. These retail pharmacies operate partially or exclusively over the Internet and ship orders to customers by mail. In just over a decade, the number of these websites has grown exponentially. Unfortunately, the majority of online pharmacies are run by criminals, and are likely to sell falsified and dangerous medicinal products.

The risks linked to this criminal market are even greater today because customers seem to underestimate the danger. According to the European Association of Mail Service Pharmacies, two million Europeans rely on self-medication and visit websites every day to order medicinal products without asking for a professional opinion first.

The following guidelines are based on the results of the European project [www.fakecare.com](http://www.fakecare.com), which aims at producing and disseminating knowledge, counter-strategies and tools across the EU to solve and mitigate the online trade of falsified medicinal products. Specifically, the guidelines provide information and advice for consumers, aimed at helping to avoid the purchase of falsified medicinal products. In order to achieve this aim, each section of the guidelines will include the following:

- Knowledge from research: direct knowledge on the topic that has resulted from the project's research activities.
- Knowledge-based tips: helpful advice drawn from the project's results aimed at mitigating the risks linked to the online purchase of medicinal products.

Furthermore, the guidelines include illustrative boxes with concrete examples of research results, as well as in depth explanations of key concepts.





## Types of online pharmacies

### Legal online pharmacies

These are the pharmacies that respect the law of the country in which they are established.

### Fake online pharmacies

These websites purport to be selling medicines but, in fact, they are 'traps' for potential buyers, who are victimised by identity fraud or theft (e.g. the operators of the sites steal credit card details and/or other sensitive information).

### Illegal/rogue online pharmacies

Illegal/rogue online pharmacies are the main system used to sell falsified medicinal products in Western markets. These websites can be accessed with ease, for instance, via spam email or through legitimate search engines.



## Falsified medicinal products

### What are falsified medicinal products?

According to the definition given by Article 1 of the Directive 2011/62/EU, a falsified medicinal product is “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, including the records and documents relating to the distribution channels used”.

Falsified medical products must be distinguished from other illegal medicinal products and the products infringing intellectual property rights. Furthermore, according to the Directive, “medicinal products with unintentional quality defects resulting from manufacturing or distribution errors should not be confused with falsified medicinal products”.

### Why are falsified medicinal products dangerous?

Falsified medicinal products are dangerous because they usually lack the correct ingredients or contain sub-standard or falsified ingredients. Those products could also contain ingredients, including active substances, in the wrong dosage. The number of those products detected in the European Union is increasing and they may have entered also in the legal supply chain. This represents an extreme threat to health and may cause a lack of trust of the patient. This danger is also recognised by the World Health Organisation (WHO).

## The Project

The European project [www.fakecare.com](http://www.fakecare.com) aims at developing expertise against the online trade of falsified medicinal products by producing and disseminating knowledge, counterstrategies and tools across the EU. The research activities were conducted in the following EU countries: Bulgaria, France, Germany, Italy, Spain, The Netherlands, United Kingdom.

In order to develop in-depth knowledge on the patterns of the online trade of falsified medicinal products - both the demand-side and supply-side - traditional and innovative methods have been used, such as:

**Web survey:** an extended web survey was conducted to profile online pharmacies' customers;

**Virtual ethnography:** researchers interacted in online communities and environments (including social networking sites such as Facebook), taking part in discussions about the online trade of medicines, and posing as customers and/or sellers;

**Honey-pot websites:** fake pharmacies were created to attract consumers, automatically monitor their behaviour, and acquire further data in order to improve the knowledge on the online trade of falsified medicinal products;

**Legal framework comparison:** an overview of the European legislation regarding the online trade of medicines was carried out in order to highlight vulnerabilities that can be exploited by organised crime groups involved in the illegal online trade of medicinal products;

**Script analysis of judicial and investigative cases:** a crime scripting approach (e.g. breaking up the crime-commission process into sequential phases) was used to analyse judicial and investigative cases in order to gather further knowledge of the criminal actors and organisations involved in the trade and to identify potential points of intervention;

**Web content analysis:** a quantitative descriptive analysis was conducted on the content of a number of legal and illegal/rogue online pharmacies in order to outline some of the key characteristics that can be used to distinguish between legal online pharmacies and fake or illegal/rogue online pharmacies.

The project is coordinated by eCrime - University of Trento and is being carried out in cooperation with Teesside University, Italian Medicines Agency (AIFA), and Centre for Research and Studies on Security and Crime (RiSCC), Interpol's Medical Product Counterfeiting and Pharmaceutical Crime Sub-Directorate, LegitScript, and the International Institute of Research Against Counterfeit Medicines (IRACM).

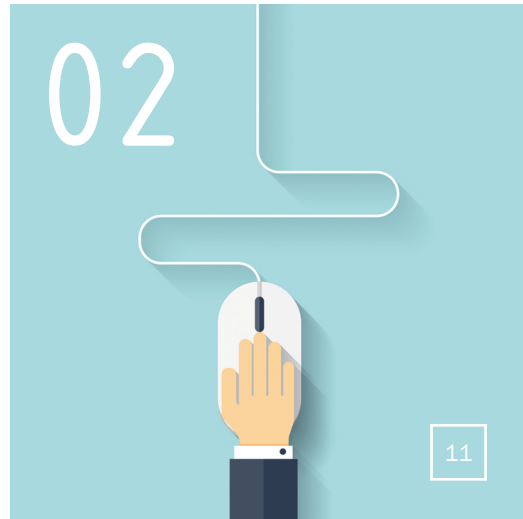
For further information, please visit [www.fakecare.com](http://www.fakecare.com).

## Trick or Treat(ment)?

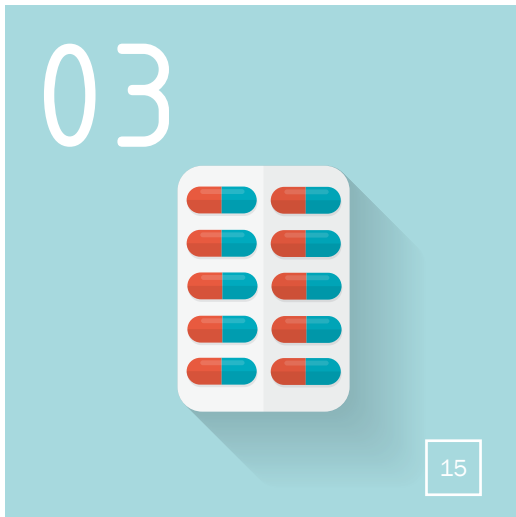
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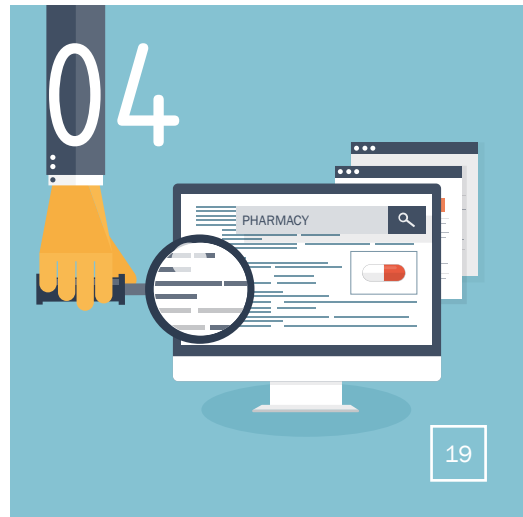
The legal framework  
in your country



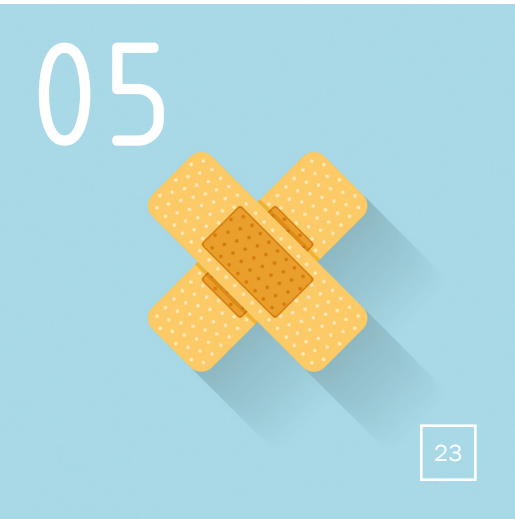
Customer profiles  
and motivations



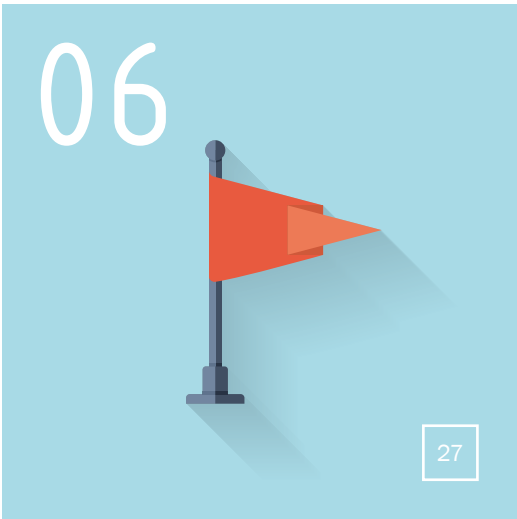
Falsified medicinal products  
and their characteristics



Illegal/rogue online  
pharmacies and their  
characteristics



Health harms associated with the purchase of medicinal products in illegal/rogue online pharmacies



Harms associated with the purchase of medicinal products in fake online pharmacies



How to get informed and report suspicious cases

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Abbreviations and clarifications

OTC: over-the-counter medicine  
POM: prescription-only medicine

*In these guidelines the technical term “medicinal product” and common term “medicines” are used interchangeably.*

# 01





# The legal framework in your country





## Knowledge from research

In the immediate future, national legislation on the online trade in medicines will be harmonised according to Directive 2011/62/EU. However, the process of harmonisation is ongoing and domestic regulations still vary among the 28 Member States. Furthermore, even after the implementation of the Directive some differences will persist. For example, selling prescription-only medicines (POMs) online will remain forbidden in some countries.

Information asymmetries create gaps and loopholes that criminals are able to exploit, particularly leveraging on the lack of knowledge of customers on this topic. Indeed, preliminary results of the Web survey delivered to individuals in the EU have shown that the majority of people either do not know anything about the legislation applicable in their country, or possess wrongful information.

Research results have shown that often criminals create illegal/rogue online pharmacies selling POMs without prescription claiming that such activity is legal because they are selling from a Member State abroad, where this is allowed. Furthermore, from the content analysis of online forums it has emerged that information on the legislation written in members' posts are nearly always wrong.

## Knowledge-based tips

-  Before purchasing medicines online, check your country's legal framework relating to the online trade of medicinal products and make sure you are aware of whether the online pharmacy is in line with legislative standards, and which types of medicines (POM and/or OTC) you are allowed to legally buy online in your country.
-  For further information, you can contact your national competent authority: the European Medicines Agency provides in its website the list of every national medicines agency, with contact information and links to their official websites [www.ema.europa.eu](http://www.ema.europa.eu) (Home > Partners & Networks > EU & the Agency > EU Member States > National competent authorities - human). Please also note that in the near future each Member States shall set up a website providing information on the national legislation applicable (see information box).
-  Do not trust legislative information provided in online forums members' posts: they are nearly always wrong! Rely only upon official sources.
-  Be aware that even in the countries in which it is legal to purchase POMs online, a valid prescription from a doctor is always needed. Websites stating otherwise are illegal.



## The falsified medicines European Directive

### Directive 2011/62/EU

Until recently, laws on the online trade in medicinal products in the EU were extremely diverse, which has created confusion among customers and has caused severe difficulties for investigations and prosecutions. Currently EU Member States are changing their legal provisions according to the (EU) Directive 2011/62 in an attempt to harmonise the differences among Member States regarding the regulation of sales at a distance of medicinal products. For example, some Member States that did not allow their sales at a distance, have now to allow at least the online sales of OTCs. Furthermore, every State must regulate in detail every aspect of the online sales of medicinal products in the country. Nevertheless, even after the transposition of the Directive, some differences among Member States regulation will persist (e.g. the online trade of prescription-only medicines will be legal in a few EU countries only).

### Information on national legislation

According to the Directive 2011/62/EU, each Member State shall set up a website providing information on the national legislation applicable to the sale at a distance to the public of medicinal products, including information on the differences between Member States regarding classification of medicinal products and the conditions for their supply.





## Research results: wrong information on national legislation

### Posts - Italian online forums

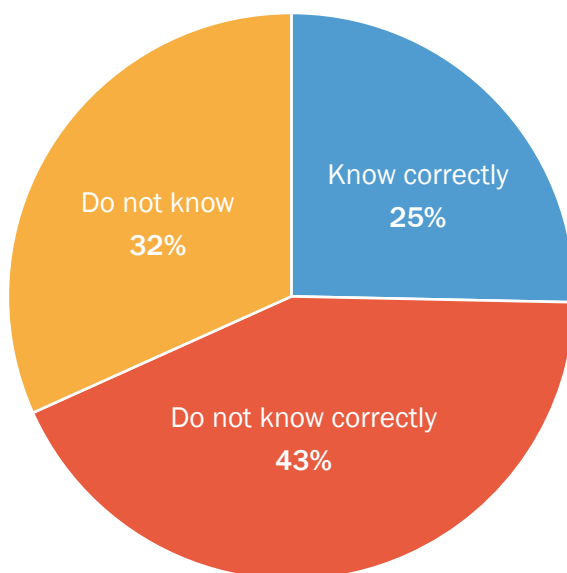
“ Even my boyfriend buys drugs online and they arrive at our home in 24 hours, in an anonymous and discreet package, from an English clinic specialised in the sale of genuine drugs. ”

“ Many websites are written in Italian but they can ship from a country outside Europe and therefore you risk having problems. You have to choose a European website, the shipment must leave from the European Union, from England if you don't want to have troubles. I can recommend [xxxx].biz. Usually I receive the pills within a week. Good evening. ”



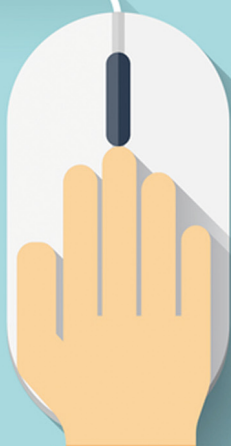
## Research results: awareness of legislation

Are European citizens aware of the correct legislation regarding the online trade of medicines?



Source: preliminary results of the customers' potential at risk questionnaire - Project [www.fakecare.com](http://www.fakecare.com)

02



# Customer profiles and motivations

## Knowledge from research

Research results have shown that EU citizens are at risk of consuming falsified medicinal products independent of sex, age, or educational level. In addition, those people who buy medicines online are often those who frequently purchase other types of goods online. In other words, individuals accustomed to ecommerce are also more inclined to purchase medicinal products online. Overall, both the virtual ethnography and the online survey have confirmed that the reasons that push customers to purchase medicines online are the following:

**No prescription:** it could be that individuals purchase medicines online because they do not want or cannot receive a prescription from a doctor, because they are too embarrassed (e.g. weight loss medicines or sexual related products) or they want to use the medicines for something other than their intended purpose (e.g. doping or recreational use)



**Avoiding shame:** individuals are too embarrassed to buy the product in person and prefer to receive medicines at home in relative anonymity

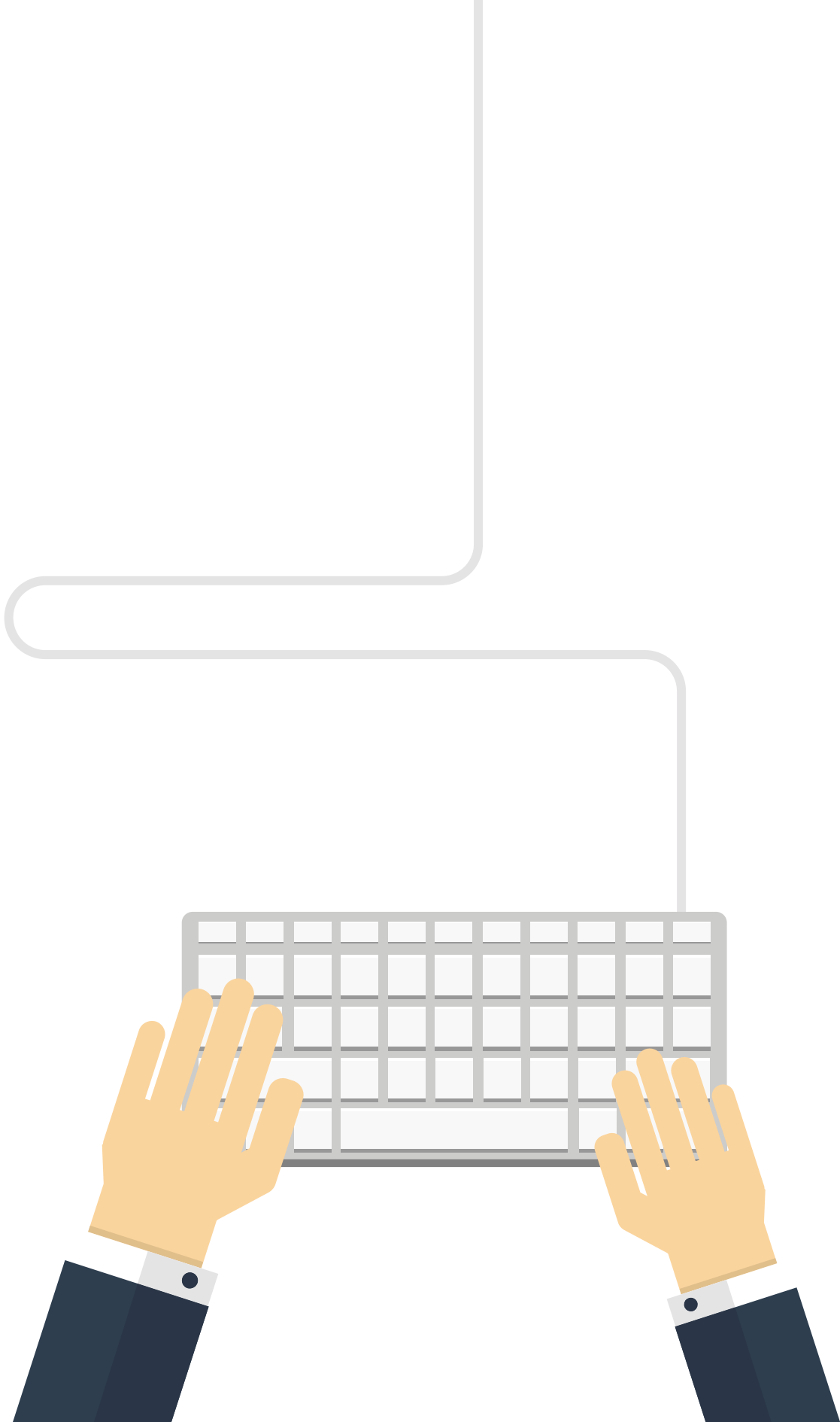


**Home delivery:** customers often prefer the convenience of receiving products at home






**Low prices:** favourable prices and special discounts usually attract customers





## Knowledge-based tips

-  Independent of your age, sex, educational level and experience of buying online, you are potentially at risk of buying falsified medicinal products - always be aware and do not 'drop your guard'!
-  Do not be ashamed to ask for help or information from healthcare professionals, and always consult a doctor before consuming prescription medicines. There are stringent rules that apply to the confidentiality of your health records, so do not worry!
-  Do not consume medicinal products for anything other than their intended use. It can be extremely dangerous to consume POMs without having information or a prescription from a healthcare professional. If they are unwilling to prescribe one, it is in your interest to trust their professional opinion.



### Research results: motivations

#### Post - Italian Online Forum

*“ I bought generic [xxxx] online [http://\[xxxx\].com](http://[xxxx].com) as a substitute to the original. The price difference is huge and it saves a lot. ”*

#### Post - Dutch Online Forum

*“ Don't make pills so expensive then this is not necessary. [xxxx] on the internet it is far far cheaper and it works fine. Why should I pay more if there is a cheaper way. ”*

#### Information Chat of an Illegal Online Pharmacy - Dutch Customer

##### **Customer:**

*“ I would like to buy some erection pills from your site, but will my doctor find out? ”*

##### **Online pharmacy:**

*“ No, it will be prescribed by our cooperating doctor. The information will stay with us and shall not be shared with another doctor. ”*

03





# Falsified medicinal products and their characteristics

Research results have shown that the medicinal products purchased by European customers in illegal/rogue online pharmacies vary. The most popular medicines are so called “lifestyle medicines”.<sup>1</sup> The virtual ethnography, as well as the analysis of investigative and judicial cases, have also highlighted increased falsification and demand for “lifesaving medicines” - i.e. medicines used to treat potentially lethal diseases like HIV, cancer and Hepatitis.

When customers purchase on illegal/rogue online pharmacies, they both violate the legislation and (above all) run the risk to get falsified and potentially dangerous products.

Overall, the project results have highlighted that the most popular types of products sold in illegal/rogue online pharmacies are the following:

Medicines to treat erectile dysfunction	Anabolic steroids, both injectable and tablets
Weight loss medicines/appetite suppressants	Hair loss medicines
Sedatives (including Benzodiazepines and Non-Benzodiazepines)	Opioid Analgesics
Antibiotics	Fertility medicines
Antidepressants	Stimulants
Medicines for cancer, HIV	Medicines for diabetes, arthritis and Hepatitis



This list mainly includes prescription only medicines (POMs). However, there are cases in which illegal online pharmacies also sell counterfeit over the counter medicines (OTCs).

<sup>1</sup> These are consumed voluntarily by individuals to improve their quality of life by treating various conditions, such as erectile problems, weight loss, or hair loss, etc. In addition, also POMs used for other than their intended use are usually sold in illegal/rogue online pharmacies (e.g. anabolic steroids used as doping).



Research results have shown that falsified medicinal products delivered to customers sometimes present some risk indicators. For instance, they may smell and/or taste different when compared to the legal products, they may have a different appearance (i.e. colour, texture, shape, packaging), or they may contain an information leaflet in a language different to that of the customer's language. However, criminals' ability to falsify medicinal products is increasing day by day, and it is becoming more and more difficult (or even impossible) to distinguish between a legal/genuine product and a falsified medicine.

## Knowledge-based tips

-  Be careful if you want to buy the types of medicines indicated above on the Internet, there is a high probability that you will be supplied by an illegal pharmacy. Do not drop your guard, even if you are search on the Internet for OTCs. All of the products sold by illegal online pharmacies are potentially dangerous!
-  If you have bought a medicine in an illegal/rogue online pharmacy do not take it independently from how it appears (e.g. smell, taste, colour, packaging), even if it looks like the genuine product. It is likely to be a falsified medicinal product!

04



# Illegal/rogue online pharmacies and their characteristics

## Knowledge from research

Being able to recognise illegal/rogue online pharmacies is key to customers' safety. Therefore, having the knowledge and skills to distinguish between legitimate and illegitimate online websites selling medicinal products is crucial. However, sometimes it is very difficult to understand whether an online pharmacy is legitimate or not.

In an attempt to tackle this, the European Commission recently adopted a common logo for use by legally operating online pharmacies in EU Member States as a guarantee of authenticity. The logo will be displayed on every legitimate online pharmacy in the EU, and will link to the websites of national authorities, which contain the list of all legally operating online pharmacies/retailers (by clicking on it customers are directed to the entry of the e-pharmacy on the national list, in order to complete the verification process).

This is an important innovation provided by the European Directive 2011/62 that will provide customers with a useful tool to easily recognise legal online pharmacies. However, criminological research has shown that criminals are able to adapt their behaviours to circumvent legislative innovation and to exploit any possible loophole or (involuntarily-created) opportunity. Consequently, criminals operating illegal/rogue online pharmacies may be able to counterfeit the logo (and even the linked websites), and display it on their sites.

Having said that, research results have shown that illegal/rogue online pharmacies have distinct characteristics that customers can use to distinguish them from legitimate sites. These risk indicators include:

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They do not require prescriptions for POMs



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They present low prices, huge discounts for larger purchases, and advertisements of promotions and trials



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The text of the website is often translated into different languages, and contains a lot of misspellings and grammatical errors, especially in languages other than English (highlighting the use of automatic translation systems)

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## The European Common Logo

By July 2015, online pharmacies and retailers legally operating in the EU should display the following logo (see example from the UK).

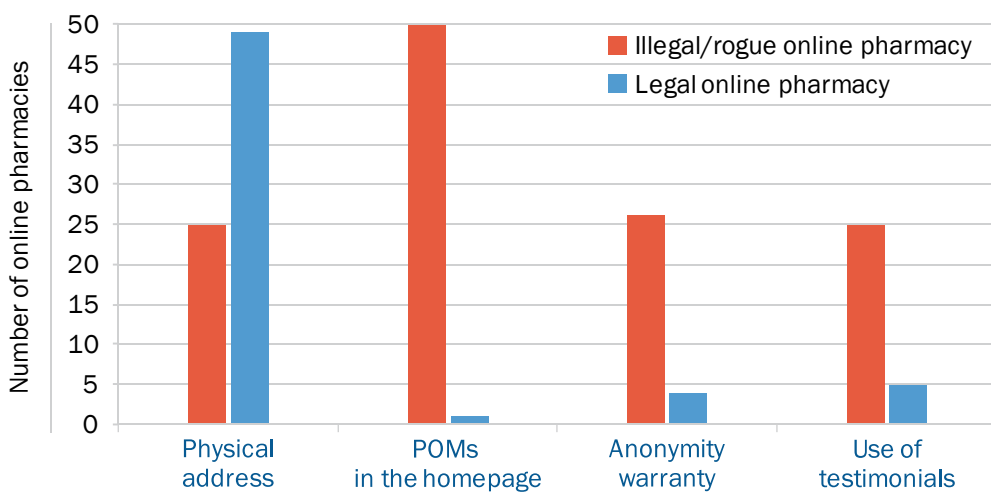


Be aware that the national flag and the text are an integral part of the logo. The flag to the left hand side of the logo corresponds to the Member State where the online pharmacy or retailer is registered or authorised. Only national flags of the EU Member States, as well as those of Norway, Iceland and Lichtenstein, are included in the scheme.



## Research results: specific features of illegal pharmacies

### Comparative analysis of the content of 50 legal and 50 illegal/rogue online pharmacies. Presence of specific features



Source: results of the content analysis of legal and illegal/rogue online pharmacies - Project [www.fakecare.com](http://www.fakecare.com)

Furthermore, following a comparative analysis of the content of a sample of legal and illegal/rogue online pharmacies, a number of other common features of an illegal website can be identified:

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The absence of any physical address



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The presence of POMs on the home page of the website



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The promotion of the anonymity warranty



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The use of testimonials



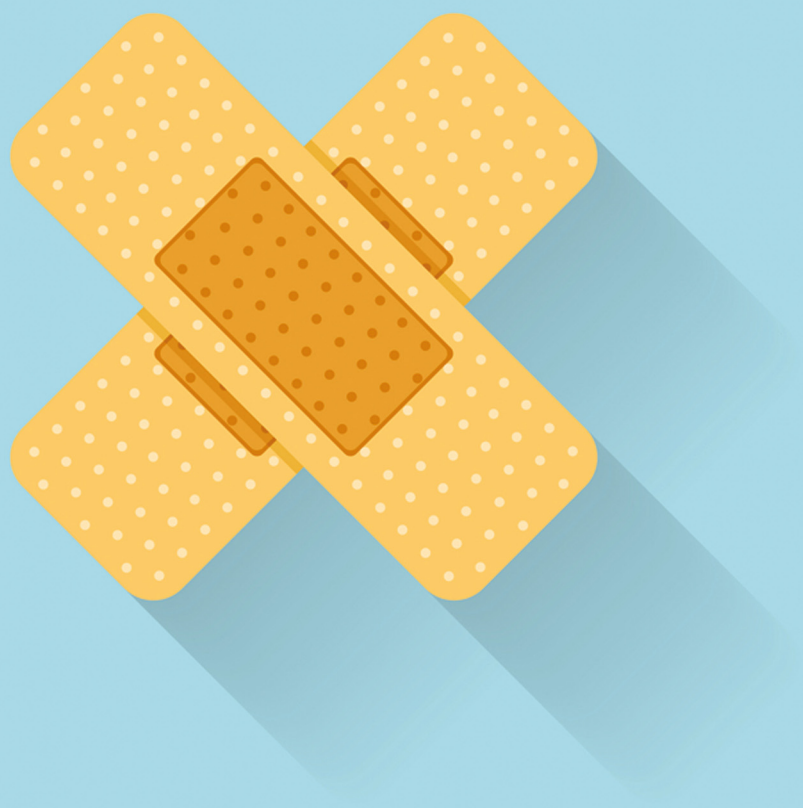
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Customers are usually directed to illegal/rogue online pharmacies by means of spam e-mails, search engines, and promotions in forums or other websites. Furthermore, the virtual ethnography has highlighted that social media sites, such as Facebook and Twitter, are used as marketing tools to promote POMs and illegal online pharmacy websites.

## Knowledge-based tips

-  Before you buy a medicine online, always check whether an online pharmacy is legal or not. In the near future a European common logo will be displayed on every legitimate website.
-  In any case, check the website for any of the risk indicators, such as (a) offering POMs without a prescription, (b) the presence of low prices, huge discounts for larger purchases, and advertisements of promotions and trials, and (c) misspellings and grammatical errors. If one or more of these indicators can be identified, the online pharmacy is illegal.
-  If the online pharmacy (a) promotes POMs on the home page, (b) does not display a physical address, (c) uses testimonials, or (d) promotes the anonymity warranty, further check the legitimacy of the site before you place an order. There is a high probability the online pharmacy is illegal!
-  If you reach an online pharmacy by means of email, promotions in forums or other websites, or via social media pages or posts advertising POMs, there is a high probability the website is illegal!

05





# Health harms associated with the purchase of medicinal products in illegal/rogue online pharmacies

## Knowledge from research

Research results have shown that there are many health harms associated with the consumption of falsified medicinal products. According to IRACM, the composition of falsified medicinal products can include:

- 
- a) insufficient quantity of ingredients or no active ingredients
- 
- b) higher quantities of one or more active principles than in genuine medicines
- 
- c) toxic ingredients (e.g. mercury, rat poison, paint, arsenic, antifreeze)
- 
- d) additional active principles that are not present in the genuine medicines.
- 

There is a high probability that such medicines can be extremely harmful, and potentially lethal. As a direct result of consuming falsified medicinal products, individuals may experience unexpected side effects, such as allergic reactions. Furthermore, the consumption of POMs without a prescription from health care professionals may cause health problems such as addiction or the worsening of a medical condition.

Results from the virtual ethnography also highlight the commonality of posts in online forums that present patients/consumers with incorrect information about the possible dangers associated with consuming medicines purchased from illegal websites.



## Research results: examples of lethal cases

### February 2014

Sarmad (18) died in hospital after he had called himself an ambulance from his flat. The teenager had been using weight-loss medicines, which he had bought off the internet in an illegal online pharmacy.

### October 2009

Amy (22) died following an apparent accidental overdose of medicines she had been buying in an illegal online pharmacy for insomnia, anxiety and stomach aches.

### August 2007

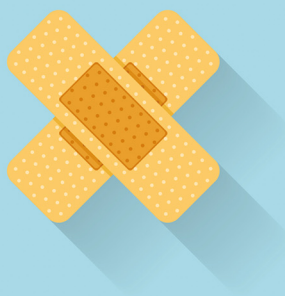
Selena (26) was found in a freezing bath trying to cool her body after taking a large dose of Dinitrophenol which she bought from a Chinese website in a desperate bid to lose weight.








## Research results: underestimate the health harms

### Post - English Online Forum

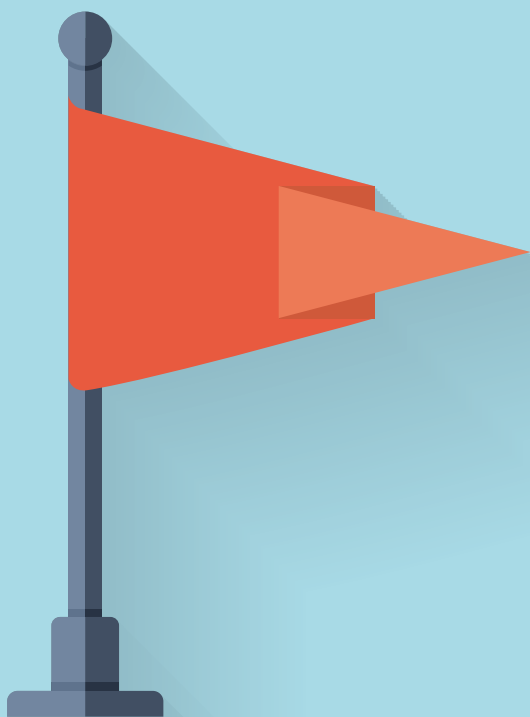
*“ Just take a look at the case of [xxxx], it's highly unlikely that somebody died just because he used this product, and the cases reported on the news were linked to the contemporary use of more than one product. ”*



## Knowledge-based tips

-  Consume POMs purchased online only if you have bought them from legal websites, with a prescription from a health care professional. Be aware that selling POMs online is only legal in some EU Member States: check your national legal framework (see section 1).
-  If you have purchased a medicine online from an illegal online pharmacy and you are yet to take it, do not use it!
-  If you have any unexpected reaction (e.g. rash, itching, hives, swelling, difficulty breathing, and/or low blood pressure) after consuming a medicine bought online, do not be ashamed or worried to contact and alert your doctor!
-  Even if you do not have any unexpected reactions after consuming a medicine bought online, but you are suspicious that you have purchased it from an illegal source, alert your doctor immediately!
-  Do not trust information provided in online forums claiming that there are no dangers deriving from the consumption of medicines purchased via illegal online sources. Instead, rely on information provided by health care professionals.

06







# Harms associated with the purchase of medicinal products in fake online pharmacies

## Knowledge from research

Research results have confirmed that there are websites that purport to be medicinal retailers but, in fact, do not sell medicines at all. These fake online pharmacies can often be traps and scams set up by criminals involved in so-called identity related-crimes - i.e. identity fraud and identity theft – being used to defraud customers of money, credit card numbers, details relating to identity, and other sensitive information. The features of such websites are very similar to illegal/rogue online pharmacies, and it is very difficult to distinguish between the two types. As a consequence, it is not possible to estimate the percentage of fake online pharmacies in operation.

## Knowledge-based tips

-  In order to recognize fake online pharmacies follow the same tips presented in section 4.
-  If you have bought medicines online, and you suspect that your sensitive data is being used fraudulently (e.g. unrecognised bank movements, supply of any type of service that you have never required), block your credit card immediately, contact your bank, and inform the relevant authorities.
-  It is more secure to use pre-paid credit cards or one-time disposable credit card numbers for your online purchases.
-  Use firewall software to protect information on your computer. Be sure that virus and spyware software programs are regularly updated.



## Identity-related Crimes

### Definitions and statistics

Identity crimes are not a new criminal phenomenon. However, the spread of the Internet and new technologies has generated a rocketing growth of such criminal actions. It is not easy to define the various criminal offences concerned and experts and researchers do not completely agree on a classification. However, the most apparent include:

- Identity theft (or impersonification): the theft or assumption of the identity of a living or deceased person for criminal purposes;
- Identity fraud: the creation of a completely or partially false identity (so-called 'synthetic identity') for criminal purposes;
- Identity-related crimes (or identity crimes): both of the above-mentioned criminal offences.

In most known cases details are used to create false documents, to request loans including mortgages, to buy goods, or to sign contracts. Victims' data were usually obtained using various channels (e.g. phishing emails, social networking sites e.g. Facebook, or via malicious software).

A survey conducted for Eurobarometer reported that on average, across the EU, 8% of internet users said they had experienced or been a victim of identity theft. This figure is similar in most EU countries, but is highest in Romania, where 16% of internet users say they have experienced identity theft, including 5% who say it has happened to them on more than one occasion. Respondents in Hungary (12%), UK (12%) and Austria (11%) also reported high levels of identity theft. The lowest levels were found in Slovenia (2%), Lithuania (2%), Greece (3%) and Denmark (3%).



## Research results: example of phishing

### Hacker attack

YouTube was the target of hacker attacks, with almost all of the phishing schemes directing people to fake Canadian pharmacy sites. Many people have been receiving spoof emails with the return address noreply@youtube.com as a result.

These emails state “Thank you for your video submission”, tell customers that they have won something, or inform them that their inbox is full. Furthermore, the emails contain a number of links, including a bogus unsubscribe link, all of which redirect unwary consumers to online ‘Canadian’ pharmacies involved in identity-related crimes.



07





# How to get informed and report suspicious cases

For any further information and advice, visit the project website:

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[www.fakecare.com](http://www.fakecare.com)



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Furthermore, do not hesitate to contact us using the following email address:

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[info@fakecare.com](mailto:info@fakecare.com)



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If you come across and/or purchase medicines from an illegal online pharmacy, you should report this to:

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your personal pharmacist and/or doctor



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your national medicines agencies. For further information visit the European Medicines Agency website where you can find a list of the competent authorities in the European Union that are responsible for human medicines: [www.ema.europa.eu](http://www.ema.europa.eu) (Home > Partners & Networks > EU & the Agency > EU Member States > National competent authorities - human)





### European project

[www.fakecare.com](http://www.fakecare.com). Developing expertise against the online trade of fake medicines by producing and disseminating knowledge, counterstrategies and tools across the EU

### Funding body

European Commission - DG Home Affairs

### Funding programme

Prevention of and Fight against Crime - ISEC 2011

### Coordinator



eCrime - ICT, law & criminology \ University of Trento

### Co-beneficiaries



Italian Medicines Agency (AIFA)



Teesside University



Centre for Research and Studies on Security and Crime (RiSSC)

### Associate partners



Interpol - Medical Product Counterfeiting and Pharmaceutical Crime Sub-Directorate



International institute for the prevention of falsified medicines (IRACM)



LegitScript





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