



02

eCRIME RESEARCH REPORTS

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FAKECARE

DEVELOPING EXPERTISE AGAINST
THE ONLINE TRADE OF FAKE MEDICINES
BY PRODUCING AND DISSEMINATING KNOWLEDGE,
COUNTERSTRATEGIES AND TOOLS ACROSS THE EU

Beneficiaries

eCrime, Faculty of Law, University of Trento (Coordinator)
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Associate partners

Interpol
IRACM - The International Institute of Research against Counterfeit Medicines
LegitScript



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European Commission - Directorate-General Migration and Home Affairs

eCrime Research Reports

No. 02

FAKECARE

*Developing expertise against the online trade of fake medicines
by producing and disseminating knowledge, counterstrategies
and tools across the EU*

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The research project was coordinated by Andrea Di Nicola, assistant professor in criminology at the Faculty of Law of the University of Trento and scientific coordinator of eCrime, Faculty of Law, University of Trento. Elisa Martini, senior researcher at eCrime acted as project manager. Gabriele Baratto, PhD student at the Doctoral School of International Studies and member of eCrime acted as vice project manager. The ICT part of the project was developed by eCrime by: Themistoklis Palpanas, now professor at LIPADE, Computer Science Department, Paris Descartes University, while he was professor at the University of Trento; Alberto Cordioli and Fabiano Francesconi while they were researchers at eCrime; Vincenzo Falletta, senior researcher at eCrime, and Walter Da Col, researcher at eCrime.

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02

The online
trade of falsified
medicinal products:
threats and needs

In the era of globalization, the sale of medicinal products has acquired an international dimension. At the same time, a huge illegal market in falsified medicines has developed. According to the definition adopted by the European Union, a falsified medicinal product is a medicine 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. This definition does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights” (Article 1, Directive 2011/62/EU).

Although it is impossible to quantify the size of this illegal market precisely, it is estimated to be globally a business of at least \$75 billion a year (Jackson, 2009; WHO, 2012). In Europe the market has grown 90% in the last 10 years, with business amounting to \$10.5 billion a year. Unfortunately, the consequences are not only economic, since the trade has increasingly detrimental impacts on public health. Indeed, there is a high probability that falsified medicines can be extremely harmful, and potentially lethal. As a direct result of consuming falsified medicinal products, individuals may experience unexpected side effects. Furthermore, the consumption of POMs (i.e. prescription only medicines) without a prescription from healthcare professionals may cause health problems such as addiction or the worsening of a medical condition.

Data gathered and processed by the Pharmaceutical Security Institute underline that reported cases rose annually from fewer than 250 in 2002 to more than 2000 in 2012. However, it is difficult to estimate the real extent of the phenomena because of the very high dark figure, and it is also very difficult to know how much is undetected (IMPACT, 2008): the problem is likely to be underestimated and the available data represent only the ‘tip of the iceberg’ (Dégardina et al., 2013; IMPACT, 2008). Moreover, it is very difficult to assess the number of victims: estimates range from

100,000 to 700,000 deaths per year (Harris et al., 2009; Bate, 2012). Therefore, the trade poses great dangers to public health, whilst reaping huge monetary rewards for criminal actors situated around the globe.

Modern information and communications technologies play a significant facilitating role in this illegal and dangerous market, and the Internet now acts as the main avenue through which it is expanding, particularly in Europe and in Western countries. Indeed, the falsification of medicinal products and the illegal online trade in medicines are two closely intertwined phenomena; and the World Wide Web represents the central hub for the illegal trade in falsified medicines (WHO, 2012). Internet usage enables criminals to sell potentially dangerous products on a large scale directly to buyers, whilst circumventing the legal supply chain. Recent figures reveal that as much as 50 per cent of the medicines bought online by UK consumers are fake (Walsh, 2011: 57) and 16 per cent of UK consumers have knowingly bought falsified or counterfeit medicines (Smithers, 2013).

Several studies have also pointed out that in recent years numerous illegal online pharmacies have appeared. Behind them there are brokers that facilitate the demand and supply mechanisms of medicinal products in order to circumvent national regulations (e.g. evading compulsory prescription) (Levaggi et al., 2009; Orizio & Gelatti, 2010). For example LegitScript estimates that among the tens of thousands of online pharmacies that operate on the Internet only about 5% are legal. Unfortunately, it is not always easy, especially for an untrained eye, to distinguish between legal and illegal websites. According to the European Alliance for Access to Safe Medicines, 62% of the medicines sold daily online could be falsified or be of poor quality. The risks linked to this criminal market are even greater today because customers seem to underestimate the danger. Indeed, 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.

Moreover, the online sale of medicines is often facilitated by social networks. Furthermore, the so-called

'deep web' cannot be ignored. It includes numerous dark net sites that are unreachable by normal browsers or through normal search engines, and can only be navigated using special software (e.g. TOR) that guarantees anonymity. The 'deep web' is increasingly used for illegal purposes, including the sale of illegal medicinal products. These Internet-based sales channels are often poorly supervised, facilitating the spread of falsified products.

At the same time, numerous fraudulent online pharmacies have appeared: these sites pretend to be legal, but are used to 'phish' sensitive data or personal information (e.g. credit card numbers) in order to resell and/or use them for illegal purposes (WHO, 2011). In this case there are no health risks; but the sites are dangerous because they are used to deceive potential purchasers of medicines online into giving information about their identity.

The EU legislator has intervened with European Directive 2011/62 to create "a Community-wide code on medicines for human use aimed at preventing the introduction of falsified medicinal products into the chain of legal procurement". The Directive also sets rules for online sales of medicinal products in European Union

countries: however, it has not yet been fully implemented by the Member States.

This scenario comprises a variety of complex issues: legal, technological, and health-based. Unfortunately, investigating and tackling this criminal market has proved to be very challenging for a number of reasons, among which: the scarcity of resources, the lack of a global harmonized legal framework and proper penalties, the transnational dimension of the market and the lack of adequate international cooperation, and the issues associated with the online dimension of the market.

In particular, systematic and in-depth knowledge on the online trade in falsified medicinal products is still lacking, with the result to jeopardize the preventive and control efforts of both law enforcement and other relevant institutions. Consistently, there is the need on one side to broaden the knowledge on this illegal market through synergies among universities, medicines regulatory agencies, law enforcement and relevant stakeholders; on the other to develop tools and counterstrategies to support the activities of the latter. Project Fakecare addresses all these issues, and in particular this report provides information both on the project and its research results.

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Abbreviations and clarifications



LEA: Law Enforcement Agency

OP: Online pharmacy

OTC: Over the counter medicines

POM: Prescription-only medicines

In this report, the technical term 'medicinal product' and the common terms 'medicine' and 'pharmaceutical' are used interchangeably. Moreover, the term 'Fakecare' will be used instead of the official title of the project 'www.fakecare.com'.



03

Project Fakecare

3.1 The project

In the European project ‘www.fakecare.com’ (herein-after referred to as ‘Fakecare’), a team of university researchers, supported by institutional actors and other relevant stakeholders, adopted a multidisciplinary and integrated approach (law, criminology, statistical and information science) in order to develop a more accurate picture of the online trade in falsified medicinal products, and to identify new tools for its investigation and prevention. Research activities were conducted by experts in seven European Member States, i.e. Bulgaria, France, Germany, Italy, Spain, the Netherlands, and the United Kingdom.

The project was coordinated by eCrime, the research Group on ICT, law and criminology of the Faculty of Law of the University of Trento (IT) in partnership with AIFA – Italian Medicine Agency (IT), RiSSC – Centre for Research and Studies on Security and Crime (IT), Teesside University (UK) (co-beneficiaries), and with the assistance of Interpol – Medical Product Counterfeiting and Pharmaceutical Crime Sub-Directorate (FR), IRACM – International Institute of Research Against Counterfeit Medicines (FR) and LegitScript (USA) (associate partners).

To achieve its aims, the project set itself the following general objectives:

- 1) to develop in-depth knowledge on the online trade in falsified medicinal products through traditional and innovative methods (for project results, see Chapter 4);
- 2) on the basis of this knowledge, to produce counterstrategies and tools to disrupt the trade (for project results, see Chapter 5);
- 3) to disseminate knowledge, counterstrategies and tools to stakeholders across the EU.

3.2 Methodology

In order to provide better understanding of the online trade in falsified medicinal products, a combination of more than one research strategy (qualitative and/or

quantitative) was used, and the results were collated at the level of interpretation, i.e. the findings from each technique were merged to derive a consistent outcome.

This research strategy is usually described as one of convergent methodology, multimethod/multitrait (Campbell & Fiske, 1959), convergent validation, or what has been called ‘triangulation’ (Webb et al., 1966). These various terms share the conception that qualitative and quantitative methods should be viewed as being complementary rather than rival. In other words, the researcher seeks convergence, corroboration, and correspondence among results obtained by means of different methods.

The triangulation design/methodology provides researchers with several important opportunities: 1) it allows them to be more confident in their results because it avoids methodological biases; 2) it can stimulate the creation of inventive methods, i.e. new ways of capturing a problem to balance with conventional data-collection methods; 3) it helps uncover the deviant or off-quadrant dimension of a phenomenon – i.e. different viewpoints are likely to produce some elements which do not fit a theory or model, so that old theories are refashioned or new theories developed; 4) divergent results from multimethod can lead to an enriched explanation of the research problem (Jick, 1979: 608-609).

However, the triangulation design/methodology is not exempt from shortcomings: 1) replication is exceedingly difficult since qualitative methods, in particular, are problematic to reproduce; 2) the research may not be clearly focused theoretically or conceptually; 3) triangulation should not be used to legitimate a dominant, personally preferred method, and each method should be represented in a significant way (Jick, 1979: 609); 4) collecting more data requires greater planning and organisation, which are resources not always available to researchers (Thurmond, 2001).

Accordingly, in order to provide better understanding of the online trade in falsified medicinal products, the following methods were adopted, and the findings of each method were merged to derive a consistent outcome.

Table 1 – Project Fakecare. Methods adopted

| Quantitative Methods | Qualitative Methods |
|--|---|
| Web survey | Virtual ethnography |
| Honey pot websites | Crime script of investigative and judicial cases and crime news items |
| Web content analysis of online pharmacies and customers' reviews | Legal framework analysis |
| | In-depth interviews with stakeholders |

Source: elaboration by eCrime – project Fakecare

3.2.1 Virtual ethnography

Some of the research data were collected via virtual ethnography in which traditional ethnographic methods – qualitative techniques used to interpret and detail in depth a set of practices via immersion in a given culture over time – were modified in order to interact in online communities and environments. This was done in both non-reactive and reactive ways (Janetzko in Fielding et al, 2008). Research began with a period of non-participant observation (sometimes referred to as 'lurking') whereby observations were made of online pharmacies (OPs), classified advertising sites and online marketplaces, as well as in public forums and social networking sites without direct interaction with users. This was an initial stage of data collection that gave the researchers opportunities to familiarise themselves with such a mass of information and specific interactions. Screenshots of images and text from forums, online pharmacies, social networking sites, and classified advertising were collected.

In the second step, the virtual ethnography included online fieldwork that made it possible to gain access to online communities (stage 1) such as social networks (e.g. Facebook, My Space, Twitter) and specialised sites (e.g. dedicated online forums) and obtain acceptance by the individuals participating in such virtual environments (stage 2). Data collection (stage 3) followed these two stages and involved collecting and evaluating sources such as text and images (non-participatory observation) and information gained from engaging in interaction with relevant actors (participatory interaction). In the latter case, the researchers were able to ask questions, thus ensuring better understanding of virtual communities by becoming members of them. Nevertheless, a distant virtual ethnography was conducted in most cases, mainly because forums have strict rules and regulations regarding discussions about medicines, and they are closely moderated, so that there was a risk of being banned from a forum if these rules were transgressed. Furthermore, in many cases there were already discussions or topics regarding the purchase of online medicines or falsified medicinal products.

In order to select the virtual environments to investigate, a literature review and online searches via Google were conducted to identify forums that related to specific topics linked to pharmaceutical consumption, such as: health forums, bodybuilding, sleep, weight loss, pro-anorexia, mental health, sexual health, men's and women's health, pregnancy and motherhood. Furthermore, several product names – such as Cialis, MMS, Testosterone, HGH, steroids, etc. – were used in order to find websites.

To avoid cross-posting and confusion, different user names were employed for each online forum. In addition to the forums selected for the analysis via specified search tools, the forum sample was expanded to include online forums identified through the 'snowball' sampling technique; moreover, references to some forums were obtained from observation of ones previously selected.

3.2.2 Crime script of investigative and judicial cases and crime news items from the press

The purpose of script analysis is to organize information that relates to a behavioural process into an event sequence. Specifically, crime scripts describe the essential stages of a criminal activity, making the decision points explicit. Criminal activities can be unfolded into separate but related phases to better identify the opportunity structures used during their commission. The focus is on the criminal activity rather than on the offenders and their motivations.

Hence, the online trade in falsified medicinal products can be seen as a process rather than as a single event because it involves stages in which resources and locations are required and decisions are made. Deconstructing the online trade in falsified medicinal products-related events into a structured sequence was performed within the crime script framework, which consists of four stages:

1. *Preparation*. Identification of the criminal opportunities. According to Tompson & Chainey (2011: 188), this stage requires consideration of opportunities to commit the online trade in falsified medicinal products (the ‘thinking thief’ approach);
2. *Pre-activity*. This step relates to the logistical or transactional instrumental actions that need to be taken prior to the activity;
3. *Activity*. This step relates to concrete actions necessary to carry out the trade in falsified medicines itself, which can take the form of various offences or non-compliance;
4. *Post-activity*. This refers to logistical or transactional steps necessary to leave the scene, i.e. the illegal activity.

For each case a document was created. It contained: a) a brief summary of the case; b) the script analysis scheme. For an example, see Annex D. Where possible, the characteristics of the product sold were summarized as well (type of medicinal product, its quality, chemical characteristics, etc.).

The researchers collected official reports, documents, etc. from LEAs, judiciary communities and crime news items on events related to the illegal online trade in falsified medicines. The cases to analyse were selected among the most significant crime events (i.e. those for which there was more information in terms of official documentation) that occurred between 2000 and 2015, trying to balance, if possible, between the more recent and the older ones. Thirty-seven (37) investigative and judicial case files were made available to researchers by the national medicinal agencies as well as by LEAs. Finally, seventeen (17) crime news items were selected from a press sample.¹

¹ A database of online news items related to the online trade in falsified medicinal products in seven EU Member States was created. Google search engine was used to collect the quantitative data. A preliminary search was run to identify a list of national newspapers furnishing the most relevant and representative data. The selection of online newspapers was guided by criteria such as (a) circulation, (b) frequency and (c) political alignment. The most widely disseminated weekly and daily national newspapers were selected. Only newspapers with online archives of records covering the selected time frame and providing information about the author, place and date of publication were chosen. A keyword search was conducted in order to find the most prevalent search terms that could be subsequently used to collect relevant news items for the database. The search started with the main keywords such as “fake medicines” and “online trade”. The search for keywords was aided by keyword suggestion tools offered by thesauri (e.g. The Merriam Webster Online Thesaurus). Moreover, not only keywords in English but also ones in six other languages of the EU Member States considered for the analysis were used. 17 items out of the 203 news items collected in the database were extracted for the qualitative analysis. Since the aim of writing

3.2.3 Web survey

In order to profile online pharmacies’ customers and thus obtain statistical information about the demand side, an extended web survey (using the CAWI method: Computer Assisted Web Interviewing) was conducted in the seven European Member States involved in the project (N=874).

The main problem with using a web survey concerns sampling bias, especially when the research requires a representative sample. In project Fakecare, because the web survey target was customers or/and potential customers that purchase online medicinal products, it was impossible to estimate the population and consequently to adopt a probabilistic sample. For this reason, it was extremely important to structure a solid dissemination strategy in order to identify as many (potential) customers as possible.

Adopted as a consequence was a convenience sampling, i.e. a non-systematic approach to recruiting respondents that often allows a potential respondent to self-select into the sample. First, the target group of respondents was identified and the most effective medium decided (e.g. Twitter, Facebook, health-related forum, etc.). Second, the diffusion of the web-questionnaire was monitored in order to adapt the dissemination process. Specifically, in the most important social and opinion hubs on the web concerning the purchase of medicinal products detected for each country involved in the research, the researchers posted: a forum thread and a page post in order to invite users to fill out the questionnaire. Moreover, academic partners, national regulatory agencies and other relevant stakeholders were involved in the dissemination process.

The questionnaire was developed using Limesurvey software – an open source platform for the creation of online questionnaires which is extremely flexible and able to contain the most complex questions of a survey. The web survey was available on the official website of the project (www.fakecare.com). Data were analysed using SPSS software.

The questionnaire was structured into three main sections: a) general opinions about the online trade in falsified medicinal products; b) specific questions

crime scripts is to provide insights into the online trade of falsified medicinal products, the choice of these particular news items was primarily driven by their potential to generate insight and provide a detailed account of the crime-commission process. Therefore, the news items were used to provide researchers with a comprehensive understanding of individual cases.

about the online purchasing of medicinal products by individuals; c) socio-demographic characteristics of respondents (see Annex C).

3.2.4 Honeypot websites

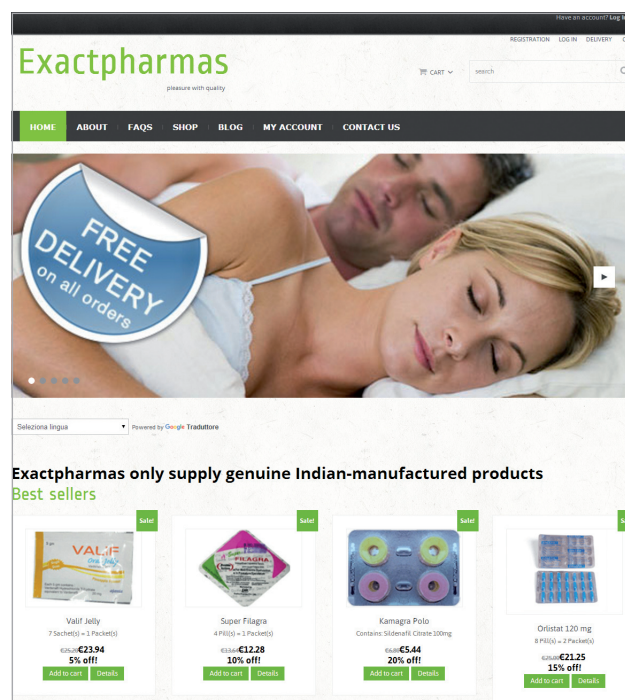
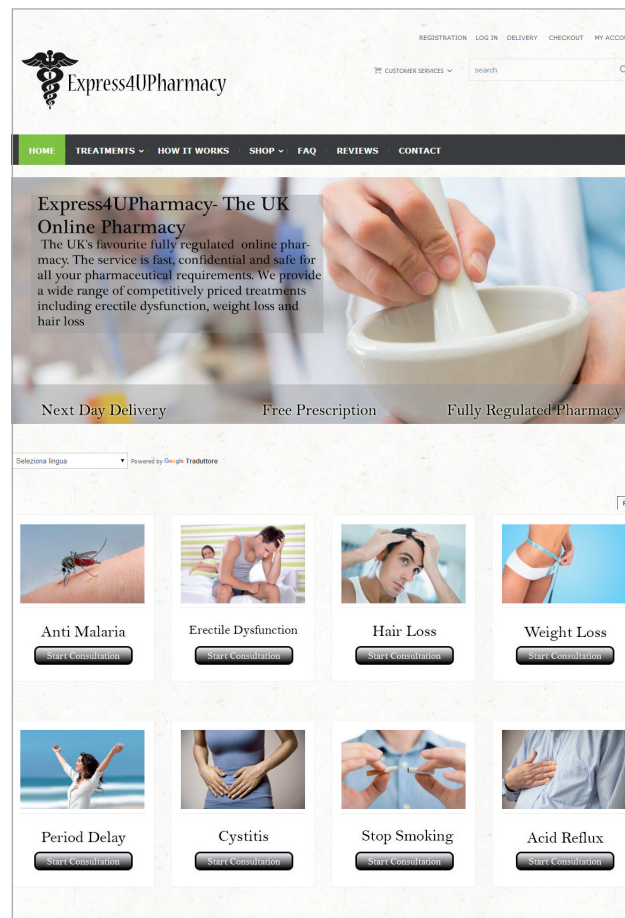
In order to attract consumers, automatically monitor their behaviour, and acquire further data to improve knowledge on the online trade of falsified medicinal products, 'honeypot' websites resembling online pharmacies were developed during the project. These websites were in two languages (English and Italian) and were live from 15 January 2015 onwards. At the end of the project, the websites were deactivated and removed from the Internet.

Research activities related to the honeypot websites were carried out with strict respect for ethical research principles, as well as all laws applicable (e.g. users' privacy). In accordance with EU regulations, on both websites there was a pop-up notification bar on the home page explaining the website's cookie policy, as well as how users could disable cookies collection. The privacy statement of the honeypots explained the aims of project Fakecare, gave the reason why data had been collected, and informed users about data processing methods and security measures. Furthermore, in the "terms and conditions" of the websites it was stated that honeypot URLs were the research names for project Fakecare, and that all the other terms mentioned in the page were only used for illustration purposes (it was expressly stated "we are a group of researchers who collect and analyse data from honeypot websites resembling legal and illegal online drug stores and provide awareness to consumers").

Since the honeypot websites were created purely for research purposes, it was not possible to purchase goods from them. At the same time, no payment processor or payment gateways were present in the websites. If users tried to complete a purchase, they were redirected to an awareness page explaining the dangers associated with the purchase of medicinal products via illegal online sources.

The websites were registered in the UK in the name of Teesside University, which was also registered as Data Controller under the Data Protection Act 1998 (UK) and was committed to protecting the privacy of all individuals visiting the websites. Data retrieved from the honeypot websites were used exclusively for the statistical and scientific purposes of the project, and were wholly anonymised so that individuals were not identifiable, not even indirectly. Moreover, no sensitive information about the users was collected.

Figure 1 – Home page of the honeypot websites. Project Fakecare



Source: elaboration by eCrime – project Fakecare

Table 2 – Description of variables and criteria used to collect information about legal/illegal online pharmacies. Project Fakecare

| Variable/Criteria | Description |
|----------------------|--|
| Location | Presence of the physical location of the pharmacy |
| POMs/No prescription | Not requirement of a legal prescription for POMs |
| POMs/Home | Presence of POMs in the homepage of the websites |
| Promoting | Presence of: promotions or offers on POMs / huge discounts for larger purchases / promotions of trials |
| Anonymity | Presence of anonymity warranty with regards to the delivery and the package |
| Testimonials | Presence of customers' reviews talking about their experience |
| Language | Presence of: multiple choice of translations of the site / misspellings and grammatical errors |

Source: elaboration by eCrime – project Fakecare

3.2.5 Web content analysis

Content analysis of online pharmacies

A quantitative descriptive analysis was conducted on the content of 50 legal and 50 illegal online pharmacies. Data were collected in a codebook checking the presence or absence of indicators that emerged from the literature review and from the previous activities of the project. The web content analysis enabled identification of characteristics that can be useful to distinguish legal online pharmacies from illegal/fake ones. The study was purely exploratory and did not use a representative sample, so that the results are to be considered solely with reference to the cases studied.

To select the sample of illegal pharmacies, a preliminary online search was conducted via Google using the keyword 'online pharmacy Europe'. Then, in order to verify whether the online pharmacy was legal or illegal, use was made of the FAST software – the ICT developed within project Fakecare and able automatically to identify illegal online pharmacies (for further information on the tool, see Section 5.1). Considered as 'illegal' was a website with a score greater than or equal to 80.

On the other hand, European legal online pharmacies were randomly selected from the official lists of legally-operating online websites available at national regulatory agencies websites. In order properly to organise the information collected from the content of the online pharmacies analysed, a matrix in the form of a coding database was created.

Content analysis of reviews by customers purchasing medicinal products on the Internet

A quantitative content analysis was conducted on reviews by customers purchasing medicinal products from (illegal) online pharmacies. The purpose was to gain better understanding of the demand and supply sides of the online trade in medicinal products. The reviews were collected via an independent company that verifies online pharmacies and compares prescription medicine prices. Online pharmacies were chosen on the basis of three main criteria: 1) number of reviews, selecting the most sites reviewed; 2) delivery in Europe; 3) the likelihood that the pharmacy was illegal or fake.² A total of 1,244 reviews were collected from 11 online pharmacies.

Statistical information was provided by the website about the ranking score (from 1 to 5) of customer satisfaction divided into the following components:

- product quality / site reliability (weighting = 40%)
- ease of website use and range (weighting = 5%)
- price (weighting = 30%)
- customer service (weighting = 10%. Optional)
- speed of delivery (weighting = 15%)

In order better to identify the sources of customer satisfaction and dissatisfaction, reviews were divided into two corpuses: negative (overall rating = 2.5) and positive (overall rating = 2.6).

² In order to verify whether the online pharmacies were illegal or fake, the websites were checked with the FAST software, considering as 'illegal' a pharmacy with a score greater than or equal to 80.

The content analysis focused on the textual part of the reviews in order to gain an idea of what consumers expect from online pharmacies. Before any treatment of the reviews, the text was purged of syntax errors in a semi-automatic way using the QdaMiner software. The reviews were then analysed using Wordstat software to produce statistical information such as word frequencies, similarity indexes, dendrograms, and word clouds.

3.2.6 Legal framework analysis

A comparative analysis of EU domestic legislation on the online sale of medicinal products and an assessment of the level of transposition by European Member States of the requirements established in Title VII A of European Directive 2011/62 were carried out in order to evaluate if legislative asymmetries still exist in the EU area and to quantify their extent. This was done on the basis of the criminological evidence that legislative asymmetries (in this case different regimes on the sale at a distance of medicinal products) may involuntarily generate gaps and loopholes of which criminals may take advantage. In order to conduct the analysis and the transposition assessment, relevant domestic provisions were collected from official sources and, when legislative texts were not available or available in languages not known to the researchers, interviews were conducted with members of national competent authorities.

The effectiveness of the EU common logo introduced by Article 85 quarter (3) of the European Directive 2011/62 was then evaluated using a criminological approach. For this purpose, a theoretical analysis was combined with a vulnerability assessment.

3.2.7 In-depth interviews with stakeholders

The information collected by qualitative and quantitative approaches was supplemented by in-depth interviews with relevant stakeholders. The interviews were conducted face to face, by telephone, or using ICT means (e.g. Skype, email, etc.). A total of sixty-three (63) individuals were selected in the European Union. Specifically:

- 10 consumers;
- 14 national and international LEA officers;
 - 8 fitness experts (personal trainers, athletes, etc.);
 - 7 traders/suppliers;
- 9 pharmaceutical company executives;
- 8 healthcare professionals (doctors, pharmacists, etc.);
- 2 drug workers;
- 3 national regulatory agency officers;
- 2 public prosecutors.



04

Knowledge

Using the research methods described in the previous chapter, project Fakecare acquired in-depth and systematised knowledge on the online trade in falsified medicinal products on:

- the demand side (see Section 4.1);
- the supply side (see Section 4.2);
- the patterns (see Section 4.3);
- the criminal opportunities involuntarily stemming from the EU legal framework (see Section 4.4);
- the vulnerabilities of the EU common logo for legally operating online pharmacies/retailers introduced by Directive 2011/62/EU (see Section 4.5).

4.1 The demand side

This Section focuses on the demand side of the online trade in falsified medicinal products, i.e. who are at-risk customers, their characteristics, their decision-making process, and determinant risk factors. More in detail, the purpose of the study was to answer the following research questions: who is at risk of buying falsified medicines online? What are customers' characteristics (i.e. socio-economic features, determinant risk factors, at-risk online social groups)? What are customers' motivations? What are customers' feedbacks about online purchases from illegal online pharmacies? What are the medicines most in demand? This information was acquired in order to accomplish Activity 1.3 of project Fakecare (i.e. 'Improving knowledge on the demand side'), and it was useful to draw up guidelines providing information and advice intended to prevent the online purchase of falsified medicinal products (for further information, see Section 5.2).

Customers' features, behaviours and motivations were investigated by means of virtual ethnography, as well as a web survey. Moreover, a quantitative content analysis was carried out on customers' reviews in illegal websites supplying medicines. Finally, in order to attract consumers, monitor their behaviours, and acquire further data to improve knowledge on the demand side, honeypot websites were created (for further information see Section 3.2). Country profiles about the demand side of the online trade in falsified medicinal products for each country involved in the project are provided in Annex A.

4.1.1 Who is at risk? Quantifying online medicine customers

Individuals at risk of buying falsified medicinal products on the Internet have been researched via a web survey in terms of who actually purchase medicines online. In particular, these data were collected delivering the

following questions: a) Have you ever bought medicines online?; b) Do you know other people who buy medicines online? The latter was chosen as a proxy variable in order to measure the indirect exposure to (falsified) medicinal products as an indicator of potential respondents' risks, as well as to mitigate social desirability bias. In fact, social desirability biases can induce individuals to answer questions about how they use the Web in a manner that they deem socially acceptable (Eysenbach, 2008: 123).

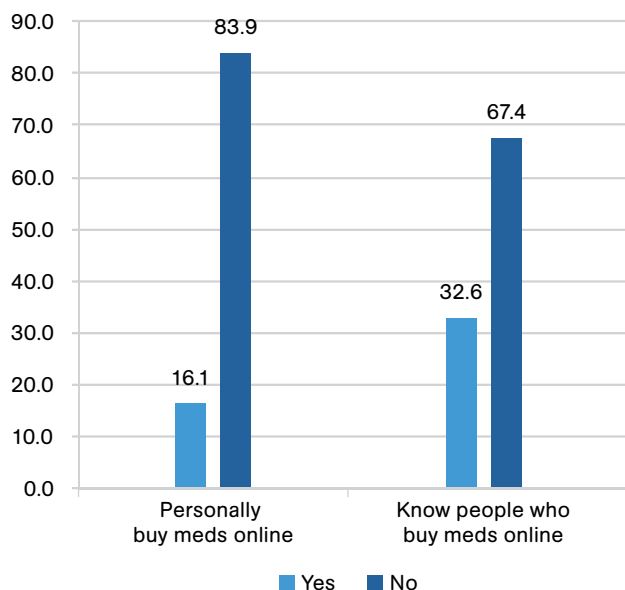
According to the results of the web survey, 16.1% of the respondents declared that they had purchased medicinal products on the Internet at least once in their life. When asked if they knew other people who had done so, the percentage doubled (32.6%), as illustrated in Figure 2. The first result was in line with those of other EU surveys: for instance, the Sanofi study (2014) showed that 18% of the respondents had bought medicines online in their lives. Although the second result seems to overestimate the number of customers, it should be considered closer to the respondents' real behaviour. In fact, as stressed above, this discrepancy could be due to the customers' tendency to answer in accordance with social norms. This bias is even more evident on analysing what types of medicinal products individuals declare that they have purchased over the Internet (see Subsection 4.1.6).

Most of the websites where individuals purchase medicinal products were found by means of an Internet search engine (69.2% of the buyers), followed by consultation of online forums/chat rooms related to medicines (14.6%). In addition, "friend's word of mouth" plays an important role in establishing, assuring and circulating the legitimacy of a seller (10.8%) (see Annex E, Table A6).

Furthermore, 2 out of 5 buyers declared that they had purchased medicines on the Internet at least three times in the last two years. The majority of individuals in this group (61.1%) had made one/two purchases, while only 15.9% had bought medicines on the Internet more than six times. Buyers were also asked if they were satisfied with their products: the majority (65.5%) said that they were very satisfied, while 5% declared that they were not satisfied (see Annex E, Table A7).

The decision by a customer on whether or not to purchase online medicinal products is a complex, multidimensional process. Both buyers and non-buyers are aware of the advantages and risks related to the purchase of medicines from illegal sources. And yet, if compared to non-buyers, buyers seem to be more informed: online buyers are proportionally more aware of the fact that the online trade in 'fake' goods may include pharmaceutical products (see Annex E, Table A8).

Figure 2 – Have you ever bought medicines online? (N=819). Do you know other people who buy medicines online? (N= 820). Percentages. Results of the web survey



Source: elaboration by eCrime – project Fakecare

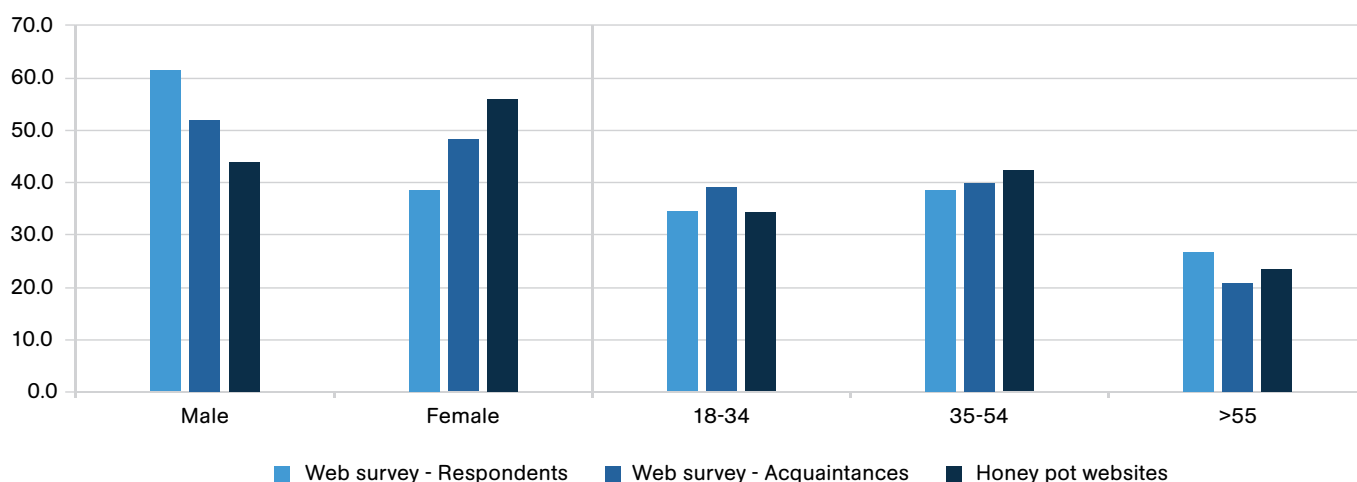
Furthermore, data from the honeypot websites confirmed that the search for and the purchase of medicinal products on the Internet are not niche behaviours among EU citizens. In fact, 5,197 individuals visited the two honeypot websites, and 16.9% of them returned more than once. Although the online promotion specifically targeted the United Kingdom and Italy, users came also from countries known to have illicit online medicines sales and trading activity, including China, Russia and Brazil (see Annex E, Table A9).

4.1.2 Who is at risk? Identifying socio-demographic features

For obvious reasons (i.e. anonymity, hidden identities and pseudonyms used by users in virtual environments), it is difficult to unpack the demographic variables via virtual ethnography. In order to profile customers at risk of purchasing falsified medicinal products on the Internet, the procedure combined the results of the virtual ethnography, the web survey results, and the demographics provided by Google Analytics in relation to the honeypot website users.³

³ In compliance with EU regulations, on the homepages of the honeypot websites there was a pop-up notification bar explaining cookie and privacy policies, and especially how users could limit use of the data. As underlined in Section 3.2.4, the data retrieved were used exclusively for the project's statistical and scientific purposes. They were wholly anonymised so that individuals were not identifiable, not even indirectly.

Figure 3 – Profile of the customers at risk of purchasing falsified medicinal products on the Internet. Sex and age classes by methods (web survey - respondents N=115; web survey - acquaintances N= 247; honeypot websites N= 611). Percentages. Results of the web survey and of honeypot websites



Source: elaboration by eCrime – project Fakecare

According to Rutter and Bryce, the consumption of counterfeit goods happens ‘across the entire range of age, sex and socioeconomic status’ (Rutter & Bryce 2008: 1158): this finding was supported by the results of the virtual ethnography. However, there are demographic differences in relation to specific pharmaceuticals. For instance, erectile dysfunction medicines are almost entirely purchased by men, while infertility treatments are chosen by women of a certain age struggling to conceive. Nevertheless, demographic quantitative data from the web survey and from the honeypot websites highlighted some further complexities in providing a profile of potential customers at risk of purchasing falsified medicinal products on the Internet (see Figure 3).

Sex

Triangulation of the project results showed that customers are at risk of purchasing and consuming falsified medicinal product regardless of sex. Indeed, while the web survey underlined that men are potentially more proactive in buying medicinal products online, the demographics of the visitors to the honeypot websites revealed the contrary (Figure 3). As already stressed, this result may have depended on the specific medicines that visitors were looking for.

The results from the virtual ethnography showed that women are at risk of consuming falsified medicinal products designed for weight loss, cosmetic, and fertility purposes – usually searching online for a cheaper option – while men are at risk of consuming fake erectile dysfunction or ‘bodybuilding’ products (see

also McDonald and Wearing, 2013: 39). These results are also confirmed by the fact that women usually visit online forums on weight loss.

Age

The likelihood of purchasing medicinal products on the Internet concerns all age groups, although resulting particularly high among the youngest. The quantitative data supported the hypothesis that people aged under 55 are the most likely to buy online medicinal products or to know someone who does so. Such individuals are also those who visited the honeypot websites more frequently, as illustrated in Figure 3.

In particular, young people and teenagers are at risk of consuming falsified medicinal products since they ‘are close to the age of onset of many drugs of abuse’ (Holloway et al, 2012). Moreover, they are very active online, particularly in social networking sites. Simply because these medicines are so readily available via the Internet, young people are more susceptible to buying and consuming them. On reviewing the literature and online conversations, it seems that young people and teenagers are significantly more exposed to the risk of consuming falsified medicinal products. Moreover, the determinant factors seem to overlap with drug diversion, whether for recreational drug use or drug misuse. This overlaps with issues of pricing and disregard for purity: young people seek out the cheapest option and are more willing to risk harmful outcomes related to the consumption of falsified medicinal products.

Education and socioeconomic factors

Education and socioeconomic factors have a weak influence on the likelihood of purchasing online medicinal products (for education, see Annex E, Table A10). For instance, the virtual ethnography showed that POMs may cost more when sold without prescription online. Consequently, customers could be induced to purchase medicinal products by other cultural and social determinant factors, such as avoiding shame and preferring to receive medicines at home in relative anonymity.

4.1.3 Who is at risk? Identifying determinant risk factors

In general, everyone risks purchasing falsified medicinal products on the Internet. Nevertheless, it is possible to identify some risk factors that may lead to dangerous behaviour:

Peer pressure and social acceptability

Lifestyle medicinal products are by far the most popular medicines sought by individuals online (see Subsection 4.1.6). This fact indicates a strong social determinant. Consequently, social criteria in terms of social acceptability and peer-pressure may play an important role in the formation of risk groups. Some personal stories found in the online forums monitored during the research support this hypothesis. For example, a woman suffering from hair loss wrote:

“ I've suffered from hair loss for a year, I've tried a lot of things - Mertz series Dukerey (anakaps, anastim, and anaphase) test Vichy, L'Oreal, Phyto. I've tried Kreschina, Priorin, Pregain, Revalid. Now I'm taking BioHtin, I cover my hair with garlic and pepper, pour on a tincture of nettle, burdock and chemrika, take a handful of vitamins daily ... the effect is nil. I've been to many doctors, hospitals, research centres - nothing - healthy as a hammer they say.... But I still have hair loss, half of my hair is gone, the hairs fall out rootless as if they've been cut off - if someone has an idea, advice - I'll accept everything. ... Tomorrow I'll try urine - that's all that's left. ”

[Bulgarian online forum]

Social determinants may induce males to begin using steroids, especially younger ones. For instance, a 17-year-old teenager recounted why he had started using

anabolic steroids at the age of 15, providing further insight into adolescent motivation:

“ I went to the gym because I had an inferiority complex that girls had more muscles than me and I was a 55 kg fat boy two years ago. Since I can remember, I've dreamed only of being a tough bastard. In my eyes and in other people's. ”

[Bulgarian online forum]

Awareness

A key prevention strategy is fostering awareness of the possibility of purchasing falsified medicinal products. Important deterrents are also knowledge and skills with which to identify – thanks to experience – or deduce from the online environment that risks or threats are possible (e.g. identifying a suspicious website, unrealistic claims, products well below market prices etc.). The virtual ethnography highlighted the frequency of posts in online forums giving patients/consumers incorrect information about the possible dangers associated with consuming medicines purchased from illegal websites:

“ 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 simultaneous use of more than one product. ”

[UK online forum]

“ I would give to everyone advice: don't order from India, America and other countries outside Europe. It's a waste of time, money and nerves. It is important that the delivery starts from a member country of the European Union. ”

[Italian online forum]

Self-rationalisation

An interesting aspect of the decision-making process involved in purchasing a potentially counterfeit, banned, or falsified medicine, was underlined, that is a self-rationalisation mechanism – i.e. a self-made justification for acting in a certain (negative) manner – was observed on several occasions. In order to justify a specific action, this process usually looked for the

weakest perceived link in the environment external to the decision-making process. For instance, the supposed lack of integrity of public authorities was used as an external justification for the use of a banned substance like sibutramine:

“ Substances are permitted and prohibited by economic interests, and not for other reasons..... And yes, Lida works, that is why they attack it. ”

[Bulgarian online forum]

Self-medication

It is widely accepted that self-medication plays an important role in health care; and with the continued improvement in people's education, general knowledge and socio-economic status, self-medication has been successfully integrated into many health care systems throughout the world. Responsible self-medication can be used to prevent and treat symptoms and ailments that do not need medical consultation or oversight. And yet, self-medication can also harm the customer or those seeking medical advice online. The virtual ethnography revealed that the Internet abounds with invitations or suggestions to try different combinations of products. For example:

“ Hello. I have contacted an operator of XX who told me that the xenical + reductil cure is possible, especially if you are not on a diet! I'll do a test, let's see how much I can lose in the next two months. Thank you, bye bye. ”

[Italian online forum]

4.1.4 Who is at risk? Identifying at-risk online social groups

Before buying, customers of online pharmacies usually consult various online forums. These are increasingly seen as places where one can ask for help, share experiences, and seek advice on choosing the most effective product or information about the dosage.

Depending on the specific pharmaceutical product and the intended use, this behaviour puts particular target groups at greater risk of social harm and/or makes them more willing to engage in deviant behaviour. In the websites or forums where these groups communicate with each other, there is evidence that medicines

are being advertised, and members sometimes discuss the use or availability of medicines on the Internet. The following groups were identified: (1) forum members discussing weight-loss supplements and medicines; (2) bodybuilding community members or, in general, people wanting to enhance their physical and sport performance; (3) forum members seeking to improve their sexual performance; (4) members discussing how to treat diseases like diabetes, hepatitis, cancer, arthritis, asthma, among others.

As regards the first group, some websites offered general tips on which medicines should be used and whether they were available. In some open forums, discussions about dangerous medicines were closely moderated. When someone asked for medicines or pills that could help them lose weight, the post was removed or adjusted in such a way that the name of the specific medicine was no longer visible. Nevertheless, this community was at much greater risk, especially because weight loss medicines are very popular for falsification. The virtual ethnography carried out in forum discussions and comment sections established that the overwhelming majority of the people engaged in such exchanges were females.

A second group observed consisted of body-builders. Their discussions were usually about androgenic and anabolic steroids. However, also other types of medicines could be of interest to them, for instance erectile dysfunctional medicines to cope with the effect of steroids. Their discussions made use of technical terms, although this does not mean that the participants knew the terms and technical prescriptions. The backgrounds of the participants could not be determined: we could not assess their expertise, but judging from the conversations, they seemed very familiar with the products' components, side-effects, recommended dosage, and consumption cycles. The most recommended and requested products were steroids, Epidrol and Gainer. Most noticeable in both forums was the recurrent topic of 'benzos' (benzodiazepines). These seemed very popular among users, even if discussions about the dangers of addiction were also present. Opiates for recreational use were discussed; surprisingly, however, lifestyle medicines (Viagra, etc.) had very few mentions.

In several forums, women shared their partners' problems by describing – subsequent – satisfactory encounters. Users gave opinions and information on: a) psychological needs, b) advice on the pharmaceutical products best for a specific problem, and c) recommendations of websites where the products could be found. Some of the individuals giving advice identified themselves as doctors, giving their medical board numbers and naming

the hospitals where they worked. Occasionally, if the product was sold in pharmacies, they stated that buying online posed no health risks. The most common products were Viagra, Cialis and Kamagra.

Individuals seeking treatments for serious diseases (e.g. diabetes, hepatitis, cancer, arthritis, asthma) formed the last target group. Though less common, there were webpages where information about treatments, natural substances, etc., could be found, together with recommended sites on which to purchase products. Information about clients was not available in forums and on open pages.

4.3.5 Customers' motivations

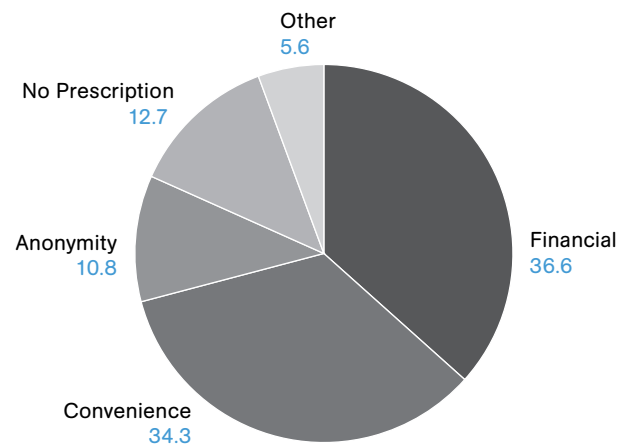
Overall, the virtual ethnography suggested that customers are induced to purchase medicines online by the following considerations:

- No prescription: it may 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 sex-related products) or because 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.

Moreover, web survey respondents who ordered medicinal products online were likely to cite convenience and cost savings as the main reasons for the decision to do so. Privacy was the least likely factor among the choices offered in the survey (Figure 4). In particular, the most important reasons for buyers to purchase medicines online were financial, i.e. there were cheaper medicinal products online (36.6%), home-delivery, i.e. it was easier to purchase online than at a traditional pharmacy (34.3%), followed by the ease of buying online without a prescription (12.7%) and by the guarantee of anonymity (10.8%).

Low prices may induce people to purchase medicinal products on the Internet as well. In fact, purchasers seem to worry about prices much more than the advice of pharmacists. The following remarks made by a user in an online French forum provide a good example:

Figure 4 – Reasons why individuals purchase medicinal products on the Internet. Percentages (N=213). Results of the web survey



Source: elaboration by eCrime - project Fakecare

“ Why do you think people buy medicines of this kind on the Internet? It's because their prices at pharmacies are excessive. In your report, it would have been wise to clarify this fact. Also specifying that they are not reimbursed by social security and, consequently, nor by supplementary health insurance. Do you really think that people want to poison themselves? I don't think so. If they visit these sites it's only because they do not have the means to buy the medicines at a pharmacy. ”

[French online forum]

As already underlined, POMs may cost more when sold without prescription online, even if, more generally, the research found that the cost of many products advertised online is considerably lower than the price charged by a pharmacy or any other store. Moreover, the greater the quantity ordered, the greater the discount offered. There follows a testimony collected from an Italian forum:

“ [You buy online] because you save; it is like buying directly from the supplier. If the product costs 80 euros at a pharmacy, from the supplier it will cost 45 euros. So those who buy online certainly do it just to save money. ”

[Italian online forum]

Online shopping offers a convenient and relatively anonymous way to remain in the comfort of the home and have goods delivered to the door. The convenience of an online diagnosis, purchase, and delivery in the privacy of the home has a particularly significant influence on the demand for so-called lifestyle medicines.

For the simple reasons of saving embarrassment, avoiding stigma, and obtaining cheaper prices, most people still prefer to order online, especially if they want lifestyle medicines. We discovered an entire blog devoted to 'good and cheap Viagra' where consumers tested products and gave feedback to others. Some websites used the competition among the better-known brands – Viagra, Tadalafil or Cialis – or comparisons among various active ingredients in medicines for erectile dysfunction to advertise consumer preferences.

Physical conditions that are considered shameful or humiliating may induce sufferers to try any suggested remedy. They thus become easy targets for the marketers of falsified medicinal products. For example:

“ 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’. ”

[Dutch online pharmacy chatroom]

Lastly, many forum discussions and posts revealed that consumers bought medicines via the Internet in order to feed a prescription medicines habit by ‘topping up’ their prescriptions because they had either become tolerant to their prescribed amount and required more or had reached the limit on the amount of prescriptions that a healthcare professional would issue. The misuse of prescription medicines is on the rise: those most commonly abused are opioids, stimulants and central nervous system (CNS) depressants or sedatives. The virtual ethnography highlighted numerous instances of prescription drug misuse where consumers had resorted to online methods. On occasion, online consumption was only one avenue used in order to buy large quantities of prescription-only medicines, and it could act as a factor multiplying addictive tendencies:

“ I’ve been taking them [Zopiclone] for years on and off, initially from my doctor...she had me on them for about 6 months, unknown to me was how addictive they were...a year on and I went weeks without a wink of sleep, I knew Zopiclone could help, so I found an Internet site I could get them from as my doctor would not prescribe me Zopiclone again”. ”

[UK online forum]

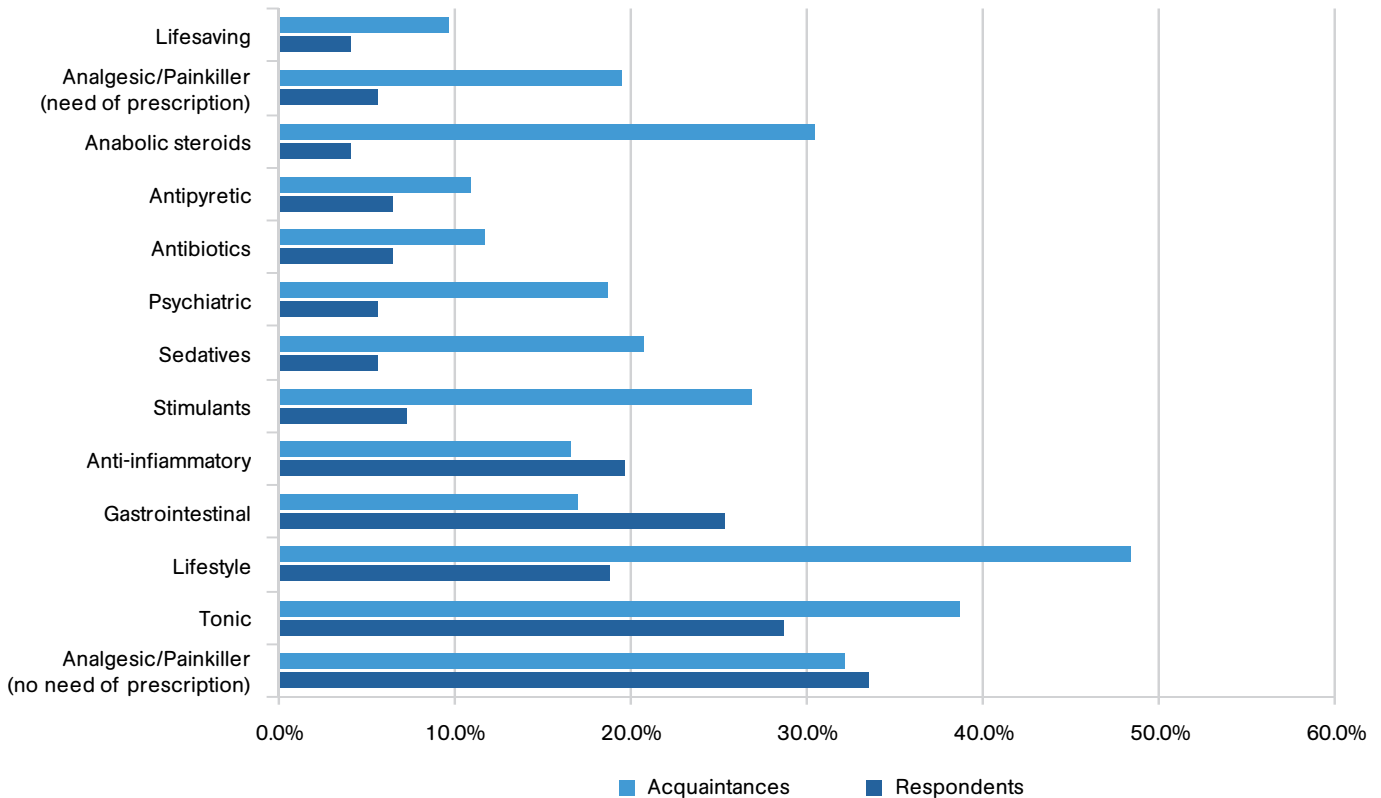
4.1.6 Types of medicinal products most in demand

In order to determine the kinds of medicinal products that respondents purchased on the Internet, two questions were administered: one on the types of medicines (OTCs; POMs; Both); the other on specific products (analgesic/painkiller; gastrointestinal; tonic; antipyretic; anti-inflammatory; lifestyle; psychiatric; lifesaving; anabolic steroids; antibiotics; stimulants; sedatives). The questions asked about purchases by both the respondents and their acquaintances.

37.1% of the respondents reported buying Internet POMs (23.5%), or both OTCs and POMs (13.6%), on the Internet. In regard to their acquaintances, the relative percentages increased considerably: 38.2% and 28.5% (see Annex E, Tables A11-A12).

Lifestyle medicines were by far the most popular products bought online. Nevertheless, respondents seemed more cautious about admitting to purchase of such products compared with their acquaintances (20.7% vs 50.0%). Another interesting result concerns anabolic steroids and psychiatric medicines, which are extremely frequently purchased online: the gap in percentages between respondents and their acquaintances was again significant (respectively 27 percentage points, 4.5% vs 31.5% for anabolic steroids, and 13 percentage points, 5.7% vs 18.7% for psychiatric medicines). Figure 5 gives a full overview of the products bought on the Internet by respondents and acquaintances. For further information on the types of medicinal products most sold on the Internet see Section 4.4.

Figure 5 – What kind of medicines have you bought online? (N=122). What kind of medicines have your acquaintances bought online? (N= 246). Percentages. Results of the web survey



Source: elaboration by eCrime - project Fakecare

The results gained through the analysis of the medicinal products that individuals searched for and attempted to purchase on the honeypot websites were in line with the results coming from both the virtual ethnography and the web survey. Indeed, the 10 most popular keywords searched on Google and Bing to access those online pharmacies concerned lifestyle medicines, such as slimming pills ('weight loss', 'lose weight') and erectile dysfunction medicines ('penis enlargement', 'erection', 'erectile dysfunction'). Figure 6 gives a full overview of the products most frequently searched using Google and Bing by visitors to the honeypot websites.

The honeypot websites were able to monitor also the potential customers' behaviour when entering the fake pharmacies. In particular, cookies trackers on the pages that they looked for and the medicines that they tried to purchase⁴ showed that lifestyle medicines

Figure 6 – Top 10 keywords searched online by users of the project Fakecare's honeypot websites. Google & Bing Campaigns

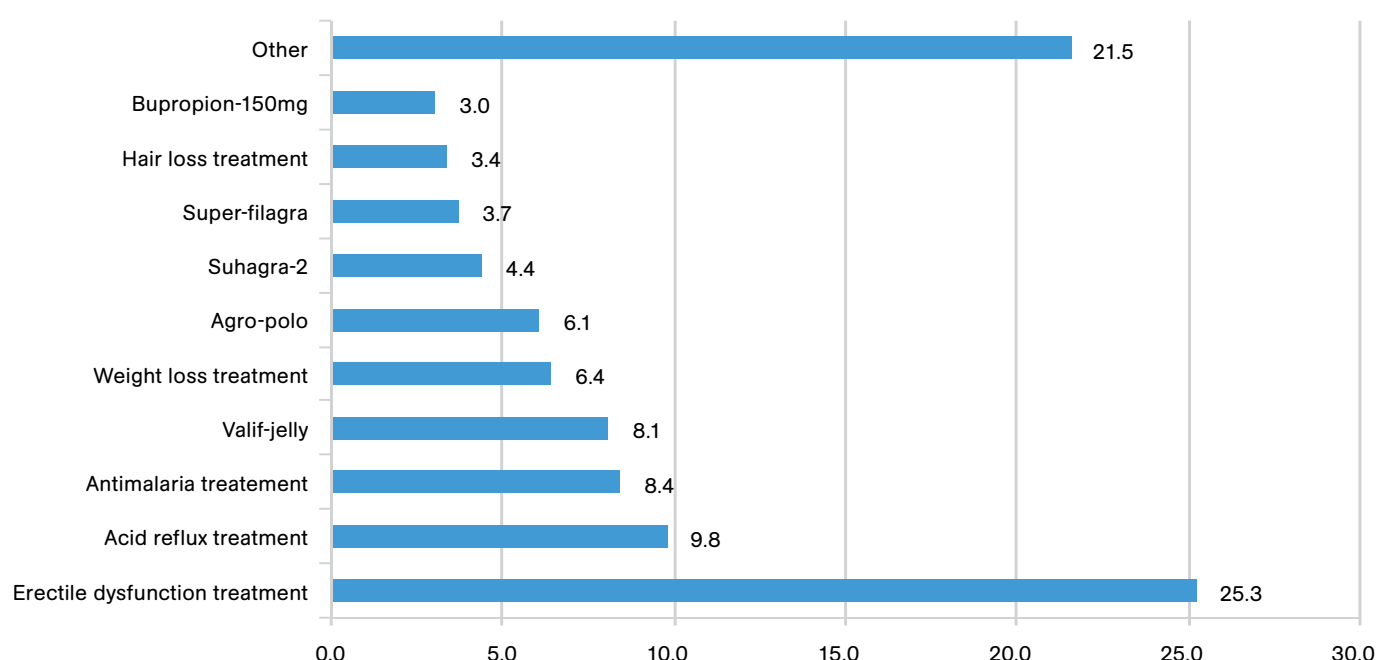


Source: elaboration by eCrime – project Fakecare

were by far the most in demand. Specifically, of the top 10 pages viewed, 47.6% concerned sexual enhancers (erectile dysfunction treatment, valif-jelly, agro-polo, suhagra-2 and super-filagra). Figure 7 provides a full overview of the products searched.

Despite the huge number of visits, only 31 purchases were attempted. They mostly concerned erectile dysfunction products (see Annex E, Table A13).

⁴ When the users proceeded to the checkout page, they were redirected to the awareness page, which explained the purpose of the project together with the privacy policy. In compliance with EU regulations, there was a pop-up notification bar on the home page explaining the website's cookie policy. For further information see Section 3.2.

Figure 7 – Medicinal products or health treatments searched for by customers on honeypot websites (N= 297)⁵

Source: elaboration by eCrime – project Fakecare

4.1.7 Customer feedbacks in illegal online pharmacies

In order to analyse the demand side of the online trade in falsified medicinal products, a quantitative content analysis was conducted on customers' reviews. The purpose was to determine opinions about purchases from illegal online pharmacies.⁶ The reviews were collected via an independent company that verifies online pharmacies and compares prescription medicine prices. The quantitative content analysis was conducted on 1,244 customers' reviews of 11 fake/illegal online pharmacies (see Section 3.2) following a three-step procedure: first, an overview of the review scores given by customers was considered; secondly, an exploratory analysis was conducted in terms of word clouds and word frequencies; third a cluster analysis of meaningful words was carried out using Jaccard's similarity index.⁷

The first step was to analyse the ratings (from 1 to 5) given by customers to the quality of the online pharmacy in regard to various aspects: delivery speed, product quality/site reliability, customer service, price, and the ease of website use and range. In order to identify which features of online pharmacies influenced the level of satisfaction and dissatisfaction, the reviews were divided into two corpuses – the negative reviews (overall rating = 2.5; n=918) and the positive ones (overall rating = 2.6; n=326) – and then analysed distinctly as well as jointly. The mean scores for each online pharmacy's features are set out in Table 3.

Features that seem most important for a good evaluation by customers are the ease of website use (mean=4.59) and product quality/site reliability (mean=4.51). This is consistent with customers' behaviour when they buy other commodities online, as established by studies on customer satisfaction with e-commerce (Lee Lin 2005; Capgemini 2015). In fact, customers commonly consider the website's design and the ease of its use as priorities when they buy online. The other characteristics are not statistically significant because their mean scores are around the

⁵ The following items were included in the category 'other': cystitis treatment, caverta, aurogra, orlistat-120 mg, penisole, kamagra-polo, period delay treatment, think baby sunscreen, kamagra, procordia, kyemagra+jelly, coppertone kids sunscreen, stop smoking treatment, avino baby continuous protection sunscreen, super-p-force or super filagra, suhagra, premature ejaculation.

⁶ Although it is possible that some reviews were fake, it is likely that criminals emulate the true attitudes of customers in order to attract them. Hence the results are not invalidated by this possibility.

⁷ The Jaccard's coefficient is a statistical measure used to compare the similarity and diversity of sample sets. It is computed from a four-

fold table as $a/(a+b+c)$ where a represents cases where both items occur, and b and c represent cases where one item is found but not the other. In this coefficient, equal weight is given to matches and non-matches. (Provalis Research, 2014: 65).

Table 3 – Mean score for each category by positive, negative, and total reviews. Results of the quantitative content analysis of customers' reviews in illegal/fake online pharmacies. N=1,244

| | Positive | Negative | Total |
|----------------------------------|-------------|-------------|-------------|
| Overall rating | 4.42 | 1.28 | 3.60 |
| Speed of delivery | 4.00 | 1.06 | 3.23 |
| Product quality/site reliability | 4.51 | 0.89 | 3.57 |
| Customer service | 4.45 | 1.23 | 3.62 |
| Price | 4.44 | 1.81 | 3.75 |
| Ease of website use and range | 4.59 | 1.93 | 3.89 |
| N | 918 | 326 | 1,244 |

Source: elaboration by eCrime – project Fakecare

overall rate. As regards the negative reviews, product quality (related to falsified medicines) and the speed of delivery were the features that received – on average – a low score. These results are consistent with the findings of the hierarchical cluster analysis (see below), i.e. the requirements for customers' satisfaction with other e-commerce commodities are the same as those found for the online purchase of medicines.

More features can be highlighted on analysing the word clouds of the negative and positive reviews, selecting the first and most frequent 100 words that appear in the review titles.

Figure 8 – Word cloud of positive review titles. Results of the quantitative content analysis of customers' reviews in illegal/fake online pharmacies

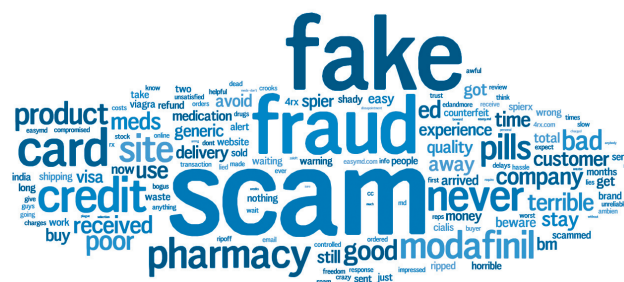


Source: elaboration by eCrime – project Fakecare

Figure 8 encompasses positive review titles; words like ‘great’, ‘good’, ‘excellent’ or ‘best’ are those that catch the attention. Yet also ‘experience’, ‘delivery’, ‘legit’ and ‘reliable’ seem to be written to promote the purchase and to underline positive experience with those online pharmacies. On the other hand, the second image (Figure 9) shows the words most frequently associated with a negative review: ‘fraud’, ‘scam’, ‘fake’, ‘pills’

and 'credit card'. As already stressed and according to other research (Mendoza, 2014), buying from illegal/fake websites exposes customers also to identity-related crimes like identity theft, credit card fraud, account takeover, etc.

Figure 9 – Word cloud of negative review titles. Results of the quantitative content analysis of customers' reviews in illegal/fake online pharmacies



Source: elaboration by eCrime – project Fakecare

A word that occurred frequently in both the positive and the negative review titles was “Modafinil”, a POM used to “improve wakefulness in patients with excessive sleepiness associated with narcolepsy or other sleep disorders” (Drugs.com). In fact, inspection of the reviews showed that Modafinil is also taken to increase or maintain concentration and stay awake longer (whether for business or study – see examples below).

“ This is awesome! The feel is so clear, no jitters, just fully alert and focused. So far so Good!! ”

(Review no. 45)

Table 4 – Most meaningful words appearing in the positive and negative customer reviews. Results of the quantitative content analysis of customers' reviews in illegal/fake online pharmacies

| Positive | | | Negative | | |
|----------|-----------|---------|----------|-----------|---------|
| | Frequency | % Cases | | Frequency | % Cases |
| Receive | 436 | 34.4 | Time | 168 | 29.8 |
| Service | 396 | 33.8 | Money | 147 | 27.9 |
| Good | 372 | 30.8 | Week | 127 | 25.5 |
| Work | 274 | 23.6 | Refund | 122 | 20.9 |
| Arrive | 270 | 24.2 | Never | 109 | 23.9 |
| Package | 261 | 19.1 | Service | 106 | 25.2 |
| Price | 258 | 23.4 | Charge | 100 | 22.1 |
| Generic | 221 | 18.6 | Wait | 95 | 19.9 |
| Quality | 221 | 21.0 | Month | 78 | 18.1 |
| Problem | 178 | 15.6 | Fake | 77 | 13.2 |

Source: elaboration by eCrime – project Fakecare

“ Well I've been taking the Modafinil (...) to have more time to study and I have noticed that they are quite effective. I'm able to stay awake a whole day without feeling like my mind wants to drift off to sleep. ”

(Review no. 133)

“ I had heard of Modafinil on a radio programme discussing the effects, use and abuse of the drug, and it occurred to me that it would be a good drug to get hold of to help me through my 12-hour long shifts as I struggle to stay awake at the end of the shifts and driving home becomes dangerous. ”

(Review no. 153)

These results match those found by other activities of the project (e.g. the web survey, the virtual ethnography, etc.): POMs to be used for other than their intended purposes are in great demand, as well as lifestyle medicines. Accordingly, Viagra and Cialis are the other two medicines that most frequently appear in both positive and negative reviews.

Analysing the word frequency within the entire text of the reviews yielded further information (Table 4).⁸ In the positive reviews, the attention centred on delivery ('receive', 'arrive'), the package, the price, the quality, and 'generic' medicines, presumably to save money (see Annex E, Table A14; Figure A2), and customers seemed to be driven by a price/quality ratio. In the negative reviews the attention was also concentrated on delivery 'timing' ('wait', 'never', 'month'); on 'money', associated with other frequent words like 'refund' and 'charge' (see Annex E, Table A14); and on 'fake' related to falsified medicinal products (see Annex E, Table A15).

⁸ Before analysis of the word frequency, the texts were 'purged' of syntax errors. The table presents the top ten most frequent meaningful words in the reviews (i.e. other terms like 'not', 'site', 'customer', etc., were excluded from data interpretation). The Frequency column shows the number of occurrences of a word within the overall text processed by the software. The % Cases column shows the percentages of reviews in which the keywords appeared.

Table 5 – Most meaningful words appearing in the positive and negative customer reviews. Proximity analysis. Results of the quantitative content analysis of customers' reviews in illegal/fake online pharmacies

| Positive Reviews | | | | | Negative Reviews | | | | |
|--------------------------------------|----------|-----------|---------|----------|------------------|-------------|-----------|---------|----------|
| Target | Keyword | Co-occurs | Jaccard | Strength | Target | Keyword | Co-occurs | Jaccard | Strength |
| 1. Quality | | | | | | | | | |
| Good | Quality | 99 | 0.263 | | Not | Good | 35 | 0.156 | |
| 2. Time of delivery | | | | | | | | | |
| Good | Time | 118 | 0.231 | | Not | Receive | 72 | 0.295 | |
| Shipping | Time | 81 | 0.188 | | Not | Arrive | 37 | 0.175 | |
| Fast | Shipping | 30 | 0.142 | | Package | Wait | 15 | 0.176 | |
| Fast | Delivery | 29 | 0.140 | | Problem | Wait | 14 | 0.169 | |
| Great | Shipping | 37 | 0.139 | | Problem | Time | 13 | 0.112 | |
| Fast | Service | 41 | 0.119 | | | | | | |
| Fast | Arrive | 29 | 0.108 | | | | | | |
| 3. Price | | | | | | | | | |
| Good | Price | 86 | 0.209 | | Not | Refund | 50 | 0.226 | |
| Great | Price | 60 | 0.206 | | Not | Charge | 39 | 0.165 | |
| Free | Shipping | 40 | 0.209 | | Scam | Payment | 8 | 0.157 | |
| Offer | Refund | 13 | 0.183 | | Scam | Refund | 13 | 0.149 | |
| Cheap | Price | 29 | 0.117 | | Scam | Money | 16 | 0.148 | |
| Price | High | 36 | 0.155 | | Fraud | Account | 5 | 0.125 | |
| Free | Charge | 17 | 0.129 | | Fraud | Bank | 6 | 0.120 | |
| | | | | | Fraud | Card | 10 | 0.081 | |
| | | | | | Fraud | Credit | 7 | 0.076 | |
| 4. Efficiency and reliability | | | | | | | | | |
| Not | Problem | 70 | 0.172 | | Not | Receive | 72 | 0.295 | |
| Offer | Refund | 13 | 0.183 | | Fake | Pill | 22 | 0.275 | |
| Excellent | Service | 54 | 0.162 | | Not | Refund | 50 | 0.226 | |
| Problem | Never | 30 | 0.141 | | Not | Contact | 47 | 0.212 | |
| Excellent | Company | 24 | 0.121 | | Not | Chat | 32 | 0.151 | |
| Free | Chat | 14 | 0.128 | | Fake | Review | 10 | 0.132 | |
| Reliable | Pharmacy | 28 | 0.108 | | Generic | Fake | 11 | 0.145 | |
| Reliable | Price | 27 | 0.103 | | Problem | Information | 7 | 0.132 | |
| Excellent | Offer | 9 | 0.077 | | Scam | Company | 13 | 0.109 | |
| Reliable | India | 11 | 0.072 | | Scam | Contact | 8 | 0.089 | |
| Satisfy | India | 11 | 0.078 | | Scam | Product | 9 | 0.087 | |

Source: elaboration by eCrime – project Fakecare

Inspection of occurrences of words in both positive and negative reviews (Table 5)⁹ showed that when customers buy from an online pharmacy, they pay attention to the following features: quality; time of delivery; price; efficiency and reliability.¹⁰ For instance, in regard to delivery time, customers are very careful about the shipping and the delivery speed, as demonstrated by several associations – i.e. ‘good/time’, ‘fast/shipping’, ‘problem/wait’ etc. Also, the efficiency and reliability of the online pharmacy are crucial criteria of evaluation; indeed customers want an excellent and reliable service, and evaluate the presence or absence of information, chat, and an efficient customer service – i.e. ‘excellent/service’, ‘excellent/company’, ‘reliable/price’, ‘not/refund’, ‘not/contact’, ‘problem/information’, etc. Customer service in particular is an important criterion of choice, and customers seem to prefer online pharmacies that offer reshipment and refund options if they are dissatisfied (Table 5), and reply to their questions on purchases of medicinal products.

These four main features characterize the demand side of medicinal products bought online. To be stressed is that such selection criteria are the same as those employed in customers’ decision-making on other commodities in e-commerce (Lee Lin 2005; Capgemini, 2015). According to these studies, customers search for faster delivery, broader choice, competitive prices and offers, detailed product information and customer service always available, ease of use, and secure payments. These are also the requirements of consumers when they buy medicinal products from online pharmacies.¹¹

⁹ This Section presents the results of exploratory hierarchical cluster analysis on positive and negative customers’ reviews using the Jaccard’s similarity index. The index was chosen for the proximity analysis of a selection of meaningful words, as well as for creation of the dendrograms. Proximity analysis provides the number of times a given keyword co-occurs with another one (CO-OCCURS). Meaningful words are chosen by looking at word clouds and word frequencies. The analysis provides the above-chance frequent occurrence in a text corpus of two terms alongside each other in a certain order. These are the so-called co-occurrences. For the proximity table the analysis was performed on words associated in the same paragraph; whereas in the dendrograms the analysis was performed on words associated in the same sentence. The associations on paragraph had a greater dispersion in the text compared to dendrograms analysis, which instead furnished a greater level of detail because they were performed on sentences. Therefore, these two levels of analysis were complementary, and dendrograms gave specific validation to the proximity analysis.

¹⁰ In retrospect, the most significant co-occurrences were grouped into broad categories already identified in other activities of the project in order to give them greater visibility and make them more understandable.

¹¹ These decisional criteria emerged in both positive and negative reviews: in the former as value, in the second as expectation betrayed – e.g. fast service vs. problem wait.

Considered below are some specific keywords chosen according to the literature, to other activities of the project, and to previous steps of the analysis (proximity analysis, word frequency, and dendrograms). In particular, the keywords considered are: ‘fraud’, ‘prescription’, ‘package’, and ‘fake’. Some quotations from reviews are reported in order to illustrate specific kinds of dangerous behaviour by customers that emerged from the literature and previous project activities. Such behaviours may influence the online purchase of medicines.

The terms ‘fraud’ and ‘scam’ are often associated especially with words relative to credit cards and bank accounts (see also Annex, Figure A1). But this is not surprising considering that all the sites analysed were illegal. This corroborates the finding of Mendoza (2014): that buying online exposes customers to health risks due to the probability of buying falsified medicinal products, and to identity-related crimes such as fraud, identity theft, account takeover, etc.

Further, it was found that several websites offered medicines in addition to those ordered, or they offered trial packs. Only very few purchasers understood from this that the pharmacy was probably illegal, while others did not consider it a problem; indeed, they regarded it as positive:

“ (...) and upon opening it was exactly what I ordered plus the free soft pill bonus for ordering so many at a time (92 100mg pills). I just popped half of one 20 minutes ago and the product is definitely authentic;.”

(Review no. 463)

“ I spoke on live chat to a consultant and she offered to send a trial pack to me obligation free! ”

(Review no. 169)

Second, attention was paid to two features already identified by the virtual ethnography and the web survey: ‘no prescription’ and ‘package’ for positive reviews (Table 6). With regard to “package”, it seems very important for customers to receive it in a “discrete” way, as described below (see also Annex E, Figure A4):

“ (...) product arrived in a nice discreet package. ”

(Review no. 218)

“ The discreet package arrived from India 13 days after I ordered and I had to sign for it. ”

(Review no. 959)

“ It comes in a discreet, white envelope with no return address and no statement of what is inside. ”

(Review no. 659)

With regard to ‘prescription’, it was apparent that numerous customers rely on these types of website to be able to buy POMs without prescription, or also to save money:

“ I’ve been using Freedom pharmacy for over 3 years, to buy my asthma meds without a prescription. ”

(Review no. 1040)

“ I don’t have insurance so going this route is actually cheaper than going to the doctor and getting the prescription. ”

(Review no. 372)

“ The package also included a piece of paper with instructions (in English) that read like a prescription, signed by a supposed doctor in Prague, but it was certainly not anything that an American pharmacy would accept as a prescription. ”

(Review no. 363)

Table 6 – Co-occurrences in positive reviews. Results of the quantitative content analysis of customers’ reviews in illegal/fake online pharmacies

| Target | Keyword | Co-occurs | Jaccard | Strength |
|---------------------|---------|-----------|---------|----------|
| Package | | | | |
| Good | Package | 60 | 0,15 | |
| Pill | Package | 43 | 0,15 | |
| Great | Package | 29 | 0,102 | |
| Prescription | | | | |
| Prescription | Doctor | 11 | 0,139 | |
| Prescription | Cheap | 11 | 0,113 | |
| Prescription | Not | 30 | 0,085 | |

Source: elaboration by eCrime – project Fakecare

4.2 The supply side

This Section focuses on the supply side of the online trade in falsified medicinal products, i.e. actors involved in the trade and their organisation, the illegal online distribution channels used, and the types of – falsified – medicines most frequently supplied.

More in detail, the aim of the research was to answer the following questions: who are the actors involved in the trade? How are they organised? What are the most popular sites? What tactics are used to advertise and market falsified medicinal products? What are the medicinal products most supplied through illegal online distribution channels? This information was acquired in order to accomplish Activity 1.2 of project Fakecare (i.e. ‘Improving the knowledge on the supply side’), and it was useful for devising innovative counterstrategies in the fight against the online trade in falsified medicinal products, such as guidelines to support LEAs during investigations and prosecutions (for further information, see Section 5.2), and to develop an ICT tool for the automatic verification of online pharmacies (i.e. FAST: for further information see Section 5.1).

The following research methods were used: virtual ethnography, web content analysis of the illegal online pharmacies, and crime scripts of investigative and judicial cases (for further information see Section 3.2). Country profiles on the supply side of the online trade in falsified medicinal products for each country involved in the project are provided in Annex A.

4.2.1 Actors involved in the online distribution of falsified medicines: features and structure

In the past two decades, the globalisation of markets (both legal and illegal) and new technologies have significantly changed organised criminal groups (OCGs). As underlined by Europol (2015), illegal online activities exhibit a decline of traditional hierarchical criminal groups and the expansion of more fluid, flexible and informal criminal networks (Europol, 2015). Accordingly, in Europe, there is no evidence on the involvement of traditional hierarchical organised criminal groups in the online distribution of falsified medicine. This is confirmed by Interpol, according to which globally only two traditional OCGs seem to be linked to pharmaceutical crime, and neither of them operates in Europe (Interpol, 2014). However, the project's results have shown one exception. Research in Bulgaria revealed that the supply of doping substances in that country is sometimes run by traditional OCGs, made up also of sportsman, and involved in other criminal activities.

The distribution of anabolic steroids was run by MMA professional fighters that were at the same time members of an organised criminal group involved in drug trafficking.

[Crime news item, BL]¹²

That said, it is possible to divide OCGs involved in the online distribution of falsified medicines into two groups:

- fluid, flexible, informal, sophisticated and well-organised transnational networks running large-scale operations;
- national-based small groups of offenders running small-scale operations.

As regards the first group, an interview with a law enforcement officer revealed that UK-based individuals may become involved in large-scale operations as 'drop shippers' by searching affiliated websites and answering adverts, some simply asking 'do you want to earn money?' Individuals expressing interest are then sent a template for an online pharmacy attached to one of the domain names bought in bulk by a large criminal operation from a legitimate webhosting company. The individual drop shippers then begin trading in falsified

medicinal products supplied to their home address by the criminal organisation. Small-scale sellers can therefore be linked to larger networks, even if only virtually.

A case analysed illustrates the inherently international nature of the criminals networks involved, and thus the difficult-to-prosecute nature of Internet crime activities:

A Belgium citizen operated a global Internet pharmacy, with a call centre in the Philippines, and a credit card processor in the Netherlands. His websites offered more than 40 prescription medicines, including brand names such as Viagra, Depakote, Glucophage, Zoloft, Lipitor, Cialis, Xanax, Ativan and Klonopin. This website accepted orders from buyers in the United States and elsewhere. He was arrested in Costa Rica and extradited to the United States after an extended undercover operation

[Crime news item, NL-USA]¹³

Moreover, in some of the cases analysed, the perpetrators were globally well connected and had access to multiple production sites of falsified medicinal products worldwide. These excerpts clearly demonstrate this point:

He was the mastermind behind a five-year plot to sell millions of fake Viagra and Cialis anti-impotence pills on the Internet. He smuggled the pills into the UK from secret factories in China and Pakistan through Dubai, Hong Kong, and the Bahamas. Some 117,000 fake Viagra pills were found at his home in Barwell, Leicestershire, UK.

[Crime news item, UK]¹⁴

¹² Source: "Mega Scandal with Lyubo The Hammer" (2013), at <http://www.mister.bg/24111/megaskandal-s-lyubo-chuka/>, 19 October.

¹³ Source: Sklamberg, H. (2014). "Counterfeit Drugs: Fighting Illegal Supply Chains" FDA, 27 February.

¹⁴ Sources: Mills, J. (2007). "Smuggler who made £5m from fake Viagra is jailed" Mail Online, 26 October. Boseley, S. (2007). "Made for Made for 25p, sold for £15. The fake Viagra that netted pill gang millions" The Guardian, 17 September. Simpson, A. (2008). "'King of Viagra' jailed for counterfeit drugs" The Telegraph, 14 October.

Immediately from the first wiretaps, it was possible to understand that the individual under investigation had strong international mobility. Indeed, he frequently travelled abroad, especially in Latin America (Paraguay, Argentina and Colombia) and in Thailand to purchase enhancing treatments. He also travelled frequently between Italy and the Canary Islands, his mother's place of origin.

[Investigative/judicial case, IT]

Criminal networks sometimes operate in two or more countries that are geographically close and with similar characteristics, such as legislation, culture and language (for instance, some criminal groups identified in Germany were also active in Austria). In this way, they can use the same *modus operandi*, storage facilities, packaging, and information.

Members of the crime networks frequently have semi-professional profiles. These individuals and groups already have some of the necessary infrastructure in place – businesses, contacts in the pharmaceutical industry, payment facilities – to assist them in the supply of falsified medicinal products.

The analysis of investigative and judicial cases highlighted that connections among criminal networks' members may be made among friends, business partners and/or family members even in large-scale operations. For example, in the United Kingdom a case involved a large group of friends and family members situated in different geographical locations in the UK and acting as a crime group. This case furnishes interesting details on the operational structure: the different roles played by each individual and team in purchasing stock from abroad, operating storage and packing units, supporting and maintaining the information and communications technologies used to advertise and trade online, or setting up and running front companies. Moreover, they could count on a network of friends living abroad and whose bank accounts could be used to launder money.

In 2004 the MHRA began an investigation into a large and complex business purported to be trading in fishing tackle, electric goods, cosmetics and jewellery. After a number of test purchases were made, they were also found to be selling both unlicensed and counterfeit erectile dysfunction drugs online. The operation was described as a 'jigsaw of individuals', male and female, who were members of a close knit group of family members and friends. Suspects were based in two teams: one in the North of England (Humberside, Lincolnshire) and another in the South of England (Brighton, London, Essex). Furthermore, a number of suspects who are yet to be charged are known to be living in Thailand, Greece, Turkey and Spain. The units and businesses implicated in the operation were based throughout the UK and the accounts and banking facilities across the globe.

[Investigative/Judicial case, UK]

As for payments, e-commerce has greatly simplified the process of buying and selling illicit goods. However, borrowing/renting friends' and family members' bank accounts or setting up offshore banking facilities are means commonly used to obscure the paper trail in online trade in falsified medicinal products. Moreover, payments are made by wire transfer or in cash upon personal delivery. In relation to doping products, the transactions are mainly carried out through gyms or other shops, using websites as additional platforms to conduct transactions.

Networks involved in large-scale operations are very difficult to track and target because of the flexible and informal nature of their crime structure. According to investigative and judicial case analysed, and in-depth interviews, such difficulties also lead to a lack of intelligence on the features of the OCGs involved in the online trade of falsified medicinal products. As Interpol (2014) recommended, a higher degree of international investigative and judicial cooperation is necessary to overcome this problem.

As regards small-scale operations, offenders often see opportunities to sell falsified medicinal products online through their day-to-day business activities and use infrastructure that they already have in place. For instance, in the investigative and judicial cases analysed in the United Kingdom:

- case 3 operated an online pharmacy alongside an Indian call centre and another retail business;

- case 4 involved gym owners/business partners who saw the opportunity to sell steroids and related prescription medicines used to ‘bulk up’ to customers at their gym before expanding their business online;
- case 6 concerned a defendant who was already involved in the pharmaceutical industry, operated companies as fronts, and was well-versed in the use of offshore banking.

In a German case, a compliant doctor prepared for a friend all the prescriptions needed to buy POMs which would then be sold online without prescription. Again, the son of an Italian pharmacist sold to a friend Viagra and other medicinal products to be used as recreational drugs. A case in the UK involved gym owners/business partners who saw an opportunity to sell steroids and related prescription medicines used to ‘bulk up’ to customers at their gym before expanding their business online. These existing businesses (gyms, shops, online shops) are used as front companies, and existing payment facilities are used for the illegal sale of medicines.

4.2.2 Illegal online distribution channels

A number of different online distribution channels used by offenders involved in the online trade of falsified medicinal products emerged. In particular: a) illegal online pharmacies, b) social media sites, c) online wholesalers

and classified advertising, d) email and spam, and e) cryptomarkets and the deep web.

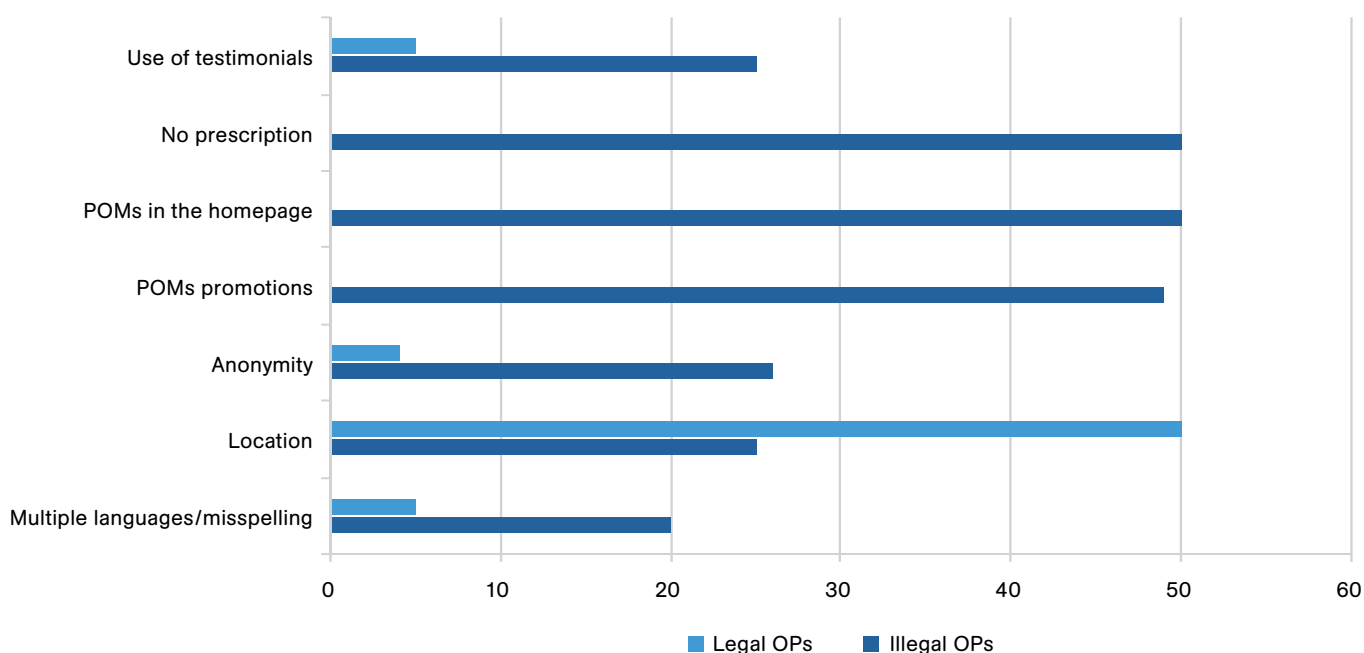
Illegal online pharmacies

The primary suppliers of medicine online are Online Pharmacies (OPs). These are pharmacies that operate on the Internet and deliver their products to consumers via shipping companies or postal services. There are huge numbers of illegal OPs (or ‘rogue OPs’) in operation.

Most of these sites offer POMs without a prescription, whereas others offer forged online prescription services which simply ask the customer to ‘virtually discuss’ their supposed health concerns with someone posing as an online doctor. Some sell only medicines used to treat erectile dysfunction, others a range of ‘lifestyle’ and ‘life-saving’ medicines. Yet others are initial points of contact before email discussions are generated and full product and price lists for an entire range of drugs, including pharmaceuticals and new research chemicals, are offered. Moreover, these sites often offer ‘special deals’ on large quantities of specific medicines and have delivery options and ‘agents available’ in a number of countries.

However, it can be very difficult for a customer to determine whether or not an online pharmacy is legitimate. Thanks to the content analysis of a sample of 50 legal and 50 illegal pharmacies, a number of features shared by illegitimate websites were identified allowing to distinguish between the two (Figure 10).

Figure 10 – Comparative analysis of the content of 50 legal and 50 illegal online pharmacies. Presence of specific features. Absolute numbers



Source: elaboration by eCrime – project Fakecare

Figure 11 – Examples of illegal online pharmacies. Italy and United Kingdom. Results of the virtual ethnography



Source: elaboration by eCrime – project Fakecare

The results can be summarised as follows:

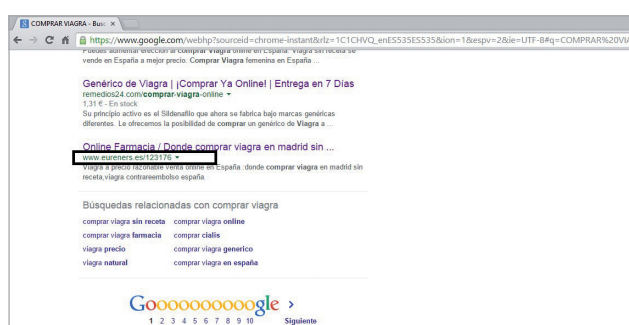
- Illegal online pharmacies never require valid prescriptions for POMs. Moreover, some illegal websites pretend to offer a valid prescription after an online ‘consultation’ with a – fake – doctor (for this purpose, customers are usually required to fill in an online questionnaire). However, this is only a ruse by the offender in order to gain customers’ trust. This indicator is one of the most significant in identifying illegal online pharmacies, as illustrated in Figure 10.
- Illegal online pharmacies always advertise POMs on the home page of their websites. Illegal online pharmacies not only offer POMs without prescription but also display such products on their home page in order to attract potential customers (usually displayed are the types of medicines most in demand, as illustrated in Subsection 4.1.6). All the illegal online pharmacies analysed had this feature.
- Only illegal online pharmacies present low prices, huge discounts for larger purchases, and promotions of trials in relation to POMs. Although products in illegal online pharmacies are not always cheaper than those sold in the legal distribution chain, other types of discounts or trial promotions are often present. According to the project’s results, 48 out of the 50 illegal online pharmacies and 0 out of 50 legal websites presented this indicator.
- Illegal online pharmacies often use testimonials. In illegal OPs there is a large presence of customers’ reviews stating opinions about the site. Hence, testimonials are sometimes used to enhance potential customers’ trust. All testimonials report positive experiences with the services provided, excellent performance, together with specific results of the products and satisfaction with deliveries. The customer reviews are often automatically translated, a further indicator that they are probably false. Testimonials are important because their objective is twofold: a) to show the benefits of purchasing online, and the good service and delivery offered (e.g. “I am satisfied with the quality of the service and products”, “prices are excellent”, “I received the products on time, as promised”); b) to counteract the possible concerns that clients may have about buying medicines online without a prescription. The testimonials play down the side-effects of the products, give recommendations about dosages, and proclaim the excellence of the products (e.g. “you saved my life guys”, “I feel alive”).
- Illegal online pharmacies often do not display a physical address. But the presence of indications of a physical location cannot be considered a relevant indicator with which to identify an illegal website, since illegal online pharmacies sometimes display a fake physical address.
- The text of the website usually contains misspellings and grammatical errors, especially in languages other than English. This indicator highlights the use of automatic translation systems.
- Most illegal online pharmacies guarantee anonymity. Illegal online pharmacies usually give an anonymity warranty about the delivery, and they promise discreet packages, trying to reassure people who resort to online pharmacies to treat problems about which they feel ashamed.

At times, not all websites are easily accessible; it may also happen that online searches are redirected to sites not related to online pharmacies. A legal link may be visible and when clicked, the user is automatically redirected to an online pharmacy. Research has discovered many legal websites (e.g. of universities, foundations, etc.) that appear when a search is made for products like erectile dysfunction medicines. This happens because, in order to achieve a visual impact, the illegal

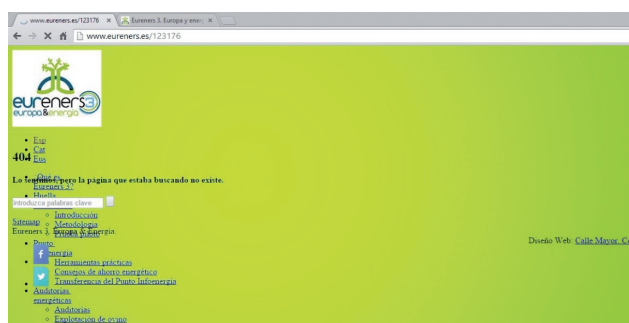
OP hacks the official website, taking advantage of its poor protection and management. The hackers introduce advertisements or names linked to products that they want to promote directly on the main pages of the websites. Such websites usually contain incorrect wording or repetitions of specific products. This enables them gradually to ascend the results pages of online search engines (e.g. Google). The screenshots below (Figure 12) provide an example of the abovementioned strategy. They break the process down into three specific steps:

Figure 12 – Example of hacker activities promoting illegal online pharmacies. Results of the virtual ethnography

Step 1: a link (www.eureners.es) is identified which originates from a page that is not related to the medicinal field.



Step 2: when the link is opened, the page shows the legal website but the content has been manipulated.



Step 3: the page changes and the user is redirected to another URL (www.spainmedcom.com) where medical products are sold illegally.



Source: elaboration by eCrime – project Fakecare

Social media website

Several social media profiles (including Facebook, Twitter and Instagram) were registered by researchers in order to gain better information on the supply side of the online trade in falsified medicinal products. Numerous examples of social media sites being used as online sites for supply were found. For instance, on Facebook, connections between sellers and buyers are established via friends' lists and groups affiliated to prescription medicines, or linked to subcultures in which prescription medicine use is prevalent and normalised. 'Friends' tend to post stock available directly on their wall or on the group page, often with photographic evidence of the product alongside their personal or business name, their contact details and the date. Some sellers use a variety of social networking sites to advertise their products. Virtual 'word of mouth' plays an important role in establishing, assuring, and circulating the legitimacy of a seller and the quality of the service offered, especially because users are concerned about becoming victims of 'scams' and being defrauded.

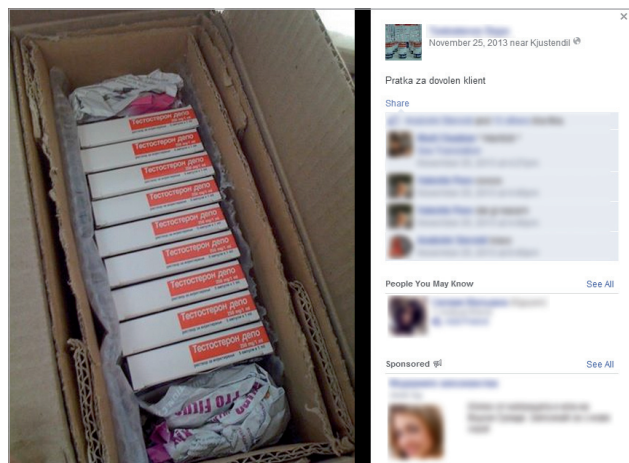
Also investigative and judicial cases show that the use of social media is an increasingly common strategy with which to sell medicinal products on the Internet, as well as to promote them. For instance, in an investigative case in Spain (the "Losa Operation") LEAs found that pharmacy technicians (Técnicos de farmacia hospitalaria) at a hospital in Madrid were marketing and distributing medicinal products via Facebook among cyclists and sportspeople.

Some sellers use several social networking sites to advertise their products. Moreover, drop shippers use a variety of online sites (email, Facebook, OPs) interchangeably to market their products, usually bought in bulk from distributors. For example, initial links made between buyers and sellers on social media sites can direct buyers to OPs and/or lead to more detailed email conversations about the products. This also explains why some sellers offer free samples or added extras in order to market particular products that they have in stock and need to sell. Other actors using social media are small-scale amateur sellers, sometimes also users/consumers of prescription medicines, a 'virtual' role that seems to mimic the 'real' street-level dealers involved in illicit drug distribution.

In order to show how social media are increasingly used to accelerate the distribution and trade of falsified medicinal products, presented below as an example is the case of Bulgaria. In the space of one month, a fake Facebook profile created by the Bulgarian expert befriended 54 people, mostly interested in steroids, and

concerned with weight-loss, fitness and body-building issues. Over 150 pages were liked and followed, many of them explicitly offering and/or advertising potentially falsified medicinal products, such as anabolic steroids and slimming supplements, including Lida, Lipovon and Meizitang.

Figure 13 – Example of the advertisement and sale of anabolic steroids on Facebook. Results of the virtual ethnography



Source: elaboration by eCrime – project Fakecare

Several profiles and Facebook pages were associated with a web-shop offering the aforementioned products. This outcome was expected: Facebook as well as

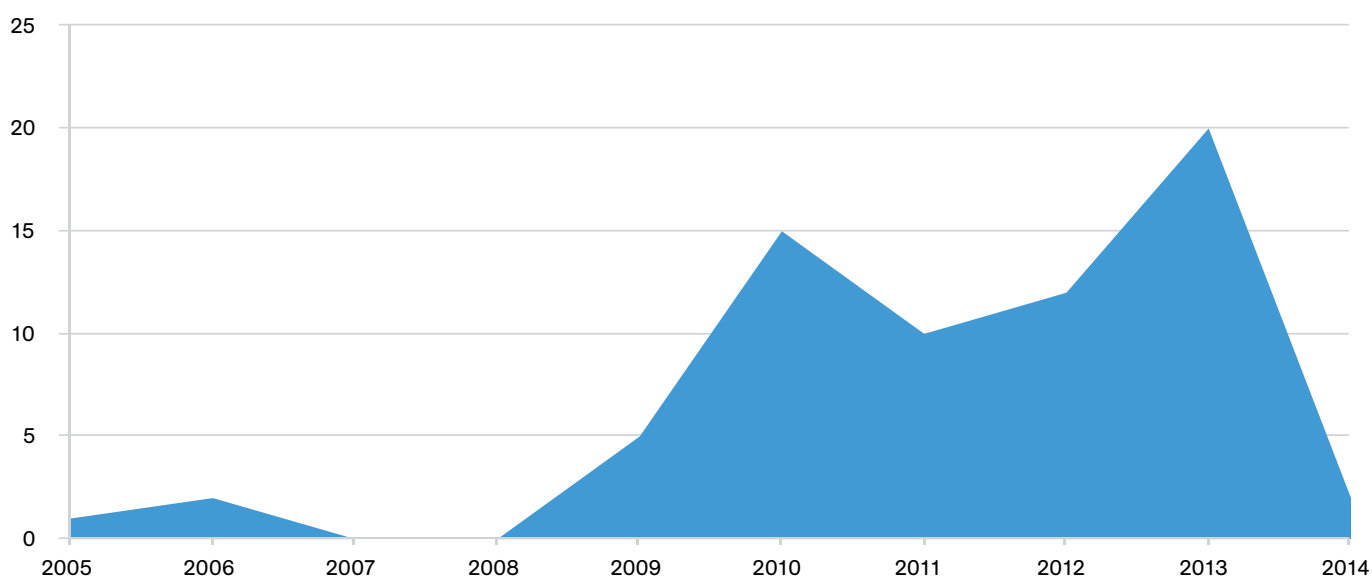
other social media have been increasingly involved in marketing efforts within a broad array of fields. Perhaps most striking and unexpected was the fact that a large number of individual profiles – not web-shops or pharmaceutical companies or importers – were involved in the distribution of anabolic steroids. These Facebook profiles use the networking power of the social media to advertise and sell anabolic steroids: they post images and publicly share information about the product. As soon as such a profile is friended and/or followed, the user starts receiving invitations to befriend and like a multitude of similar profiles. Prices are also publicly available. However, discussions on specific matters are kept private through the messaging function.

The analysis of web-page contents and profiles showed a clear and upward trend in the use of Facebook to market and distribute anabolic steroids. The customers targeted were generally adolescent males (15/16 years of age) and heavy users of Facebook. Moreover, the research results showed that it is easy for them to be reached and exposed to potentially dangerous substances. The Bulgarian case clearly demonstrates the problem, as illustrated in Figure 14.

Online wholesalers

The research found suppliers selling large quantities of illicit pharmaceutical chemicals, materials, equipment or finished medicinal products in legally-operating online marketplaces, thus violating the terms and conditions of those websites.

Figure 14 – Number of Facebook pages and profiles in the Bulgarian language with advertisements or discussions about anabolic steroids and fitness supplements. Period 2005-14. Results of the virtual ethnography



Source: elaboration by eCrime – project Fakecare

UK researchers found large quantities of powdered Active Pharmaceutical Ingredients (APIs) under their generic names. For example, Zopiclone, a non-benzodiazepine, which is a Sanofi Aventis patented product, was being sold in a powdered form in 1.000 kilo quantities directly from a chemicals company based in mainland China. Moreover, the equipment needed to press pills at home was also for sale (see Figure 15).

Figure 15 – Example of a legally-operating online marketplace fraudulently used to sell medicinal products. Results of the virtual ethnography

The screenshot shows a product listing for 'Zopiclone intermediates 43200-81-3' on a B2B platform. The listing includes a company profile for 'Zhejiang Chemicals Import & Export Corporation', a large image of a white powder in a container, and detailed product information. The product details section lists CAS No. 43200-81-3, EINECS No. 203-254-2, Purity 99.8%, and Appearance: white or light Aromatics Compounds/yell... Other Names: 6-(5-CHLOROPYRIDIN-2-YL)-5-HYDROXY... MF: C7H9NO, Type: Agrochemical, Brand Name: zhechem, Model Number: BP/USP. The packaging and delivery section states: Packaging Detail: 25kg/ woven bag or required, Delivery Detail: ready stock. The listing also shows a price of US \$350 - 450 / Metric Ton, a minimum order quantity of 1000 Kilogram/Kilograms, and a supply ability of 10000 Metric Ton/Metric Tons per Year. The port is listed as Shanghai, and the payment terms are L/C,D/A,D/P,T/T. There are buttons for 'Contact Supplier', 'Chat Now!', 'Start Order', 'Add to Inquiry Cart', and 'Add to My Favorites'.

Source: elaboration by eCrime – project Fakecare

Marketplace websites do not usually have a specific category (like books/cars/toys) for medicines, but when specific search terms are used, some pages usually appear under the category 'miscellaneous'. The amounts of advertisements and types of medicines offered on these websites are far smaller than those on the OPs.

Online marketplaces are used by both low-turnover individual retailers and online shops to advertise and offer mostly falsified slimming pills, erectile dysfunction medicines, and steroids. Payments are made in cash upon delivery. In many cases, especially if the seller is an individual without the support or association of an online store, a meeting is arranged for the transfer of the goods and payment.

For instance, in an online marketplace in Bulgaria, researchers found an advertisement posted by a woman regarding a medicinal product containing sibutramine (see Figure 16). Although sibutramine is an illegal substance, the seller had displayed her name, telephone number, and location. When the researcher asked if the products were dangerous, she responded that 'all

pharmaceutical products may have side effects and if a person is healthy there should not be any problems, apart from the usual palpitations'.

Fig. 16 – Example of a legally-operating online marketplace fraudulently used to sell medicinal products containing sibutramine in Bulgaria. Results of the virtual ethnography

The screenshot shows a Bulgarian online marketplace advertisement for 'Sibutramine Hydrochloride Monohydrate Capsules 15 mg'. The ad is titled 'Продавам китайски добавки за отслабване' (I am selling Chinese supplements for weight loss). It includes a photo of a box of 'Reduce-15mg' capsules and a blister pack of yellow capsules. The ad text mentions 'Публикувано на 03 Ноември в 18:01 ч.' (Published on 03 November at 18:01) and 'Управление на обявата, Обявата е видна 68 пъти' (Manage the ad, The ad is visible 68 times). There is a search bar and a 'Направи VIP' (Make VIP) button. The price is listed as 'Цена 36 лв.' (Price 36 BGN) with a 'Купувам!' (Buy!) button.

Source: elaboration by eCrime – project Fakecare

Email and spam

A typical way in which illegal online pharmacies promote their business is through spam emails. According to Kaspersky Lab,¹⁵ in 2014 the proportion of spam in email flows was 66.8%; and in 2013 Symantec (2014) reported that pharmaceutical spam accounted for 18% of all spam. The top spam emails are those promoting erectile dysfunctions medicines and OPs. Moreover, according to the Spamhaus project¹⁶ update in July 2015, Canadian Pharmacy is the first among the world's 10 worst spammers and spam gangs.¹⁷

¹⁵ Source: <https://securelist.com/analysis/kaspersky-security-bulletin/69225/kaspersky-security-bulletin-spam-in-2014/>.

¹⁶ The Spamhaus Project is an international nonprofit organization whose mission is to track the Internet's spam operations and sources, to provide dependable realtime anti-spam protection for Internet networks, to work with Law Enforcement Agencies to identify and pursue spam and malware gangs worldwide, and to lobby governments for effective anti-spam legislation.

¹⁷ When the popular press was covering the price advantage of Canadian pharmacies, a large number of Internet pharmacies, including those not based in Canada, exploited the opportunity to gain consumer trust by presenting themselves as Canadian pharmacies (Ivanitskaya et al., 2010).

Spamhaus described Canadian Pharmacy as:

“ [...] a long time running pharmacy spam operation. They send tens of millions of spams per day using botnet techniques. Probably based in Eastern Europe, Ukraine/Russia. Host spammed web sites on botnets and on bullet-proof Chinese web hosting. ”

Spam activities promoting pharmaceutical products are widespread, particularly in relation to medicinal products for erectile dysfunction. The current volume of unwanted email messages demonstrates an increasingly active collaboration between spammers and hackers. The activity of spammers is well structured: they use specific programs to generate and send billions of emails a day; an activity that requires a huge amount of time and money. An average mailing list used by offenders involved in spamming contains approximately a million email addresses. Their aim is to send the maximum number of messages within a minimum amount of time, before being identified and blocked by anti-spam software.

As said, during the virtual ethnography, numerous introductions to sellers made via social media were continued by email discussion. Many claimed to be based in the UK, Pakistan or USA, and offered a wide range of medicines, including pharmaceuticals, anabolic steroids, new chemicals, and well-known illicit products used for recreational purposes.

Cryptomarkets and the ‘Deep Web’

So-called ‘online black markets’ constitute another distribution channel for falsified medicinal products sold on the Internet. Designed for online anonymity, Tor (or The Onion Router)¹⁸ offers layered encryption to buyers and sellers. It is a network designed to pass IP addresses and carry out web transactions through numerous relays, using random and anonymous URLs in order to conceal users’ locations and Internet activities. Once Tor is accessed, buyer and seller trade in digital currencies, such as Bitcoin,¹⁹ and use data encryption and decryption tools to encrypt and decrypt messages. This has provided distributors of falsified medicinal products with a relatively anonymous and unregulated online marketplace. Indeed, the researchers found numerous

sellers of POMs, steroids, and other illicit medicines on the deep. As an example, Table 7 illustrates the case of the German market.

Given that the user base is growing, the Tor Network might be an interesting option for many suppliers, since it provides even more anonymity than the regular and open websites. The Tor-network and black-marketplaces, such as Silk Road 2.0/3.0, are not yet popular among the general public. But considering the anonymity of the Tor-network, in the near future it may become a popular channel for the sale of falsified medicinal products.

Online forums

Criminal entrepreneurs involved in the falsified medicine online trade exploit discussions in Internet forums in the knowledge that potential customers tend to be more interested in a product if it is perceived as ‘authentically’ endorsed. Online forums also allow the rapid transmission of messages and information about products to a much wider audience. Criminals involved in the trade who pose as consumers can manipulate this process, or do so more directly via the use of affiliates.

For instance, identical repetitive comments with links to websites selling ‘Lida’ slimming pills have been posted in several Bulgarian online forums. The comments reported in Figure 17 have been posted in at least 15 different forums.

Figure 17 – Example of posts in a Bulgarian online forum advertising ‘Lida’ slimming pills. Results of the virtual ethnography



Source: elaboration by eCrime – project Fakecare

¹⁸ For details on the technical features and *modus operandi* of the Tor network see McCoy, et al. (2008).

¹⁹ Bitcoin is a peer-to-peer electronic currency system. See Reid & Harrigan (2013) for an overview of the technical aspects.

Table 7 – Medicinal products sold via the online black market in Germany by category, products, price, time of shipping and description. Website: Silk Road 3.0. Results of the virtual ethnography

| Category | Product | Price | Shipping | Description |
|-----------------|---|---------------------------|----------|---|
| Adentipressants | Escitalopram 10mg x 50 tabs (CIPRALEX) | € 86.839/ 0.334530 BTC | 5 days | Genuine, from Europe, not expired (“like what some vendors supply”). Only within EU, 100% success rate |
| | 1xMirtazapin 15 mg TAD Pharma | € 4.5705/ 0.017606 BTC | 2 days | Only to Germany |
| | 1xMirtazapin 30 mg 1A Pharma (deutscher Hersteller) | € 6.3987/ 0.024649 BTC | 2 days | Only to Germany |
| Stimulants | 30mg Methylphenidat - Medikinet | € 15.539/ 0.059863 BTC | 3 days | Only to Germany. Pills sent in envelopes between two sheets. Language: German |
| Sedatives | Lorazepam 2.5mgx30tabs (ATIVAN) | € 73.128/ 0.281709 BTC | 1 day | Genuine, from Europe, not expired (“like what some vendors supply”). Only within EU, 100% success rate |
| | Oxazepam 10mgx30tabs | € 68.557/ 0.264103 BTC | 5 days | Genuine, from Europe, not expired (“like what some vendors supply”). Only within EU, 100% success rate |
| Opioids | 1x8mg ORIGINAL SUBUTEX ! Germany ! no nasty naloxon ! | € 30.165/ 0.116205 BTC | 2 days | We was Vendor from Germany and new here. You can see a lot of german feedback, when you wont. All tablets offered by me come directly from German Pharmacies! Original, good. “http://imagexutrag65hxl.onion/image.php?Di=” |
| | Chloprothixene 50mgx30tabs [STRONG OPIOD POTENTIATOR] | € 50.275/ 0.193675 BTC | 5 days | Genuine, from Europe, not expired (“like what some vendors supply”). Only within EU, 100% success rate |
| | SUBUTEX - Original Buphrenorphine - 7x8mg ! 24H Delivery from Germany | € 169.10/ 0.651454 BTC | 2 days | We was Vendor from Germany and new here. You can see a lot of German feedback, when you wont. All tablets offered by me come directly from German Pharmacies! Original, good. “http://imagexutrag65hxl.onion/image.php?Di=” |

Source: elaboration by eCrime – project Fakecare

4.2.3 Supplying and marketing strategy

Criminals use different methods to offer and advertise medicines. Although the Internet is still the primary tool for both supplying and selling, the online trade in falsified medicinal products may come in many forms. On-line purchases are delivered by two main vectors: first express freight, and second postal freight, given that a large percentage of online buyers choose 'home deliveries'. The crime networks have distributors which use couriers to deliver products previously acquired online or by telephone. In regard to doping products, however, the transactions are mainly carried out through gyms or other shops, using websites as additional platforms for transactions. A case investigated from 2010 to 2012 in the Netherlands provides a vivid example of a site specialized in falsified medicinal products:

On 9 December 2010, Eli Lilly and Company received a notification of a consumer regarding counterfeited Cialis, sold on the website [www.Super\[xxx\].nl](#). An undercover investigator hired by the pharmaceutical company bought 20mg Cialis as a test purchase to establish if the products were counterfeited. The website was owned by a fake identity, who ran an administrative single man business company. However, the bank account was registered to another identity. The website from which the medicine was sold [www.Super\[xxx\].nl](#) was temporarily secured. On December 20th, 2010 a second notification from Eli Lilly and Company was forwarded; this time counterfeited Cialis was sold on the website [www.Erectie\[xxx\].nl](#). On 28 February 2012, the case was closed for it expired. Both [www.Erectie\[xxx\].nl](#) and [www.Super\[xxx\].nl](#) are still active.

[Investigative/Judicial case, NL]

The illegal trade in falsified medicinal products is dangerous also because falsified products are not only sold on the Internet but may also enter the legitimate distribution chain. The MHRA, for instance, reported a dozen known cases of false medicine prescriptions reaching patients through the legal supply chain in the UK since 2004 (Towers, 2012). For example:

Having smuggled fake pills from China and Pakistan, he used to sell them not only through online pharmacies but via the traditional supply chain. The investigation by the MHRA revealed that his fakes had trail leading to XX, a Leicester businessman and a company called XX. Enterprises based in Edgware (north London) owned by XX and his wife XX—a registered pharmacist—who introduced the fake pills into the legitimate supply chain.

[Crime news item, UK]²⁰

Likewise, falsified medicines were introduced into the legal chain comprising pharmacies, hospitals, and care facilities. For instance:

At least 100,000 doses ended up being given to patients. When a wholesaler spotted a flaw on the packaging, almost 40,000 packs had to be cleared from shelves. He was convicted of conspiring to defraud pharmaceutical wholesalers, pharmacists and members of the public. In addition he was convicted of selling or supplying drugs without a marketing authorization and acting as a company director while disqualified.

[Crime news item, UK]²¹

Moreover, the uncontrolled nature of the Internet only enhances these advantages. As the cases that we studied demonstrate, spamming has a great deal of responsibility for the trade in falsified medicinal products via the Internet because it works as an advertisement and promotion mechanism. Among other promotion tools, researchers identified marketing techniques based on personal contacts. In several cases, word-of-mouth marketing was used to sell unlicensed and falsified anabolic steroids in gyms. Moreover, social media channels were of huge importance in the distribution: sellers had direct contacts with their potential clients and could use a range of means to convince people to purchase their products. The

²⁰ Sources: Mills, J. (2007). "Smuggler who made £5m from fake Viagra is jailed" Mail Online, 26 October. Boseley, S. (2007). "Made for 25p, sold for £15. The fake Viagra that netted pill gang millions" The Guardian, 17 September. Simpson, A. (2008). "'King of Viagra' jailed for counterfeit drugs" The Telegraph, 14 October.

²¹ Source: Sears, N., & Greenwood, C. (2011). "Fake cancer drugs given to thousands: Conman jailed for importing two million doses" The Daily Mail, 11 April.

“friend get friend” and “rewarding regular consumers” schemes were used for the same purpose:

The National Police arrested XX and his partner XY in Seville for their alleged involvement in smuggling anabolic substances. As reported by the National Police, this operation, which has been one of the largest seizures of the substances in the city, started after a previous investigation had determined the existence of several persons engaged in the sale of anabolic medicines in XX's gyms. Illegal substances were stored in their home in Seville and distributed on demand to major buyers, most of them sports fans and amateur bodybuilders. Importantly, the offending couple also made use of their contacts with nightclub doormen and gym employees to advertise anabolic pills to potential customers.

[Crime news item, ES]²²

4.2.4 Types of medicines most supplied through illegal online distribution channels

Medicinal products supplied in illegal online distribution channels resulted to be of very different types. The most popular medicines are the so-called ‘lifestyle medicines’ (e.g. medicines for erectile dysfunction, anabolic steroids, weight loss medicines, pharmaceuticals for birth control or smoking cessation). However, the virtual ethnography and the analysis of investigative and judicial cases also highlighted the greater promotion of ‘lifesaving medicines’ (i.e. medicines used to treat potentially lethal diseases like HIV, cancer and hepatitis). More in general, it can be stated that the most popular types of products sold through illegal online distribution channels are the following, being at the same time the most in demand (see Subsection 4.1.6):

- 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;
- psychiatric medicines;
- fertility medicines;
- antidepressants;
- stimulants;
- medicines for cancer, HIV;
- medicines for diabetes, arthritis and hepatitis.

4.3 The patterns

This Section focuses on the patterns of the online trade in falsified medicinal products. More specifically, it describes the sequence of steps taken by offenders in the crime-commission process. The criminals involved in the online market of falsified medicines adopt a *modus operandi* that entails criminal activities other than those illustrated in Section 4.2, which concerned the distribution of falsified medicines. Specifically, the aim of the research was to answer the following questions: where are falsified medicinal products manufactured? How are medicinal products and/or other equipment acquired by illegal entrepreneurs? How are falsified medicinal products transported? What are the tactics used by offenders to avoid investigations and prosecutions? How is money laundered? This information was acquired in order to accomplish Activity 1.1 of project Fakecare (i.e. ‘Improving knowledge on the patterns of online trade in falsified medicinal products’), and it was useful to explore challenges in tackling the illegal online trade of medicines and outline techniques to consider during investigations (for further information see Section 5.3).

For this purpose, investigative and judicial cases, as well as crime news items were analysed using a crime script approach. In instances where some information was missing or details were lacking, interviews were carried out with stakeholders (for further information see Section 3.2). Country profiles about the patterns of the online trade in falsified medicinal products for each country involved in the project are provided in Annex A.

²² Source: Rodriguez, C. (2012). “Detenido un matrimonio con 100.000 dosis de anabolizantes listas para vender en gimnasios” El Mundo, 4 September.

4.3.1 Manufacturing

The investigative and judicial cases analysed had little or no information about the origin of falsified medicinal products sold via the Internet. However, according to in-depth interviews with stakeholders and crime news analysis, falsified medicines are imported from China, India, Pakistan, Thailand, and other Asian countries, as well as from Western Europe. And some EU countries act as transit points for medicine smugglers. For instance:

XX was the mastermind behind a five-year plot to sell millions of fake Viagra and Cialis anti-impotence pills on the Internet. He smuggled the pills into the UK from secret factories in China and Pakistan through Dubai, Hong Kong, and the Bahamas. Some 117,000 fake Viagra pills were found at his home in Barwell, Leicestershire, UK.

[Crime news item, UK]²³

XX ran a company in Luxembourg which purchased the fake drugs from China for GBP 1.4 mln, when they had a retail value of at least GBP 4.7 mln. According to the investigation by the MHRA, fake pharmaceuticals were supplied by Chinese national YY. The latter was later arrested offering similar fakes for sale in the Internet to undercover customs agents in the United States and jailed for six-and-a-half years in 2008.

[Crime news item, UK]²⁴

Although in the majority of the cases analysed falsified medicinal products had been smuggled from abroad, several instances of the domestic manufacture of falsified medicines were discovered. They clearly suggest that the production-distribution network does not start solely in Asian countries, which are the main source of the problem, but falsified medicines are also produced locally. The chemicals and equipment were obtained by different methods, such as legal or illegal

purchases (commercial websites, auction websites), or they were sourced through social networks, and either set up in the premises or stored. The equipment used ranged quite widely from common equipment to more specialized equipment that may be difficult to obtain (like magnetic stirrers). The disruption of a clandestine laboratory producing anabolic steroids in Alicante in 2013 provides a striking example:

The Guardia Civil dismantled a clandestine laboratory in Alicante that was producing anabolic substances, steroids, and growth hormones. Two people were arrested for alleged drug offences and ones against public health. The laboratory was installed in a house in Benitachell, Spain, and equipped with abundant instruments, scales, material mixes and several dimension tables, which were reportedly used to manufacture illicit drug products with active ingredients from China. The detainees allegedly prepared counterfeit anabolic substances, steroids and growth hormones which were offered in the Spanish market and abroad through a website.

[Crime news item, ES]²⁵

Domestic manufacturing was found also in other EU countries:

Carabinieri NAS discovered in Perugia a garage in which a 20-year-old youth, passionate about chemistry but without a licence, had been running a sort of pharmaceutical company. Hundreds of kilos of active ingredients bought online from China, Singapore and Moldavia were seized, along with machinery, again purchased through Asian websites. The quantities were sufficient for the production of about 100,000,000 pills. The youth had also invented new formulas to create anabolic steroids.

[Investigative/judicial case, IT]

²³ Source: Mills, J. (2007). "Smuggler who made £5m from fake Viagra is jailed" Mail Online, 26 October. Boseley, S. (2007). "Made for 25p, sold for £15. The fake Viagra that netted pill gang millions" The Guardian, 17 September. Simpson, A. (2008). "'King of Viagra' jailed for counterfeit drugs" The Telegraph, 14 October.

²⁴ Source: Sears, N., & Greenwood, C. (2011). "Fake cancer drugs given to thousands: Conman jailed for importing two million doses" The Daily Mail, 11 April.

²⁵ Source: Europa Press (2012). "Dos detenidos y dos imputados, uno menor, acusados de falsificar fármacos y venderlos por Internet" 22 August.

During an investigation, judicial authorities discovered some hidden laboratories in Germany where chemical precursors ordered online and produced in China were prepared to be sold as steroids and growth hormones to local amateur athletes.

[Investigative/judicial case, DE]

The most frequent cases of illicit manufacturing of medicinal products concerned the illicit production of anabolic steroids. In some of these cases, medicines were made with unlicensed active ingredients from China, including unlicensed growth hormones. For instance, an individual manufactured various anabolic steroids containing unlicensed human growth hormones in his home in the United Kingdom:

XX ran websites, which sold deadly drugs to keen bodybuilders around the world from a house in Southend, UK. The factory was uncovered after police officers raided the property in March 2011 and found powdered steroids and specialist liquids, which are used to convert it into its injectable form. Unlicensed human growth hormones were also discovered. XX supplied anabolic steroids and sold other drugs which needed prescriptions. Drugs were sold online. The MHRA investigation led to seizure of 26,000 unapproved prescription pills and steroids, and prosecution of 4 fake online pharmacy operators.

[Crime news item, UK]²⁶

4.3.2 Acquisition of medicinal products and/or other equipment

Medicinal products are usually acquired directly by offenders on the Internet and then sold illegally online and offline. For instance:

The manufacturer bought the active ingredients online from Asian and Eastern European websites, choosing only the safest delivery and the best quality. After the production, the medicinal products were offered on the Web (mostly treatments for erectile dysfunction and anabolic steroids since they are the most popular online). He advertised them principally on specialized sites and forums, but also on generic forums, social networks, and by email.

[Investigative/judicial case, IT]

The apprehended individuals purchased anabolic steroids through different online channels from abroad. Once they received the products, they resold them offline to the customers of their gym.

[Investigative/judicial case, IT]

In other cases, falsified medicinal products were brought from Asia through an intermediary. For instance:

XX ran a company in Luxembourg, which purchased the fake drugs from China for GBP1.4 mln, when they had a retail value of at least GBP 4.7 mln. According to the investigation by the MHRA, fake pharmaceuticals were supplied by Chinese national YY. The latter was later arrested on offering similar fakes for sale in the Internet to undercover customs agents in the United States and jailed for six-and-a-half years in 2008.

[Crime news item, UK]²⁷

²⁶ Source: Echo News (2012). "Canvey man laundered £422,000 for illegal steroids factory", 7 November; MHRA (2012). Press release: "Essex man receives 12 months suspended sentence for laundering £422K from illegal sales of medicines", 16 November.

²⁷ Source: The Daily Mail (2011). "Fake cancer drugs given to thousands: Conman jailed for importing two million doses", 11 April.

Products could also be acquired from pharmacies using false prescriptions. For instance, in a Spanish case that occurred in 2011-2012 (the so-called 'Operation Package') the medicinal products were not only acquired abroad but were also purchased from Spanish pharmacies using false prescriptions:

The organisation distributed falsified medicinal products in Spain. The products were acquired in China, Portugal, the UK, Singapore, Thailand and India. Some products were also acquired from Spanish pharmacies using false prescriptions. Sometimes the person receiving the products was not in Spain, but in a third country before entering Spain. The organisation was in charge of stocking up in the south of Spain and the product was marketed/distributed online or by telephone. The products were delivered by personal or postal couriers.

[Investigative/judicial case, ES]

The medicines available online have sometimes been stolen from the legal distribution chain and then re-introduced to consumers via online pharmacies. The risks that such medicines pose for the health of consumers are often related to the perpetrators' improper storage and transportation, or linked to modification of the expiry date. Subsequently, stolen medicines are very unlikely to meet the quality specifications set by national and international standards.

The investigations started after some thefts of very expensive hospital medicines for the treatment of cancer and other serious diseases [...] The organisation's masterminds were Italian wholesalers, specifically in Milan, Monza, Sondrio, Naples, Pavia, Genoa, Caltanissetta and Crotone. The medicinal products were taken directly from pharmaceutical companies, from hospital warehouses or during transportation and were then sold abroad after being hidden through fictitious invoices issued by companies with headquarters in England, Switzerland, Malta and Ireland. This operation often interrupted the cold chain required for storage.

[Crime news item, IT]²⁸

4.3.3 Transportation

Since in the majority of the cases studied the perpetrators obtained falsified medicinal products from abroad, the illegal transportation of medicines across international borders or EU national jurisdictions in violation of applicable laws and regulations was the most common practice. In some cases, it also became evident that source countries, especially those with weak export laws, often do not control export medicines, and criminals exploit these legal gaps to manufacture and export falsified medicinal products.

It emerged from the analysis that there is not one definitive process in the online trade of falsified medicinal products. Medicines are usually smuggled by mail, but criminals use other means as well: for example, in one case, medicines were smuggled in a car or by courier companies, whereas companies like Money Gram or Western Union were used for money transfers. Moreover, payments were made by wire transfer or in cash to the personal courier on delivery. For instance, in a case that occurred in Spain in 2011-2012 (Polymer Operation) a criminal organisation sold falsified medicinal products online or by telephone. The main distributor acquired the products from the owner of a dental care centre. The offenders bought the products from China or from a chemical business in Madrid and distributed them online. Courier companies or personal deliveries were used for transportation, and companies such as Money Gram or Western Union were used for money transfers. Over ten people were responsible for the deliveries throughout Spain.

Moreover, the smuggling of falsified medicines usually takes very complex forms: a packet of pills may pass through one or more intermediaries, such as brokers, trading houses and agents, before reaching the destination. In one case, falsified medicines from China were smuggled to the UK via an intermediary in the United States. In another similar example, unlicensed doping and performance-enhancing medicines entered Spain via Switzerland.

Activities by intermediaries may sometimes involve repackaging, re-labelling and mixing. Such trade arrangements can provide better opportunities for criminals to introduce illicit products into the distribution chain. In one case, the perpetrators used original packaging to make the fakes appear authentic:

²⁸ Source: La Repubblica (2015). "Traffico internazionale di medicinali rubati: 19 arresti, danno da 30 milioni per ospedali e case farmaceutiche", 2 April.

A key part of the fraud committed by XX and his conspirators was a pretence that the medicines had originated in France rather than China. Special French-style bar-code labels were produced and imported separately from the drugs, and then added on an industrial estate in Basingstoke.

[Crime news item, UK]²⁹

Another case recorded in Gran Canaria in 2013 provides further insight into the complexity of the smuggling routes used in the trade of falsified and illicit medicines:

The Guardia Civil has arrested two persons in Gran Canaria to disrupt the distribution of doping products and performance-enhancing drugs in an operation in which 16.8 kilos of anabolic steroids and other banned drugs in sport have been seized. The operation, called “Zangief”, was initiated when health authorities in Switzerland detected a package with fake sport drugs sent from Hungary to Switzerland, from where they would be sent to Gran Canaria. The drugs allegedly came from underground labs in Romania. The persons arrested in Gran Canaria had changed the packaging and falsified the labels so that they appeared to buyers as goods that had been purchased in Spain and had full warranty for consumption.

[Crime news item, ES]³⁰

4.3.4 Detection avoidance tactics

Interviews with national and international law enforcement and health regulatory agencies highlighted a number of techniques used by illegal entrepreneurs trading falsified medicines online in order to avoid efforts to close them down and bring them before the courts. They included:

- The use of affiliate and sub-affiliate networks to ‘muddy the waters’: An affiliate network is constructed in two ways: a) by entrepreneurs who are responsible for a number of websites illegally trading in medicines (the websites often have very similar if not identical templates); b) by the use of ‘affiliates’, whereby larger criminal organisations operating OPs pay commercial entities commissions to surf the web and post links to their OPs on various online sites;
- Buying domains from ‘rogue registrars’. These non-compliant registrars tend to ignore law enforcement and regulatory agencies’ requests to block and shut down specific sites deemed to be associated with the illegal sale of medicines;
- Identifying law enforcement and health regulatory agents visiting their sites. Illicit suppliers attempt to identify law enforcement and health regulatory agents posing as customers. Specifically, they check the details of visitors (including the frequency of visits and the debit/credit card used for purchases). If a visitor is found to be making a number of visits to a number of their affiliate sites, as well as using the same card for payment, they will be blocked or re-directed to another website;
- Avoiding the WHOIS check performed by law enforcement authorities and regulatory agencies in order to identify illegal online pharmacies;³¹
- Re-routing payments between offenders through intermediaries to hide the link between illegal activities and payments. Illegal entrepreneurs largely avoid asking for bank payments and prefer money transfer services (such as Western Union) because they are extremely easy to conduct, and – for smaller transactions – no identification is required. In addition, illegal entrepreneurs establish multiple banking relationships in numerous ways. They have been known to ask family members, friends and/or acquaintances to lend their accounts for a number of transactions, or they have rented the accounts of others for a short time.
- Avoiding the provision of any personal information and details on delivery items accompanying the merchandise that they send (such as delivery notes, invoices, leaflets etc.).

²⁹ Source: Sears, N., & Greenwood, C. (2011). “Fake cancer drugs given to thousands: Conman jailed for importing two million doses” The Daily Mail, 11 April.

³⁰ Source: ABC (2013). “Tráfico ilícito de fármacos: auge en Internet y atractivo para los narcos” 14 September.

³¹ WHOIS is a free internet service that may be used to gather information regarding the Internet infrastructure utilised by offenders. It checks: the company acting as the ‘registrar’, the registrant of the domain name (basically the company or individual who has bought the domain name), the registration date, the IP address, the company address. Sites such as whois.domaintools.com can be used to perform the check.

4.3.5 Money laundering

In some cases, criminal networks set up off-shore banking facilities to launder money. This occurred, for instance, in the UK, where in 2004 the MHRA began an investigation into a large and complex business purported to be trading in fishing tackle, electric goods, cosmetics and jewellery. After a number of test purchases were made, the business was also found to be selling both unlicensed and falsified erectile dysfunction medicines online. Moreover, the analysis of these activities via crime news items suggests that perpetrators who rationally weigh up the expected costs and benefits of breaking the rules. It is therefore clear that individuals who consider committing a criminal offence always pay great attention to whether the crime will pay well and whether it will incur a high risk of police intervention.

In all the crime news items analysed, the perpetrators collected revenues and stored them either at home or in banks. For example, in one case officers found GBP 48,000 in cash stashed under the bed at a criminal's home in Romford, Essex (UK). In another case, offenders collected the crime proceeds in several bank accounts. In a case already mentioned, the offender is currently serving an eight-year prison sentence, not only for importing and selling over two million doses of falsified medicinal products, but also for fraud and money laundering offences relating to large-scale infiltration of the legitimate supply chain:

He was found guilty of all charges at Croydon Crown Court and in addition to the confinement was ordered to pay GBP 5,599,003 by way of confiscation. He was convicted of fraud and money laundering offences in April 2011 and since that time law enforcement agencies have been trying to trace the proceeds of his offending abroad and seize them. He has consistently refused to disclose where he has put the money gained through his offences. The North West Regional Asset Recovery Team (NW RART), a specialist police team, have conducted an inquiry on behalf of the MHRA to find the money resulting. The investigation revealed that [XX], who led a lavish lifestyle driving expensive cars, used companies in the tax haven of Mauritius to cover his illicit activities.

[Crime news item, UK]³²

³² Source: Sears, N., & Greenwood, C. (2011). "Fake cancer drugs given to thousands: Conman jailed for importing two million doses" The Daily Mail, 11 April.

The following case concerns another sophisticated money laundering scheme that involved several countries:

Two pharmacists, three physicians, and five website operators were indicted by the US authorities on charges of conspiring in a scheme that allowed people to buy prescription pain medication without a legal prescription online in 2012. From 2010 until November 2012, customers seeking certain prescription-only highly addictive medications would visit one of the websites run by these groups and complete an online medical questionnaire in which they were asked a series of questions regarding their medical history. Following the customer's order and completion of the questionnaire, the website operators would transmit the questionnaire to doctors, who would issue a prescription without conducting an in-person medical examination and reviewing medical records. Once issued by the doctor, the prescription was sent to a pharmacy. The investigation later revealed that during the course of the scheme, bank accounts controlled by B, I., and K. received hundreds of thousands of dollars from Website Operators, including from bank accounts located in Cyprus, Hong Kong, and Israel. Bank accounts controlled by R. and/or L. received in excess of USD 13,000,000 from Website Operators.

[Crime news item, BL]³³

³³ Standart (2012). "Започнаха българската афера за лекарства" Стандарт, 1 December; US Department of Justice (2012). "Manhattan U.S. Attorney Announces Charges against 10 Individuals In Multi-Million Dollar Internet Pharmacy Fraud Scheme" Press Release, 29 November.

4.4 Hot medicines

The term ‘hot medicine’ is not yet in common use at both institutional and academic level. For the purpose of this study, hot medicines can be defined as both branded and generic products which have the highest likelihood of being falsified (or counterfeited) and traded in particular on the Internet.

This Section profiles ‘hot medicines’ and their characteristics by analysing all the factors that seem most relevant to determining the probability of a given medicinal product being falsified and traded online: specifically, the role of the Internet, the types of products at risk, geographical differences, and the trade-offs involved (i.e. demand vs. supply; emergency vs. ordinary use; private vs. institutional use). Such information has been acquired in order to accomplish Activity 1.4 of project Fakecare (i.e. ‘Understanding hot medicines’).

4.4.1 Preliminary remarks

As already stressed in the previous Sections of this report, lifestyle medicines are the hot medicines most commonly sold over the Internet. Many people in Europe, as well as in almost all the developed countries, use the Internet to buy substances – both medicines and herbal products – to ‘cure’ themselves and change their lives, to overcome their limits, fears, ordinary problems and needs. This is the case of erectile dysfunction treatments and men’s/women’s health products, weight-loss, anorexiants, anti-baldness and anti-smoking pills, but also doping substances. These products are largely advertised by the mass media and are also much discussed through social networks, blogs and forums.

The growing demand for them has aroused notable criminal interest and consequently determined the escalating supply and massive presence of falsified medicines online. Lifestyle medicinal products are today falsified on a large scale, meaning that most websites located in almost all regions of the world sell fake copies. The examples of Pfizer’s Viagra or Eli Lilly’s Cialis are representative. Recently, the same situation has arisen for medicines used to treat diabetes, cholesterol and high blood pressure, but also painkillers. The fact that most of them are prescription medicines is not an obstacle for the illegal supply chain because a prescription is never required.

Based on this scenario, project Fakecare sought to go beyond the existing knowledge base and focus on other types of products which are or may be at risk in the short term. In detail, starting from an extensive analysis

of scientific/grey literature, and relevant cases investigated at international level,³⁴ the analysis focused on the following main questions:

- What medicinal products are more vulnerable to counterfeiting, falsification and online trading?
- What are the issues and factors which directly impact on the sale of counterfeit and falsification medicines both offline and online, and are likely to influence the phenomenon of hot medicines?

In light of the research results, it seems that the likelihood of a medicine being counterfeited, falsified and traded online results from a wide range of assorted factors that determine the interaction between the online and the offline demand for and supply of (falsified) medicines. In fact, the Internet is not a separate context, and medicines which are ‘hot’ on the Web are usually medicines characterised by strong demand also offline. In particular, significant interdependencies can be observed between the geographical dimension – e.g. the location where the medicine is both produced and largely used, and the location from which the demand originates – and the typology of (hot) products themselves.

That of hot medicines is a very specific issue which to date has not been subject to systematic scientific analysis by criminologists. At the beginning, researchers tested the possibility of applying to the online trade in falsified medicinal products the VIVA (i.e. value, inertia, visibility, and accessibility) (Cohen & Felson, 1979) and the CRAVED (i.e. concealable, removable, available, valuable, enjoyable, and disposable) (Clarke, 1999) models. These are the mnemonics used by environmental criminologists to identify attractive items to steal and eventually to trade illegally. They were specifically created for predatory crimes in order to describe why certain products are more likely to be stolen, to identify potential vulnerabilities in new prototypes, and mostly to develop crime prevention programmes and solutions to enhance security features and reduce opportunities for crime.

However, from the very beginning of the research, the successful application of these models to medical products trafficked online appeared problematic. The peculiarities of the Internet as a sales channel, as well as the structural changes in the logistics were among the fundamental reasons. Furthermore, online smuggling

³⁴ The investigative operations analysed for the purpose of this study are those by Interpol: specifically, Pangea, Mamba, Storm, Cobra, Giboia, Porcupine. Operation Onymous conducted by the FBI and Europol to take down Silk Road 2.0 was also analysed.

glers of illegal medicinal products do not need to be selective like, for example, a burglar when choosing their targets, because the Internet is first of all a showcase, and the ability to offer a broad catalogue of products is an important advantage. As a result of the limits existing in the criminological research, the methodology had to take account of the lack of an extensive literature of reference and of the difficulties of applying the VIVA or the CRAVED models, and consequently of the need to develop a new approach to the issues of online hot medicines from a criminological standpoint.

In detail, in order to obtain the results, the methodological approach was mostly qualitative and included in particular the analysis of secondary sources related to both scientific literature and grey sources. Specific attention was paid to official documents and reports issued by international and national public authorities and private organisations, as well as to case-studies and information related to judicial cases and investigations. Moreover, media representations of the phenomenon were considered especially in order to conduct a geographical analysis of the criminal dynamics.

Accordingly, the research hypotheses were the following:

- In developed countries, the risk of a medicine becoming a hot medicine is directly proportional to its economic value and relevance of use. Hence medicines with higher monetary value and importance in curing life-threatening and chronic diseases are more vulnerable to counterfeiting and falsification.
- In developing countries, the risk of a medicine becoming a hot medicine is directly proportional to the demand for it. Hence medicines used to cure diseases widespread in the population are more vulnerable to counterfeiting and falsification.
- The risk of a hot medicine being traded via the Internet is higher if the medicine is used mostly by people living in developed countries (due to their easy access to the Web) and if the medicine is a self-medication and/or a medicine with restricted/regulated access.

These working hypotheses originated from analysis of the issues and trade-offs which seem most relevant to the phenomenon of medicine counterfeiting and falsification. In particular:

- role of the Internet;
- types of products;
- emergency vs. ordinary use;
- demand vs. supply;

- private use vs. institutional supply chain/use;
- geographical differences.

Each of these aspects is briefly analysed in the following Sections.

4.4.2 Role of the Internet

The Internet is magnifying the problem of counterfeiting/falsification because it is at the same time the most up-to-date international showcase and the most active operational hub for the distribution of falsified medicinal products through business-to-business (B2B), business-to-consumer (B2C) and even consumer-to-consumer (C2C) linkages. The Internet is an always-open global (falsified) medicines market where almost everything is available and easily obtainable.

Furthermore, the Internet is becoming the most composite source of information for people, who can consult social networks, blogs, forums, and generic websites to find tips, facts and personal experiences on almost all diseases, symptoms and possible remedies. Like medicines, also information can be misleading, falsified or even fraudulent, as highlighted by the results of the virtual ethnography activities.

Finally, the Deep Web and the Dark Net represent a new frontier in the phenomenon of medicine counterfeiting and falsification because they are changing how individual criminals as well as informal organised groups and traditional organised crime are exploiting cybercrimes in order to improve the criminal supply chain of counterfeit and falsified medicines (Interpol, 2015b). The cases of Silk Road and Evolution Marketplace, which offer prescription medicines for sale to the public, are emblematic of the central role played by medicines and other related substances (e.g. Novel Psychoactive Substances – NPS) in their activities. As explained by Interpol, before Silk Road 2.0 was shut down in November 2014, the most commonly advertised medicines on the website were prescription medicines, and among them, the most commonly advertised therapeutic category was “Relaxants”, where the main medicine type advertised was benzodiazepine. The possibility of using crypto-currencies – in particular Bitcoins – is an important crime facilitator because it further supports anonymity. It also facilitates the laundering of money, while reducing the risk of law enforcement because tracing and monitoring activities are extremely difficult to implement. In fact, once the Bitcoins payment has been transferred, the money is usually held by a trusted intermediary until delivery occurs, with missing packages qualifying for partial refunds.

In synthesis, the Internet perfectly matches the (legal and mostly illegal) demand, on the one hand, and the supply of (original and falsified) medicines on the other. On the demand side, the Internet enables people to look for what they want and/or need without constraints, embarrassment or limitations of any kind. Of course, the possibility of accessing the Web, especially through broadband connection, is a key enabling factor and, at the same time, a driver of criminal opportunities. On the supply side, the Internet enables criminals to sense, understand and address the demand, to advertise their products, and to sell them on a large scale (FDA, 2014).

The Internet has enlarged the boundaries of the phenomenon of medicine counterfeiting and falsification in many respects. Due to the presence of the Web, counterfeiting and falsification are:

- impacting on the patterns of production, distribution, and consumption of counterfeit and falsified medicines;
- affecting almost all classes of therapies and increasing the range of falsified products and products at risk;
- intensifying geographically and involving a greater number of regions;
- increasing individual and collective health risks;
- escalating the emergence of medicine-resistance;
- affecting and altering the relationship between individuals/patients and medical professionals;
- exacerbating the illegal diversion of medicines, thefts (e.g. cargo thefts, thefts of expired products to be refilled with fake ones, etc.) and other related criminal practices (e.g. ID theft, payment card fraud, etc.).

From the criminological standpoint, the Internet should not be considered a separate and disconnected framework. On the contrary, it is a crucial component of a complex criminal phenomenon which is strictly interconnected between the physical and digital dimensions. The Web's distinctive role is represented by the amplification of legal as well as illegal opportunities to sell and buy original and falsified medicinal products produced in the 'real' world.

That is the main reason why hot medicines need to be analysed with a variety of diverse elements taken into account. The type of product is one of the most important.

4.4.3 Types of products

According to the findings of the desk research, knowledge on the types of medicines most vulnerable to both counterfeiting/falsification and online trade is still fragmentary. At an operational level, the falsification and counterfeiting of medicinal products do not always coexist with online illegal trading of medicines. In fact, in some cases products are counterfeited or falsified and traded only through physical channels, while in other cases, false medicines enter also the online legal/illegal supply chain. In both cases, they reach private citizens as well as public and private healthcare providers. However, data, statistics and analyses are often focused on national dimensions and are based on diverse methodological approaches, so that it is difficult to determine the phenomenon on a global scale.

In terms of a typology of products, the online situation appears to be particularly confused. While in the 'real world', macro-categories of reference can be created according to the available data (especially on seizures), in the case of the Internet almost all therapeutic categories are at risk. In fact, the project's results have shown that illegal online pharmacies usually have an extensive catalogue of available medicines. This is confirmed by the results of online enforcement operations (e.g. Interpol Pangea, Cyber Monday).

Analysis of a sample of ten online medicine retailers confirmed this scenario and found that:

- The categories of Erectile Dysfunction/Men's Health/Women's Health are still online bestsellers and are largely advertised also on homepages.
- Online retailers can be grouped into three main categories according to the types of products sold. In detail:
 - a. The first category comprises retailers that mostly sell erectile dysfunction medicines and related products, together with lifestyle medicines (e.g. weight or hair loss, herbal products). The list of products is usually quite limited and mainly addresses the problems which usually frustrate people;
 - b. The second category comprises retailers that mostly sell erectile dysfunctions products and lifestyle medicines, but also products which are widely used/requested to treat the most widespread/serious illnesses (e.g. cancer treatments, anti fungal, antibiotics, blood pressure and cardiovascular medicines, diuretics). These websites seem to promote a self-medication approach;
 - c. The third category comprises retailers that appear to have a medical-oriented approach which

can easily deceive people into believing that they are dealing with reliable online retailers. In fact, the list of categories is substantial and addresses the vast majority of serious illnesses, including cancer, HIV, Alzheimer and Parkinson.

- There is no therapeutic category and medicinal product immune from the risk of being counterfeited/falsified and/or illegally traded online. The most vulnerable therapeutic categories defined by the Pharmaceutical Security Institute³⁵ were regularly present on the websites analysed and seem to represent the next frontier of counterfeiting and falsification after erectile dysfunction treatments.

In this scenario, where the supply is apparently able to address whatever needs and requests, the demand should be considered the key factor to assess the risk of a medicine becoming a hot medicine and being traded online. In fact, from the criminal standpoint, which is mostly based on a rational and profit-oriented approach, high usage and high monetary value are the most important features of products inducing investment in their illegal reproduction and trade, also on the Internet. In regard to the demand side, the typology of the most popular products online seems to change rapidly, and it often differs according to the geographical region.

4.4.4 Demand vs. supply

The relationship between demand and supply is crucial for understanding the criminal dynamics of the phenomenon of medicine counterfeiting and falsification. In particular, demand plays a vital role in making a medicine become a hot medicine. In fact, with specific reference to the Internet, demand should be considered one of the most important drivers of crime because it has the potential to direct the flow of falsified medicinal products at a global and regional level.

³⁵ Accordingly, medicines in the genito-urinary, anti-infectives and central nervous system therapeutic categories accounted for the largest number of incidents. These three categories were seen as comprising medicinal products which were the most frequently targeted by individuals engaged in pharmaceutical counterfeiting and falsification. More in general, five therapeutic categories had a percentage increase on a year to year basis. Specifically, the metabolism therapeutic category led with the largest percentage increase at +139%, largely due to an increase in the number of counterfeit or falsified diabetes treatments being detected and/or seized. Categories with large number of incidents included also anti-infective (+63%), respiratory (+29%), hormones (+21%), central nervous system (+9%), and cardiovascular (+8%). Source: <http://www.psi-inc.org/therapeuticCategories.cfm>. Last accessed on: 03 October 2015.

As shown in Section 4.1 of this report, on the Internet, demand may be further incentivised by important key factors (e.g. lower prices and availability of special offers; no need for medical controls/prescription; privacy/anonymity protection; etc.).

People who use the Internet to buy medicines can obtain a wide range of products, at a lower price, but also more easily (e.g. no prescription, anonymity, rapidity, etc.). Many of them mostly rely on a 'self-diagnosis' approach and a 'self-prescribing' culture (UNICRI, 2013). However, the geographical area of residence, income, as well as the level of confidence in new technologies play a role in how people perceive and/or use online pharmacies. In fact, people living in developed countries have greater opportunities – and also related risks – to use the Internet, also for health needs.

On the supply side, it is important to draw a clear distinction among (online) mail order/legal pharmacies, illegal Internet traders, and wholesalers who buy medicines online and introduce them into the legal supply chain.

4.4.5 Emergency vs. ordinary use

Evidence shows that in the event of serious public health medical emergencies, epidemics, and/or global pandemics, the medicines used both to treat the patients and to prevent the disease from spreading are exposed to a high risk of being falsified and traded online.

In times of crisis, falsified medicinal products are more likely to enter the legitimate supply chain and become a large-scale threat because medicine supplies are uncertain and demand is high. In fact, many people – although not directly exposed to real health risk – become worried about the possibility of obtaining the medicines in the case of need and decide to buy them as precaution. This is the case, for example, of people with serious chronic diseases, travellers, hypochondriacs, but ordinary people as well. From this standpoint, the Internet becomes a crucial point of reference for both citizens looking for easy-to-get medicinal products, and for criminals, who can rapidly and easily address the fears and needs of worried people.³⁶

³⁶ The most recent case is the H1N1 pandemic in 2009. In fact, during the so-called "swine-flu" pandemic, the number of websites offering anti-viral medicines and products to diagnose, prevent, treat or cure the H1N1 influenza virus increased dramatically. According to available sources of information, the number of Internet scammers offering fake anti-swine flu Tamiflu medicines surpassed those selling counterfeit Viagra. This was confirmed also by the hundreds of mil-

It should be stressed that in some regions the risk of epidemics is far greater than in the rest of the world, so that the probability of falsified medicinal products infiltrating the legitimate supply-chain and distribution channels, as well as hospitals, is very high. This is the case, for instance, of malaria, but also AIDS and tuberculosis. Accordingly, emergency use should be considered a major criminal opportunity for new hot medicines at both national and global level.

4.4.6 Private use vs. institutional supply chain/use

One of the most important issues related to medicine counterfeiting and falsification and to the online trade in (hot) medicines is the context where medicines are used and by whom.

Private use of the Internet to buy medicines is a consolidated practice; however, the institutional use is growing apace. In fact, legitimate customers – i.e. public and private health care providers – are starting to obtain medicines from wholesalers on the Internet, thus extending their supply chain on a global scale. The main reasons are the possibility both to cut their costs and to speed up the medicine-purchase process, and in some cases also to access products which are not available/easy to obtain. This institutional use of the Internet is likely to pose increasing dramatic risks to the safety of citizens because of the difficulties of controlling and securing the demand, the supply, as well as the products and the channels used.³⁷ Furthermore, it may determine new opportunities for specific categories of medicines to be falsified and traded online. For instance, since 2011, the FDA has notified more than 100 medical practices in 29 States that they may have purchased counterfeit cancer medications distributed by an illegal online Canadian pharmacy (FDA, 2014c), and the list of similar cases is extending day by day.³⁸

At present, there is no specific evidence on the role played by the Web. Certainly, direct e-mails and mass online advertising campaigns are among the most frequently used tactics to target clinical settings for the

sale of counterfeit/falsified and unapproved medicines (ECHCR, 2013). Furthermore, it is evident that falsified medicinal products addressed to professional and institutional stakeholders are mostly high-cost and lifesaving medicines, such as anticancer medicines or ones for chronic diseases. Medicines in high demand, such as antiviral or pain-killers but also medicines for cosmetic surgery, are particularly vulnerable as well.

In Europe, the recent case of Roche's cancer medicine Herceptin is emblematic of the new trend, which is affecting in particular the institutional use in developed countries.³⁹ In the following months, additional warnings about possible illegal exportation at EU level of stolen and counterfeit or falsified packages of Roche's cancer medicines Avastin and MabThera were issued with reference to year 2013 (AIFA, 2014).

4.4.7 Geographical differences

Although the Internet is global and has no spatial limitations or physical boundaries, local geographic dynamics and differences seem to have an important role in the phenomenon of (hot) medicines counterfeiting and falsification both offline and online. In fact, geographic peculiarities contribute to determining risks, challenges, opportunities and favourable conditions for medicines to become 'hot'; subsequently, they influence the offline and online trade of fake/hot medicines, thus making them a global threat.

For example, a European consumer/patient affected by a serious disease (e.g. rare/chronic/degenerative/genetic/life-threatening) can use the Internet to buy illegally from online foreign operators medicines

lions of fake pharmaceutical spam adverts and websites intercepted by security software, many of them trying to sell falsified antiviral medicines to worried customers.

³⁷ According to a recent study (Schaefer & Perz, 2014), the problem of in-hospital infections is growing in the United States, being caused by medicines thefts and contaminated syringe re-use by hospital employees.

³⁸ For further information visit: <http://www.safemedicines.org/counterfeit-drug-incident-encyclopedia.html>.

³⁹ In March 2014, the Italian Medicines Agency (AIFA) received a warning from a UK wholesaler about a suspicious batch of products purchased from an Italian wholesaler. The investigations by NAS - Italian specialised agencies of the Arma dei Carabinieri - discovered that vials of Herceptin had been stolen in Italy, also from hospitals and clinics, to be then falsified and resold across the continent with few or none of its active ingredient. The vials were traded illegally and entered the legitimate supply chain of other EU Member States mostly by way of documents, records, packaging and labelling falsification. For further information visit: <http://www.agenziafarmaco.gov.it/it/content/furti-di-medicinali>; http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/04/news_detail_002076.jsp&mid=WC0b01ac058004d5c1. Last accessed on: 03 September 2015. The criminal scheme was operated by a group of Italian wholesalers in cooperation with some EU wholesalers from Hungary, Slovenia, Slovakia, Romania, Latvia and Cyprus, which issued the invoices used to 'sell' the stolen vials to Italian authorized operators, which, in turn, exported the counterfeit products to other European markets. In particular, the Italian wholesalers sold the counterfeit products to wholesalers active in the UK, Germany and the Netherlands which further redistributed them in Finland, Spain and Portugal.

which are not approved and/or available in her/his own country of residence, as well as medicines which are too expensive where she/he lives. From the patients' standpoint, the Internet makes it possible to resolve diverse problematic situations that they have to face on almost a daily basis; patients can exploit the loopholes and differences existing between national laws/regulations to gain access to medicines and therapies which are sometimes their last hope (see also Section 4.5). The point is that the risks of receiving falsified medicinal products instead of genuine ones is very high, and among other factors this depends also on the region, and on the types of medicines that are bought online.

In synthesis, geographical differences matter also for the online trade of (falsified) medicines because products, supply-chain, production and distribution patterns, as well as regulations and controls, vary considerably according to the region of reference, and this impacts also on the type and level of risks for citizens.

According to the WHO (2011), the incidence of counterfeit and falsified medicines is very low in most industrialized countries with regulatory systems and effective market controls (Australia, Canada, Japan, New Zealand, United States and most of the European Union). It represents less than 1% of the value of the market. This percentage is much higher in many African countries, in some areas of Asia and Latin America, and in developing countries, with up to 20-30% (sometimes 50%) of the market. The distribution channels in these regions are less controlled, and it is more difficult to prevent counterfeiters from infiltrating supply networks.

Besides their capacity to manage and control the supply chain and distribution channels, national legislation and policies may become drivers of crime with reference in particular to pricing and rules on Internet online sales.

Finally, the geographic scenario is also important for the Internet framework because it is at the basis of the online supply chain of falsified medicinal products. In fact, regardless of their region of residence, in case of need or interest, people can potentially gain access to whatever type of medicine that is available in other countries. Their origin of respectively production and distribution may impact on the vulnerability level of certain types of products. In particular, the illegal diversion of pharmaceuticals, which is strictly related to the diverse legal rules and pricing policies adopted at national level, is likely to become a growing *modus operandi* to enhance the supply of (bogus and hot) medicines over the Internet.

4.4.8 Profiling hot medicines

Study of the phenomenon of (hot) medicines counterfeiting and falsification highlights the complexity of the criminal dynamics and the difficulty of separating the online domain from the physical dimension. It is also difficult to identify those elements which actively influence the vulnerability of given medicines to counterfeiting, falsification and online trading, because at present no therapeutic category is immune from the risk of being falsified.

Lifestyle medicines are among the most targeted products, but case-histories and seizures at global level confirm that also high-value and intensive-usage medicines have recently been exposed to increasing risks of being counterfeited and falsified worldwide. However, finding a possible logic in the criminal choices and dynamics which characterize the online domain is extremely complex, because the supply of falsified medicinal products seems to address whatever request or need that is expressed by customers at a global level. That is to say, there are some features of certain products which may somehow make them become 'hot products' but do not allow the development of a predictive model/approach.

Conversely, with reference to the offline context, it seems easier to highlight the factors which may determine hot products by considering the flows of both the demand and supply, as well as production and distribution patterns. Hence, based on the knowledge obtained in the development of this study, an attempt was made to classify the most important factors with both a direct and indirect impact on hot medicines. More in detail, product features appear to be among the main factors determining the vulnerability of medicines to counterfeiting, falsification, and online trade.

Within this category, various factors should be considered and assessed. In particular, the manufacturer (e.g. the ownership of patents, trademarks and other IPR related issues which may influence the positioning and importance of the products in the market), accessibility (e.g. over-the-counter medicines vs. prescription-only medicines), the level of market penetration, the price, the dosage forms, the type of packaging, and the therapeutic categories, are among the most important elements to consider when attempting to profile products most vulnerable to falsification and counterfeiting.

4.4.9 Final remarks

Understanding the reasons why a medicine may be more exposed to the risk of falsification/counterfeiting and online trading is challenging because, besides the lack of literature of reference, it is necessary to consider a wide range of diverse elements to analyse a complex global criminal phenomenon.

In fact, after an initial analysis, it seems that all medicines are vulnerable – or may become vulnerable – to criminal activities, thus becoming illegally available online and offline. Information and data concerning the online supply of medicines taken from investigations and seizures by law enforcement agencies worldwide underline that the phenomenon concerns almost all therapeutic categories on a global scale. Furthermore, the current scenario is so fragmented and evolving to such an extent that it can be difficult to predict the changes that are likely to emerge in the short to medium term.

In order to go beyond the immediate surface of the phenomenon, project Fakecare has tried to consider all the main elements that make up this intricate mosaic and to assess them. The results confirm the complexity of the issue, but also that it is possible to draw some interesting distinctions: for example, according to geographical areas of reference or types of use.

Moreover, from the scientific standpoint, project Fakecare contributes to the understanding of ‘hot medicines’ and highlights the need for further research developed on the basis of an inter-disciplinary approach. Finally, improved data/information-sharing and more structured public-private cooperation should be considered priorities. They will not only improve academic knowledge, but also help to develop innovative analysis which may be useful to support LEAs operations, as well as pharma-industry initiatives. To this end, researchers have developed a tool that supports pharmaceutical companies, law enforcement agencies, and public institutions to determine the risk of a given medicine being falsified and traded online (i.e. Fakecare Hot Medicines Tool). For further information see Subsection 5.2.3.

4.5 EU legal framework and criminal opportunities

“Opportunity makes the thief” (Felson and Clarke, 1998). Criminals act rationally: like legal entrepreneurs, they take rational decisions on ‘if’, ‘how’, and ‘when’ to invest in a criminal market, exploiting existing – criminal – opportunities. Sometimes, such opportunities are involuntarily created by the legislation. For instance, the presence of difficult-to-prove criminal offences may obstruct investigations and prosecutions, giving offenders incentives to commit such offences. At the same time, it may happen that unintended criminal opportunities are created not by the law itself, but by gaps and loopholes stemming from legislative asymmetries.

This Section focuses on the European legal framework concerning the sale at a distance of medicinal products. It highlights existing legislative vulnerabilities that criminal entrepreneurs may exploit in the online sale of falsified medicines, and it suggests possible mitigation strategies.

4.5.1 Criminal opportunities involuntarily stemming from the legal framework

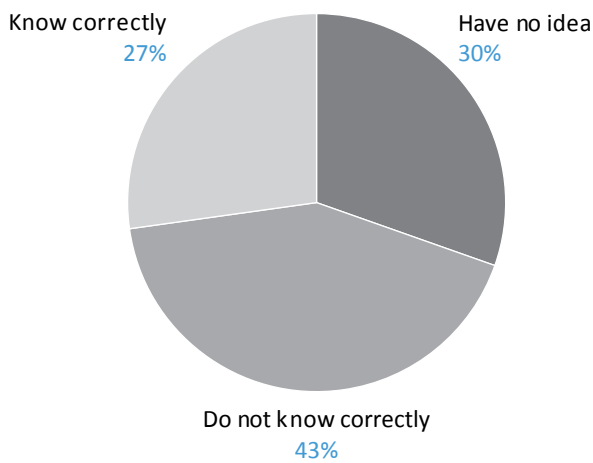
Until recently (i.e. July 2015), laws on the sale at a distance of medicinal products in the EU were extremely diverse, which created confusion among customers and caused difficulties for investigations and prosecutions. Legislative asymmetries create gaps and loopholes that criminals are able to exploit, particularly by leveraging on the lack of knowledge of potential customers. Indeed, the results of the web survey conducted on individuals in the EU showed that the majority of people either do not know anything about the legislation applicable in their country or possess wrong information (see Figure 18).

The research results showed that criminals often create illegal online pharmacies selling POMs without prescription claiming that such activity is legal because they are selling from a member state abroad where it is allowed. Below an example of an illegal online pharmacy offering POMs to Italian customers providing misleading information about the legislation:

“ All the medicines that we supply are legally produced and delivered from England, Germany, The Netherlands, or Sweden. ”

[Illegal online pharmacy, Italy]

Figure 18 – European citizens and knowledge of their national legislation concerning the online trade of medicines. Percentages. Results of web survey (N=783)



Source: elaboration by eCrime – project Fakecare

Furthermore, the virtual ethnography showed that information about the legislation written in members' posts is nearly always wrong. As an example, in Italian online forums several posts about the legality of buying POMs from the United Kingdom were found:

“ Even my boyfriend buys [prescription] medicines 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 medicines.

Many websites are written in Italian but they may ship from a country outside Europe, so 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 problems. I can recommend [XXXX].bix. Usually I receive the pills within a week. Good evening. ”

[Italian online forum]

4.5.2 The EU Directive 2011/62

In May 2011, the European Council adopted Directive 2011/62/EU with the aim of protecting the legal distribution chain from infiltration by falsified medicinal products. Specifically, the European act amended Directive 2001/83/EC in order to create “a Community-wide code on medicines for human use aimed at preventing the introduction of falsified medicinal products into the chain of legal procurement”.⁴⁰ The Directive advocated a wide set of responses to the illegal trade of falsified medicinal products. They can be clustered around four main points:

1. Introduction of a first definition of “falsified medicinal products”. According to Article 1, a falsified medicinal product is a medicine 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”. Finally, the last sentence clearly states that the “definition does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights” (i.e. counterfeit medicines);
2. Improvement of safety and traceability devices, as well as of distribution chain controls. The Directive foresees the obligation to introduce security devices on the packages of certain medicinal products in order to verify their authenticity. Moreover, it introduces new requirements for improving controls on the distribution chain (e.g. definition and regulation of “brokering of medicinal product” activities);
3. Introduction of new requirements for pharmaceutical companies, raw materials and excipients. The Directive lays down new requirements to be applied by pharmaceutical companies (even outside the European Union) concerning the verification process, manufacturing practices, inspections, etc.;
4. Harmonization of Member States legislation on the sale at a distance of medicinal products (see next Section).

⁴⁰ Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products. Retrieved from: http://ec.europa.eu/health/files/eudralex/vol-1/dir_2011_62/dir_2011_62_en.pdf. Last accessed on: 06 December 2015.

4.5.3 Sale at a distance to the public (Title VII A)

“Title VII A” of the Directive foresees a set of measures to be applied by Member States in order to harmonize domestic legislation on the sale at a distance of medicinal products in order to tackle the illegal trade of medicines over the Internet. According to Article 85c, “Without prejudice to national legislation prohibiting the offer for sale at a distance of prescription medicinal products to the public by means of information society services, Member States shall ensure that medicinal products are offered for sale at a distance to the public by means of information society services [...]”.

Thus, some member states that prohibited the sale at a distance of medicinal products must now allow at least the sale of over-the-counter medicines (OTCs). At the same time, the Directive left the issue of the sale at a distance of prescription medicines (POMs) to be settled by Member States.

According to the Directive, only individuals entitled to supply medicines under domestic law may sell medicinal products at a distance. Thus, Member States still have the competence to decide what entities are allowed to sell medicines, even at a distance. The Directive has also introduced a “common logo” to be displayed by every legally operating website supplying medicines in the European Union (see also Section 4.6), as well as a set of minimum standards to be respected by online pharmacies/retailers.

Finally, in order to raise customer awareness about the legislation, Member States have the obligation to set up a website providing – among other things – information on the national legislation applicable to the online sale of medicines, including information on the fact that there may be differences between Member States regarding classification of medicinal products and the conditions for their supply. The website must also contain information about the risks related to medicinal products supplied illegally, information about the purpose of the “common logo”, and the list of persons entitled to sell medicines online in the Member State.

4.5.4 Assessment of transposition of Title VII A

As highlighted in the previous Subsection, EU Member States are currently changing their legal provisions according to EU Directive 2011/62 in an attempt to harmonize the differences among domestic regulations. This operation is crucial in order to reduce the criminal opportunities stemming from legislative asymmetries within the European Union.

At present, even if some Member States have not yet transposed the Directive into their domestic legislation although the date of transposition has recently expired (01/07/2015), in the majority of the European countries it is allowed sell medicines at a distance. More in detail, in 21 Member States it is possible – or it will be possible in the near future – to sell only over-the-counter medicines (OTCs), while in the other 7 it is possible to sell also prescription-only medicines, as illustrated in Table 8 and Figure 19.

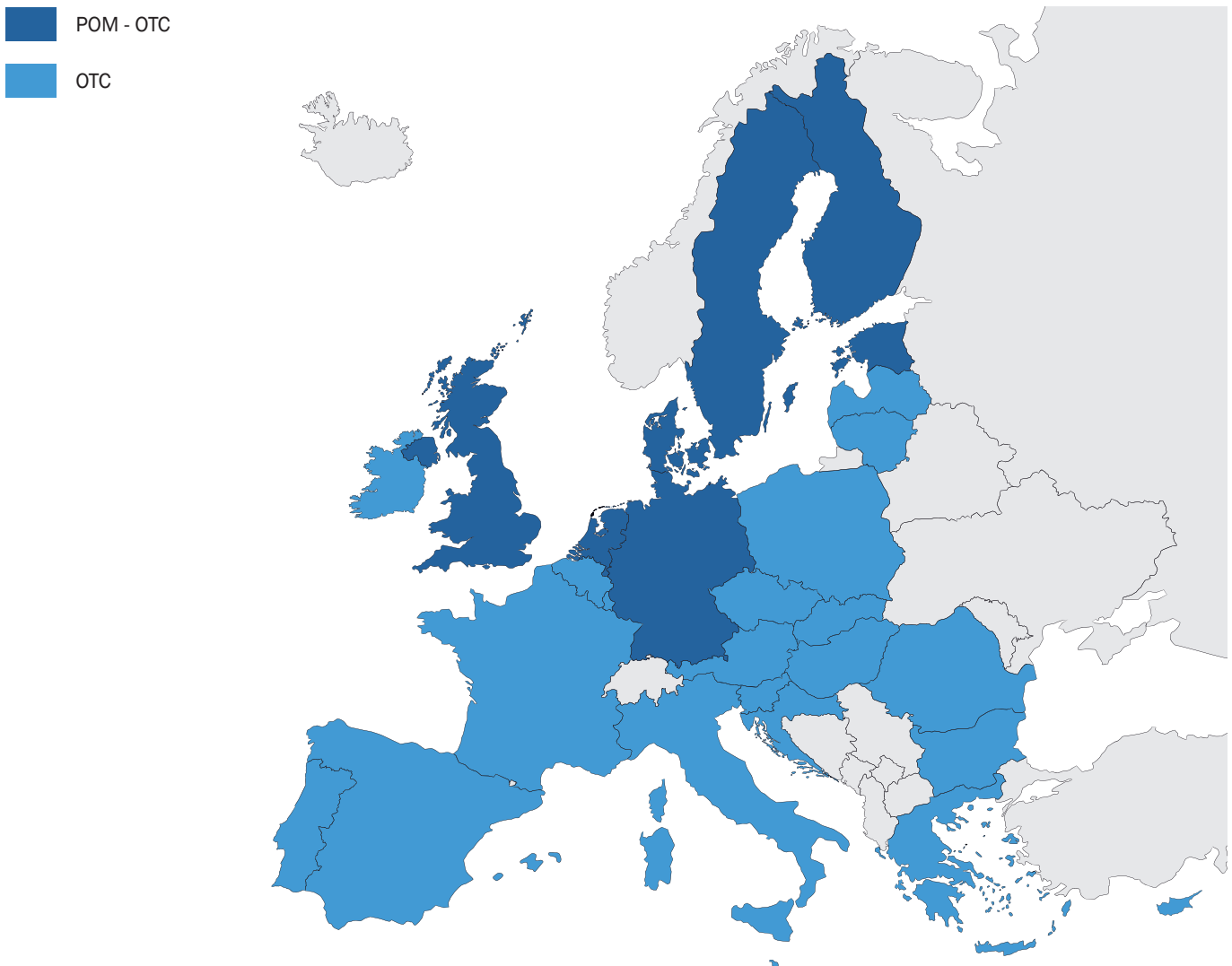
However, some specific features of domestic provisions within those groups are still not harmonized. First, as illustrated in the previous Subsection, it is still up to Member States to decide what entities are allowed to sell medicines at a distance. For instance, in the United Kingdom OTCs can be sold also through trading platforms like Amazon and eBay, while in other Member States this is not possible. Second, Member States that allow the online sale of POMs have also introduced limitations and/or specific procedures for such purchases that differ country by country.

Table 8 – Assessment of transposition of Article 85c (Title VII A) of European Directive 2011/62 by Member State (December 2015)

| POM - OTC | OTC | | |
|----------------|----------------|-------------|----------|
| Denmark | Austria | Greece | Malta* |
| Estonia | Belgium | Hungary | Poland |
| Finland | Bulgaria | Ireland | Portugal |
| Germany | Croatia | Italy* | Romania* |
| Netherlands | Cyprus | Latvia | Slovakia |
| Sweden | Czech Republic | Lithuania* | Slovenia |
| United Kingdom | France | Luxembourg* | Spain |

* not entered into force/ prevision on future legislative amendment

Source: elaboration by eCrime – project Fakecare

Figure 19 – Assessment of transposition of Article 85c (Title VII A) of European Directive 2011/62 by Member State (December 2015)

Source: elaboration by eCrime – project Fakecare

4.5.5 Criminal opportunities still existing and possible mitigation strategies

Although the harmonization process deriving from the European Directive can be considered an important step forward for the European legal framework, some important legislative asymmetries still persist, thus creating opportunities that criminals can exploit. Indeed, even if the majority of the Member States comply with the Directive's requirements, and although the European Legal framework is now more harmonized than it used to be, national laws on the sale at a distance of medicinal products still possess a degree of heterogeneity. The only strategy to eliminate criminal opportunities stemming from legislative asymmetries is to fill existing gaps and create a more harmonized legal framework.

Since this process may take a long time (and may even be opposed by some Member States), in the meantime mitigating legislative vulnerabilities requires informing the public about the correct legislation applicable in their country. As underlined in the previous Subsection, Member States are under the obligation to set up websites providing such information. The list of these websites is available on the webpage of the European Medicine Agency (www.ema.europa.eu > Human regulatory > Falsified medicines > Buying medicines online). However, a preliminary analysis of the content of such websites found that information about the legislation contained in national websites is often hard to retrieve and difficult to understand for the general public. At the same time, even if the deadline for transposition of Title VIIA of the Directive has been passed, some of these sites are still under construction or under development. As a consequence, at present it is not possible to express any final judgement on the suitability of these websites for raising the general public's awareness of both the correct legislation applicable and the risks deriving from purchases from illegal online sources.

4.6 The EU common logo and its vulnerabilities

Being able to recognise illegal websites supplying medicines is a key issue for customers, law enforcement agencies, and other relevant authorities. However, it is sometimes very difficult to understand whether or not a website is legitimate. To overcome this problem, the European Directive has introduced a common logo for use by legally-operating online pharmacies. However, in the past similar verification schemes implemented in other sectors (e.g. other types of ecommerce) have been forged. For this reason, the project sought to identify possible vulnerabilities in the EU common logo. Such analysis is essential to gain better understanding of the opportunities that criminals may exploit in the online sale of falsified medicines, as well as to evaluate the effectiveness of EU counterstrategies introduced by the European Directive 2011/62.

4.6.1 The European common logo for online sale of medicines

Article 85 quarter (3) of European Directive 2011/62 has introduced a common logo for legally-operating online pharmacies/retailers in EU Member States to use as a guarantee of authenticity. According to the same Article, the Commission had to adopt implementing acts regarding the design of the logo as well as the technical, electronic and cryptographic requirements for verification of the authenticity of the common logo. On this legal basis, the Commission issued a concept paper for public consultation with a view to preparing the implementing act.⁴¹ After the consultation, on 24 June 2014 the Commission adopted the new common logo through the Implementing Regulation 699/2014.⁴² Thereafter, Member States had one year to ensure that the provisions on the common logo were applied: as of 1st of July 2015, all legally-operating online pharmacies/retailers in the European Union should display the logo.

⁴¹ Implementing act on a common logo for legally-operating online pharmacies/retailers offering medicinal products for human use for sale at a distance to the public concept. Paper submitted for public consultation. Retrieved from: http://ec.europa.eu/health/files/falsified_medicines/commonlogo_consult.pdf. Last accessed on: 10 December 2015.

⁴² Commission implementing regulation (EU) no. 699/2014 of 24 June 2014 on the design of the common logo to identify persons offering medicinal products for sale at a distance to the public and the technical, electronic and cryptographic requirements for verification of its authenticity. Retrieved from: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0699>. Last accessed on: 10 December 2015.

Figure 20 – The EU common logo for online sale of medicines

Source: elaboration by eCrime – project Fakecare

The logo must be clearly displayed on every page of the online pharmacy/retailer's website, and it must be recognisable throughout the Union, while enabling identification of the Member State where the website is established (European Commission, 2015). The national flag and the text are an integral part of the logo, as illustrated in Figure 20.

The EU common logo links to the website of the national competent authority responsible for maintaining a list of legally-operating online pharmacies/retailers registered or authorized in the country. By clicking on the logo, customers are directed to the national list and, once there, they must check whether the online pharmacy/retailer is listed in order to complete the verification process. The information transiting between the websites authorised or entitled to supply medicinal products at a distance to the public and the websites hosting the national lists must be secured by appropriate means.

4.6.2 Vulnerabilities of the European common logo

The EU common logo for legally-operating online pharmacies/retailers is an important innovation provided by European Directive 2011/62. However, in the past, similar public and/or private authenticity logos and verification schemes implemented worldwide in other sectors (e.g. other types of ecommerce) have been forged. Indeed, criminals may counterfeit the logo, display it on their sites, and copy the linked website, as illustrated in Figure 21.

These vulnerabilities were acknowledged also by some relevant stakeholders and national competent authorities when responding to the concept paper during the public consultation before issue of the implementing act by the Commission:⁴³

National Association of Pharmacies – ANF (PT)

“ However, we also believe that the adoption of a logo can be counterproductive since it can introduce a false sense of security among citizens. Logos and a national list of legally-operating online pharmacies/ retailers with reciprocal links can be easily falsified and, instead of improving safety, these may facilitate the dissemination of illegal internet pharmacies. ”

Federació d'Associacions de Farmàcies de Catalunya – FEFAC (ES)

“ It is easy to fake webpages, also a second, pseudo-“official” webpage that approves the first fraudulent webpage. [...]. You may face situations such as this: a person visits a fraudulent pharmacy webpage with copied logo. The person then clicks on the logo to make sure the website is legit, and is taken to another fake webpage that “approves” the pharmacy page. There may be an additional risk that clicking on a fake logo activates computer viruses (on top of selling bogus drugs). ”

Consejo General de Colegios Oficiales de Farmacéuticos de España (ES)

“ [...] the presence of the logotype alone is not sufficient and that the patient/consumer [...]. On the other hand, taking into account that an URL may be redirected or modified in such a way that the false URL may pass unnoticed by the average user [...]. ”

Pharmacy Forum (NI, UK)

“ [...] the Forum has some reservations with regards to the common logo for internet pharmacies and the potential for the logo to be copied. Such logos are easily counterfeited, and may provide a false sense of security for patients. ”

European Federation of Pharmaceutical Industries and Associations – EFPIA

“ However we are concerned that if the system is not set up with care there is a strong likelihood that illegal operators will be able to copy the logo, place it on illegal pharmacy websites and link it to fake authentication pages. This could mislead patients into believing that they are purchasing from an authorised online pharmacy.

[...] the simple presence of the logo on a web-page will not be sufficient to ensure that the online pharmacy/retailer is authorised, as the logo may have been copied. Equally, clicking on the logo on a page will not provide a guarantee of authenticity as the page to which the logo links could also be fake. ”

General Pharmaceutical Council (UK)

“ At the GPhC we already have a web-based searchable register of pharmacies that are registered with us. [...] We have however encountered incidents where owners of registered pharmacies have just copied our logo onto their website instead of first applying to us for approval to display the logo. [...] To circumvent the reciprocal hyperlink embedded in the logo, owners have simply hyperlinked other information beneath the copied logo, (such as their pharmacy's unique registration number), directly to their pharmacy's entry on the web-based register instead.

In summary we support the desire to provide greater assurance to the public when purchasing medicinal products over the internet but remain concerned that the EU logo could give false assurance as it appears possible to copy the logo onto websites that have not been approved by the relevant national competent authority. ”

Alliance for Safe Online Pharmacy EU – ASOP (UK) & European Alliance for Access to Safe Medicines (UK)

“ Similar national logos have, in the past, been forged. ”

National Association of Boards Pharmacy – NABP (US)

“ One stakeholder who runs a similar, voluntary scheme, reports to us that there have been occasional examples where the logo they have adopted appears to have been illegitimately copied by non-registered pharmacies, despite their considerable efforts. ”

Pharmaceutical Group of European Union, Groupement Pharmaceutique de l'Union Européenne – PGEU, GPUE

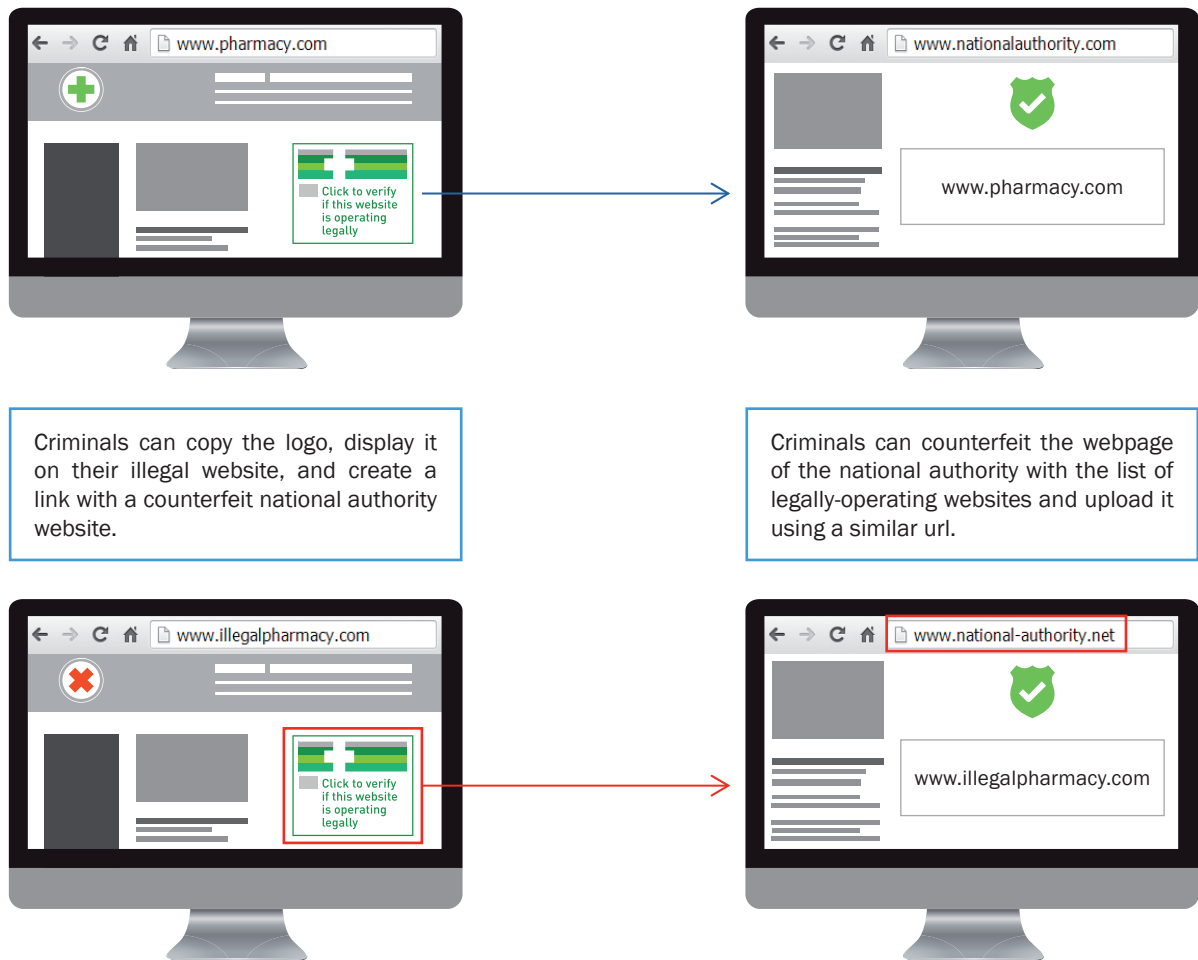
“ PGEU has consistently argued that the use of a Common Logo to identify legally authorised sellers of medicines is potentially counterproductive. For example, there can be no assurance that both the Logo and the national list of legally operating pharmacies and retailers can be excluded from risk of falsification. ”

The Netherlands

“ The Netherlands are of the opinion that a common logo will also not be a solid instrument to determine right from wrong. The selling of falsified medicinal products is highly profitable. Falsifiers will sooner or later be able to copy the common logo. And we certainly don't want to refer people to illegal websites/suppliers and make them think that they are legitimate ones. On the other hand: offering them no tool at all is also not a favourable option. ”

⁴³ Responses to the concept paper submitted for public consultation concerning the implementing act on a common logo for legally-operating online pharmacies/retailers offering medicinal products for human use for sale at a distance to the public. Retrieved from: http://ec.europa.eu/health/human-use/falsified_medicines/developments/2013-02_common_logo_pc_en.htm. Last accessed on: 10 December 2015.

Figure 21 – Vulnerabilities of the EU common logo for legally-operating online pharmacies/retailers.

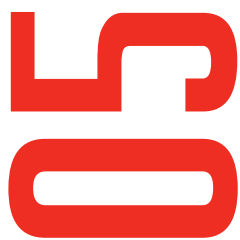


Source: elaboration by eCrime – project Fakecare

The results of a vulnerability assessment have shown that both the EU logo and the verification scheme can be counterfeited in a few minutes, with basic computer skills, and spending only the money necessary to purchase a fraudulent domain to upload the copied version of the websites hosting the national lists.

Moreover, the verification scheme introduced by the European Union has not always been well implemented by online pharmacies/retailers. Indeed, an analysis of

a large number of European legally-operating suppliers has shown several problems, among which: the logo is not displayed at all; the image of the logo contains some errors (e.g. it is smaller or different); the link does not work, or the logo is linked to pages other than the national register of legally-operating online pharmacies/retailers (e.g. a web page with the text of the European directive). It will be difficult for the national competent authorities to control the correct application of the system by legally operating websites.



Counterstrategies and tools

Project Fakecare, on the basis of the in-depth knowledge presented in the previous chapter, has developed counterstrategies and tools to fight the online trade of falsified medicinal products. Specifically:

- an ICT tool to automatically detect illegal online pharmacies, i.e. the Fakecare Alert System Tool (see Section 5.1);
- a tool devised to determine the risk that a given medicine may be falsified and traded online, i.e. the Fakecare Hot Medicines Tool (see Section 5.2);
- guidelines for customers and LEAs (see Section 5.2);
- a syllabus for a university course on pharmacrime (see Section 5.2).

5.1 FAST: an ICT tool to automatically detect illegal online pharmacies

This section focuses on FAST – Fakecare Alert System Tool, an ICT tool devised for the automatic verification of online pharmacies and developed in order to accomplish Objective 2 of project Fakecare: “Producing counterstrategies and tools (including an ICT tool) to disrupt such a trade, based on this knowledge”.

This section is structured as follows. First, an introduction provides some background knowledge together with a preliminary analysis of requirements, explaining some basic theoretical concepts and terminology. There follows an overview of the system architecture, including some information on implementation. Finally, the results from a real test case for evaluation of the tool’s performance are reported. The section

concludes with discussion of possible further developments to improve the functionalities of the current prototype and to remedy some of the limitations highlighted.

5.1.1 Introduction

As widely discussed in Section 4.2, medicines are being sold online in a conspicuous number of websites. In this context, ‘online pharmacy’ denotes a website dedicated to the sale of medicinal products. Most online pharmacies are not compliant with national regulations or, more often, deliberately violate the law by selling falsified and/or dangerous products that may harm unaware users. Law enforcement authorities are committed to curbing the spread of such illegal websites. Continuous monitoring of the Web is therefore necessary in order to reduce the chances of consumers finding themselves in situations that may expose their health to serious risks.

LEAs should consequently be equipped with tools enabling the evaluation of suspicious online pharmacies. In particular, given the huge number of reported websites, on the one hand it is crucial for authorities to focus their actions on those websites likely to be illegal; on the other hand, it is also important to ensure that these actions are accomplished as rapidly as possible.

According to task 2.1 of the project, research centred on “Developing an ICT prototype to enable law enforcement and other relevant agencies to automatically detect illegal online pharmacies”. Hence an ICT tool, named FAST (Fakecare Alert System Tool), was designed and developed so as to provide all agencies and institutions committed to the fight against the online trade in falsified medicines with a tool supporting the manual work of analysts in identifying illegal online pharmacies.

In particular, the tool was designed with the capability to assign a score automatically to a suspicious website. This score measures the level of risk, expressed in percent, of the given website, and it is computed using a data mining algorithm entirely developed at eCrime.⁴⁴ The fundamentals behind the FAST algorithm are discussed in the next subsection.

5.1.2 The FAST algorithm

When visiting an online pharmacy, most people find it very difficult to tell if the website on which they have landed is legitimate or illegitimate.⁴⁵ However, after exploring a sample subset of known illegal online pharmacies, even an inexperienced observer may start to notice recurrent patterns in the visualized contents, i.e. some of the features characterizing an online pharmacy. For example, the webpage structure (positioning of text and images), as well as the language adopted, or the particular products offered, may exhibit similar properties among illegal sites. An experienced analyst, whose task is manually to review and verify the legitimacy of an online pharmacy, is usually able to retrieve implicit information merely from the presence or absence of the above-mentioned features.

This manual verification process could be assisted by a data mining algorithm able to extract such implicit

information automatically from a set of known legitimate and illegitimate online pharmacies. The algorithm should then be able to process a new (unknown) online pharmacy and determine its legitimacy by automatically recognising implicit patterns involving certain features previously learned from the training set of known legitimate and illegitimate samples. In other words, the algorithm to be chosen must solve a classification problem.

The classification problem may be stated thus: given a set of ‘labelled instances’ (i.e. known legitimate and illegitimate online pharmacies) and a new unlabelled instance to process, required is an algorithm with the ability to extract implicit rules from the previous training set, and to use this knowledge to assign a class label (i.e. ‘legitimate’ or ‘illegitimate’) to the new instance.

The algorithm upon which FAST is built has been designed and developed by eCrime researchers, and it relies on two different kinds of analysis:

1. Analysis of textual web content, i.e. text analysis;
2. Analysis of outgoing web links, i.e. network analysis.

The algorithm makes it possible to combine these two analyses to solve the classification problem and, furthermore, to calculate a risk index. The risk index is a normalised score, given in percentage (0% - 100%), estimating the probability that the processed online pharmacy is illegitimate. Analysing web content to find text similarities within known websites, as well as evaluating trust in a network of URLs, are two approaches commonly adopted in the web-mining literature (Manning et al., 2008; Rajaraman & Ullman, 2011).

More in detail, with the first approach (text analysis) it is possible to solve a classification problem using text-mining algorithms that allow the extraction of relevant features and the construction of a model characterizing the two classes. Using proper document representation models (e.g. vector space models (Salton et al., 1975), n-gram graphs (Giannakopoulos et al., 2008) and similarity metrics (e.g. tf-idf weighting (Sparck Jones, 1972) for the vector space model, containment/size/value similarity (Giannakopoulos et al., 2012) for the n-gram graphs), it is possible to evaluate the distance between each of the known labelled instances and a new unlabelled instance. The latter may thus be assigned a label together with a confidence measure.

As regards the second approach (network analysis), the aim is to construct the network of outgoing web links (URLs) from a set of online pharmacies, and to use network trust algorithms (e.g. TrustRank (Gyongyi et al., 2004), EigenTrust (Kamvar et al., 2003)) to assign

⁴⁴ The FAST algorithm, its further refinements for performance optimization, as well as the ICT tool’s architecture design and software implementation have been developed at eCrime by Alberto Cordioli (original concept, main contribution), Fabiano Francesconi, Vincenzo Falletta, and Walter Da Col under the supervision of Themistoklis Palpanas and Andrea Di Nicola.

⁴⁵ In the rest of this section, the terms ‘illegal’ and ‘illegitimate’ are used interchangeably, as well as ‘legal’ and ‘legitimate’.

a ‘reputation’ score to each node in the network on the assumption that legitimate online pharmacies are very unlikely to link to illegitimate ones. On using this score as a metric to assess the legitimacy of an online pharmacy, it is possible to classify a new unlabelled instance by extracting its network of outgoing web links and computing the corresponding trust score.

The combination of these two approaches creates an ensemble algorithm: given a new online pharmacy to classify, the likelihood of its belonging to the illegitimate class is computed using both text analysis and network analysis. Then the normalised weighted sum of the two results gives the final risk index s . This score may range from 0% (minimum risk, i.e. the website is considered legitimate) to 100% (maximum risk, i.e. the website is considered illegitimate). Setting a threshold at $sthresh = 50\%$ then makes it possible to classify a website as legitimate if the corresponding score is less than or equal to the threshold ($s \leq sthresh$). Conversely, if a website receives a score greater than the threshold ($s > sthresh$), it will be classified as illegitimate.

The algorithm is the most important component of FAST. It is the decision engine powering the ICT tool, and it has been implemented as one among several blocks within a flexible modular architecture, which is described in the next subsection.

5.1.3 Architecture

FAST has been implemented as a distributed web application (see Figure 22) following the client-server model. Each component has a modular architecture, designed and developed at eCrime, based on the SOA (Service Oriented Architecture) paradigm. The tool is made up of two main components: a front-end and a back-end.

The front-end is implemented as a web application (see Figure 23). There is no need to install any software; it is accessible via the most common browsers

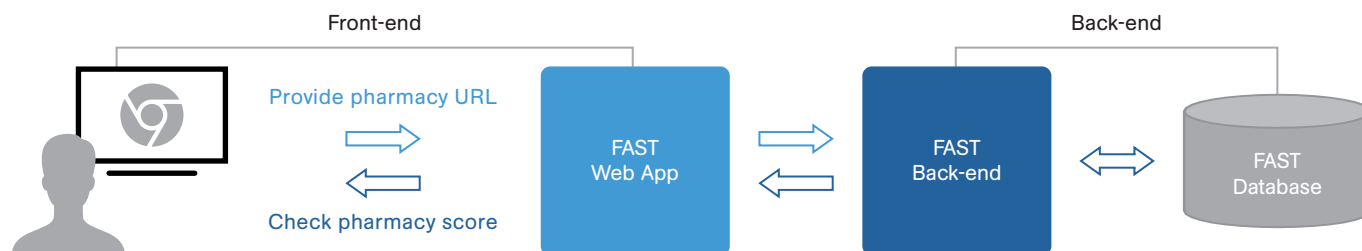
(e.g. Google Chrome, Firefox, Safari, and Internet Explorer) by pointing them to the login URL, available on the project website. The login screen is available through a plain HTTP channel, or it may be served through a secure HTTPS channel. Valid credentials are required to pass the authentication and authorization steps.

A simple graphical user interface (GUI)—available in English, Italian and French, according to project requirements—allows analysts to submit the URLs that they want to check, either in interactive mode or in batch mode. Once a request has been submitted, it is added to the list of processed websites available on the panel on the left side of the screen. Clicking on an entry in this list will show details of the given pharmacy on the main area. Details include: the risk index, information on hosting and domain (e.g. IP address, registrar), information on server location (City, Country), a screenshot of the website. When the investigations for a given website have concluded, analysts can certify the legitimacy or illegitimacy of the latter by simply clicking the corresponding button on the central evaluation panel. Using the evaluation panel also provides feedback to the underlying algorithm, thus improving the training stage.

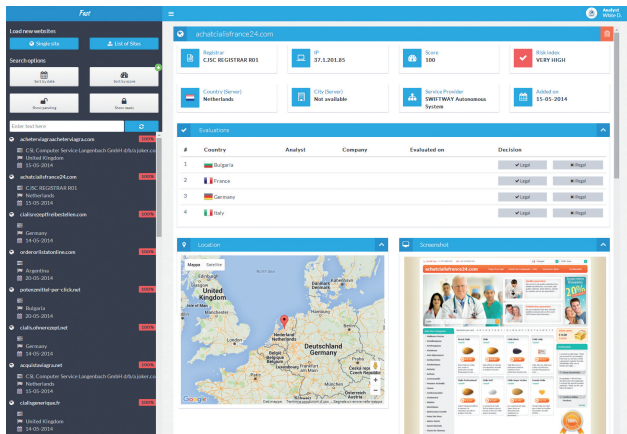
The front-end has been designed and developed to have a client with which the final user can interact, sending requests and presenting the responses in a human readable form. The graphical layout, as well as the information to be displayed, may be changed according to different options. The current version is therefore just one of the many possible faces that can be assigned to the tool. However, the main component of FAST is the back-end.

The back-end encompasses several modules with a key role in the decision-making process for the automatic verification of online pharmacies. The input interface is implemented via a RESTful web service (see Figure 24) accepting commands and requests from the client and providing the corresponding responses. The web

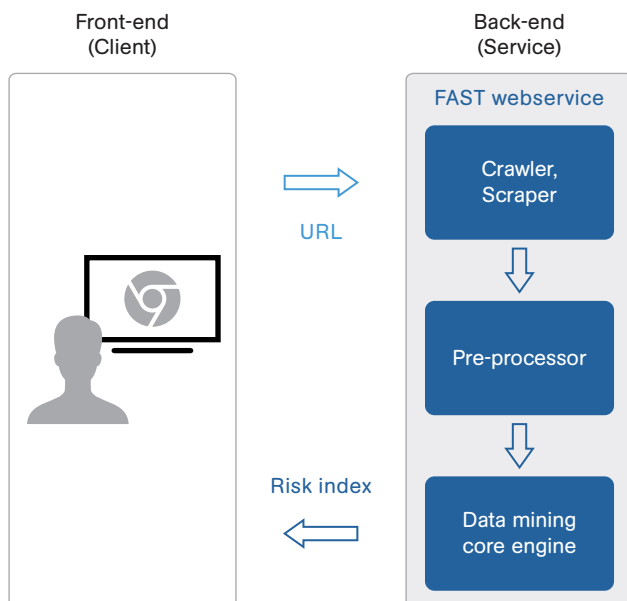
Figure 22 – FAST architecture



Source: elaboration by eCrime – project Fakecare

Figure 23 – The FAST Web Application

Source: elaboration by eCrime – project Fakecare

Figure 24 – The FAST Web service

Source: elaboration by eCrime – project Fakecare

service accepts as a request a URL (or a list of URLs in a plain text file) and then performs a series of steps before returning the final response.

The request is first passed to a module which is responsible for visiting the URL concerned, crawling the corresponding web pages (following the outbound links from the landing page) and scraping the downloaded content in order to extract raw data to store in a local database. Then, a pre-processing module is responsible for manipulating the data stored in the database and performing some normalisation tasks in order to convert these data into the proper format accepted by the next module. Finally, the normalised

data are passed to the data mining core module. This implements the algorithm discussed in the previous subsection, which effectively computes the risk index for the online pharmacy. The results of the evaluations are sent back to the client when they become available, and they are also stored in the local database, allowing the safe storage and the retrieval of previous analyses even if the website is no longer available.

5.1.4 Evaluation and experimental results

Dozens of international representatives from LEAs, health regulatory agencies, non-profit organizations expressed interest in testing FAST after it was presented at several meetings—such as those organised by Interpol and Europol—held during project Fakecare. An application server running FAST has been set up at the University of Trento, and individual credentials have been created for those requesting to test the tool free of charge.

A long list of acknowledgements, positive feedback on the tool's accuracy and the user's experience have been received, as well as numerous suggestions on new features to add and some functionalities to improve. FAST has been appreciated for both its effectiveness in measuring the level of legitimacy of an online pharmacy and the amount of time saved by the analysts. It seems from their comments that there is currently no other tool able to retrieve and create a bundle of useful information about suspicious online pharmacies under investigation.

The following subsections provide an overview on the experimental tests carried out to assess the tool's performance.

Training data collection

The FAST data mining algorithm described in subsection 5.1.2 solves a classification problem. Consequently, a training setup must be run before the actual tests can start. In the training phase, the algorithm builds a knowledge-base by extracting implicit patterns from a set of known legitimate and illegitimate online pharmacies. After this training phase, the effective detection may be performed on a new set of online pharmacies to be verified, with a prediction returned for each of them. Therefore, the training phase requires a set of labelled instances to be available: that is, a list of URLs of known legitimate and illegitimate online pharmacies must be collected.

In order to speed up this collection process, a list of 1,630 known illegitimate URLs and 210 known legiti-

mate URLs was kindly provided by LegitScript. That list was only a small fraction of the entire list of online pharmacies monitored by LegitScript, which at that time comprised about 41,545 entries. Nevertheless, it helped eCrime researchers save time: otherwise, they would have had to conduct a long manual search of online pharmacy URLs on the Internet followed by a manual classification (as indeed was done later to collect a small test set of legitimate examples).

The online pharmacies addressed by the URLs provided were crawled, scraped and normalized in order to construct the effective dataset employed for the training phase of the algorithm. Some of the websites were not reachable at the moment of crawling; hence the final training dataset consisted of 1,292 illegitimate instances and 167 legitimate instances.

It should be mentioned that, since all the collected websites were in English, the training phase produced a predictive model optimised for the analysis and detection of illegitimate online pharmacies with English content. Further optimisation for other different languages may be possible, depending on the data collected during the training phase.

Test results

FAST was tested on a real investigative scenario: that is, the enforcement actions organised at Interpol headquarters in Lyon, France, within the context of Operation PANGAEA VII. A sample test dataset containing 4,368 suspicious websites, including those provided by public and private actors, was made available by Interpol to eCrime researchers visiting the headquarters during the operation activities. The test dataset was processed using the FAST tool, producing the results shown in Table 9.

Table 9 – Results from Operation PANGAEA VII

| Description | Values |
|---|--------|
| N. of websites classified as illegal (score >50%) | 4,168 |
| N. of websites classified as legal (score <=50%) | 200 |
| Total n. of websites processed by FAST | 4,368 |

Source: elaboration by eCrime – project Fakecare

As discussed in subsection 5.1.2, for each website processed the algorithm returns a risk index s , i.e. a score measuring the likelihood that the given website is illegal (illegitimate). When a threshold is set at $sthresh$

= 50%, if the score falls in the interval between 0% and 50%, the website is classified as legal, whereas if the score exceeds the thresholds then the website is classified as illegal.

The results in Table 9 show that FAST processed a list of 4,368 websites, only 200 of which received a score below 50% and were therefore predicted as legal. On the other hand, 4,168 websites were assigned a score above the threshold, and were consequently predicted as illegal.

As regards the ground truth, to be pointed out is that on conclusion of the operations more than 11,800 illegal websites were shut down, including the 4,368 websites processed by FAST. The predictions shown in Table 9 consequently denote a good level of accuracy.

Subsequently, a sample test set containing only legally certified pharmacy websites was manually collected by eCrime researchers in order to run a performance evaluation focused on the negative class (i.e. the legal websites). Table 10 shows the results from this test run.

Table 10 – Classification of a list of legal websites

| Description | Values |
|---|--------|
| N. of websites classified as illegal (score >50%) | 10 |
| N. of websites classified as legal (score <=50%) | 108 |
| Total n. of websites processed by FAST | 118 |

Source: elaboration by eCrime – project Fakecare

Note that the latter test dataset contained a smaller number of instances than the previous test dataset collected during PANGAEA VII. It was difficult to collect a sample dataset containing a number of legitimate instances of the same order of magnitude as that in the illegitimate sample dataset provided by Interpol. Combining the results from the two separate tests yields the following confusion matrix (Table 11).

A confusion matrix is a particular contingency table showing the connection between two variables, namely ‘prediction’ and ‘truth’. Since these two variables are both binary, there are only four possible outcomes: i) an instance (i.e. a processed website) predicted as legal is actually legal (True Negative); ii) an instance predicted as illegal is actually legal (False Positive); iii) an instance predicted as legal is actually illegal (False Negative); iv) an instance predicted as illegal is actually illegal (True Positive).

Table 11 – Confusion Matrix

| | Predicted as Legal | Predicted as Illegal | Total (by row) |
|-------------------|-----------------------------------|------------------------------------|----------------|
| Known Legal | 108 True Negative (TN) | 10 False Positive (FP) | 118 |
| Known Illegal | 200 False Negative (FN) | 4,168 True Positive (TP) | 4,368 |
| Total (by column) | 308 | 4,178 | 4,486 |

Source: elaboration by eCrime – project Fakecare

Given a confusion matrix, it is possible to calculate some known performance indexes referring to the class of known illegal pharmacies, denoted as the ‘Positive class’. In particular, in what follows three useful indicators are considered, namely precision, recall and overall accuracy.

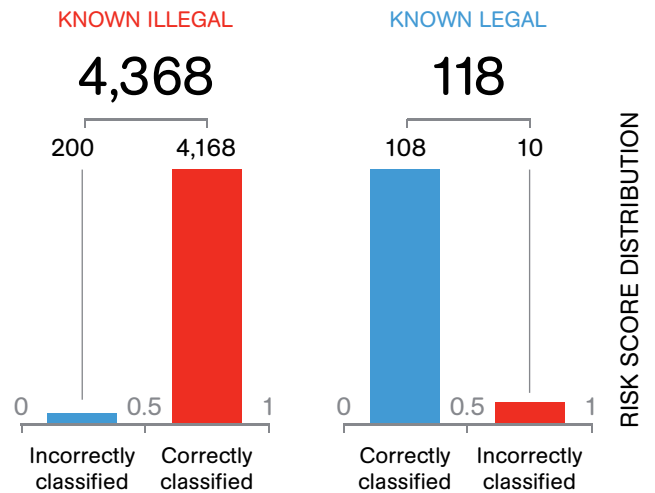
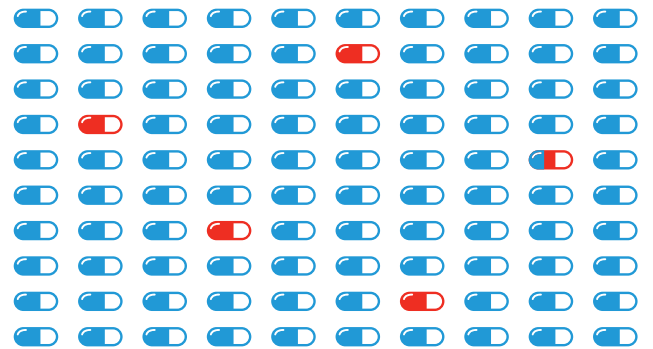
The precision index is defined as the ratio of True Positive instances to the sum of all the Positive predictions (i.e. False Positives + True Positives). The recall index is defined as the True Positive ratio, i.e. the ratio of True Positive instances to the total number of known illegal instances (i.e. True Positives + False Negatives). Finally, overall accuracy is defined as the ratio of all the correct predictions (i.e. True Positives + True Negatives) to the sum of all the processed instances. Table 12 summarizes the computed performance indexes.

Table 12 – Performance indexes

| Precision | Recall | Overall accuracy |
|--------------------|--------------------|-----------------------------|
| $\frac{TP}{TP+FP}$ | $\frac{TP}{TP+FN}$ | $\frac{TP+TN}{TP+TN+FP+FN}$ |
| 99.76% | 95.42% | 95.31% |

Source: elaboration by eCrime – project Fakecare

According to the numbers shown above, the precision index states that out of 100 alerts about potential illegitimate websites, more than 99 are correct, i.e. the corresponding websites prove indeed to be illegitimate. The recall index states that out of 100 known illegitimate websites, more than 95 are correctly detected. The overall accuracy is self-explanatory: out of 100 total predictions, more than 95 are found to be correct. Figure 25 provides a graphical representation of the results shown in Table 11 and Table 12.

Figure 25 – FAST risk score distribution and overall accuracy**FAST OVERALL ACCURACY****95.3%**

Source: elaboration by eCrime – project Fakecare

As a final note, given the larger size of the test dataset (4,368 illegal samples + 118 legal samples = 4,486 total samples) compared to the one used for training (1,292 illegal samples + 167 legal samples = 1,459 total samples), further performance optimisation for future tests may be achieved by merging the two datasets and repeating the training phase using the resulting extended dataset.

5.1.5 Final remarks

FAST has shown good potential as a means to recognize and distinguish between legal and illegal pharmacy websites, thus accomplishing a specific task of the project. Further work would involve the development of an improved web crawler module addressing the need for the automatic retrieval from the Internet of a list of suspicious websites to process if none is available. The resulting enhanced version of FAST would be able to scan the Internet automatically, starting from a set of pre-defined keywords related to the pharmacy domain. Once crime intelligence analysts had defined such keywords, they could be passed as input using the web application or directly loaded into the FAST back-end. The improved web crawler module would search for the corresponding relevant websites, and then visit and retrieve them as if the actual URLs had been passed.

Another application would be the periodic monitoring of known legal websites. Using a white-list of websites that should be monitored, the FAST back-end could be configured to check periodically if the content has changed. Then, if something suspicious is detected, it would raise an alert. Periodic monitoring could be useful for the automatic checking of websites at high risk of being hijacked, thereby discovering illegitimate unwanted changes in their content.

In conclusion, to be noted is that FAST has been the first joint effort undertaken by researchers, LEAs, health regulatory agencies and non-profit organizations to develop a software for the automatic verification of online pharmacies. It has required considerable effort in terms of ideas produced, time spent on running code and testing algorithms, sharing feedback among criminologists, computer scientists, law enforcement agents and analysts. eCrime researchers would like to thank Interpol for its constant support and firm belief in the added value of this project. Enthusiastic feedback has been received at recent events, such as those organised by Europol at its headquarters in The Hague and by Interpol in Brussels, where FAST was presented to representatives of international organizations and LEAs.

eCrime researchers want to continue working on this topic also in the 'post-fakecare era', being supported in doing so by all the institutions involved in the fight against the illegal trade of online medicines. A proposal could be the creation of a multi-actor working table: that is, a joint effort by law enforcement and regulatory agencies, pharmaceutical companies, and research institutions. This threefold synergy would ensure that the valuable results achieved so far are not wasted, and it

would make it possible to find resources with which to engineer and refine the current FAST prototype into a robust and stable version freely available to LEAs.

5.2 Other tools

5.2.1 Guidelines for customers and LEAs

The risks linked to the online trade of falsified medicinal products 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. At the same time, tackling this illegal market is a challenge for law enforcement agencies (LEAs) for a number of reasons. In fact, it is estimated that 10 per cent of the medicines supplied globally are falsified and that 1 million people die every year after consuming falsified medicinal products (WHO, 2006). Moreover, the Internet now acts as the main avenue through which this criminal market is expanding. In Europe, the online market in falsified medicinal products is expanding at a rapid rate. IRACM (2013) reported that the trade had increased 90 per cent since 2005, with an estimated turnover of \$200 billion. Therefore, the trade poses great dangers to public health, whilst reaping huge monetary rewards for criminal actors situated around the globe.

For these reasons, two sets of guidelines have been created containing information and advice drawn from the project's results. One, entitled 'Trick or treat(ment)? Guidelines for safe online purchases of medicinal products in the EU', provides information and advice to Internet users with the aim of helping them to avoid the online purchase of falsified medicinal products. The other guidelines, intended for LEAs, are entitled 'Search and Stop. Guidelines to tackle the online trade of falsified medicinal products'. They suggest how to tackle the illegal online trade in falsified medicines by outlining a series of points and techniques to consider during investigation.

To download the guidelines, please visit the project's official website: www.fakecare.com.

5.2.2 Syllabus for a university course on pharmacrime

The online trade in falsified medicinal products involves a series of complex issues: legal, technological, and health-based. But it is not without consequences for the various actors involved in preventing and combating pharmaceutical crimes at various levels of the public and private sectors.

Firstly, the police must implement new web intelligence strategies for the collection of evidence in order to improve enforcement actions, including the identification and closure of illegal online pharmacies. Secondly, pharmaceutical companies must understand the dynamics of the online illegal trade of medicinal products in order to develop counterstrategies and actions to protect themselves.

Finally, public or private institutions that deal with the sale of medicines, health, and communication must increase the range of skills needed to communicate the risks arising from the incautious use of the Internet to purchase medication outside legal channels. It is necessary to provide knowledge and specialized tools for the prevention of, and fight against, internet-related pharmaceutical crime. The need to develop advanced training in this field has been reaffirmed internationally by the relatively recent ‘Consultation on the phenomenon of falsification and pharmaceutical e-commerce of the Italian Senate’ (12th Permanent Commission on Health and Hygiene), which recommended the involvement of universities in the systematic training of professionals, including ad hoc university courses (Italian Senate, 2010). Moreover, the need for training is also affirmed nationally in the UK by references to the need for relevant professionals and the public to be educated and informed about the challenges of the pharmaceutical supply chains and the dangers of sourcing products from outside the assured supply chains – for example by purchasing unlicensed products online – which is one of the strategic themes in MHRA’s corporate strategy 2013-2018 (MHRA, 2013).

Project Fakecare has addressed this need by developing a proposal for a high-level training course. The module is intended for law enforcement officers, judges, professionals from the private sector (e.g. associations, consumer associations, pharmacists, security officers of pharmaceutical companies) and the public sector (e.g. officials of ministries, local authorities, etc.). The syllabus has been designed for Italian and United Kingdom universities. The course provides participants with advanced and multidisciplinary skills for preventing and combating pharmaceutical crimes, with particular attention paid to those illegal pharma-

cies that take advantage of new technologies and the Internet. For detailed information on the course proposal see Annex B.

5.2.3 Fakecare Hot Medicines Tool

As widely discussed in Section 4.4, it is not a simple task to determine the magnitude of the risk of a medicinal product being falsified/counterfeited and traded online. For this reason, as part of project Fakecare an instrument named the “Fakecare Hot Medicines Tool” was designed and developed with the purpose of supporting pharmaceutical companies and LEAs in such evaluation. Pharmaceutical companies can use it to improve their production process so as to create “secure-by-design” medicines proofed against falsification/counterfeiting actions, while law enforcement agencies can exploit it to support investigations and to prioritise controls and inspections.

More in detail, project efforts were aimed at creating (a) a methodology with which to assess the risk of a given medicine being falsified/counterfeited and traded online, as well as (b) an easy-to-use application to conduct such evaluation.

Figure 26 – The Fakecare Hot Medicines Tool Application

Fakecare Hot Medicines Tool

How to use the tool

Welcome to the Fakecare Hot Medicines Tool, an instrument devised to **determine the risk** of a given medicinal product being falsified and traded online. The tool (developed under the European project Fakecare) is a user-friendly application that assess a medicine's falsification risk by using a set of simple questions on product features. In order to generate the risk index, **every question** shall be answered. Results will be displayed within a **5 risk categories scale**: low risk (green), mid-low risk (yellow), mid risk (orange), high risk (light red), extreme risk (red).

1 IPH-related feature

What is the IPH-related feature of the medicinal product under analysis?

- ☐ Generic medicinal product
- ☐ Branded product with patent protection
- ☐ Branded product with expired patent protection
- ☐ New product with patent protection pending
- ☐ Other

2 Dosage form

What is the dosage form of the medicinal product under analysis?

- ☐ Injectable
- ☐ Vials
- ☐ Symp
- ☐ Tablet
- ☐ Capsules
- ☐ Jelly
- ☐ Other

3 Typology

What is the typology of the product under analysis?

- ☐ Anabolic steroid
- ☐ Anti-viral
- ☐ Antibiotic
- ☐ Antidepressant
- ☐ Cancer/IV medicine
- ☐ Diabetes, arthritis or hepatitis medicine
- ☐ Erectile dysfunction treatment
- ☐ Fertility medicine
- ☐ Hair loss treatment
- ☐ Opioid analgesic
- ☐ Sedative (benzodiazepine/benzo)
- ☐ Sport supplement
- ☐ Stimulant
- ☐ Weight loss/appetite suppressant
- ☐ Other

4 Accessibility

In your country, how is the product under analysis accessible?

- ☐ Needs a prescription
- ☐ Does not need a prescription
- ☐ Not authorized

Source: elaboration by eCrime – project Fakecare

(a) The first step was the development of a mechanism for risk assessment. Research identified five indicators determining the likelihood of a medicine being falsified/counterfeited and traded online (i.e. “origin”, “IPR/patent”, “type”, “dosage form” and “accessibility”). Each indicator was further divided into several categories concerning the ways in which it might vary (for instance, the indicator “dosage form” was composed of the categories “injectable”, “vials”, “syrup”, “tablet”, “capsules”, “jelly”, and “other”).

Since neither indicators nor internal categories have the same importance in determining the likelihood of a medicine being falsified/counterfeited and traded online, national and international experts on the online trade of falsified medicines (e.g. members of LEAs, scholars, etc.) were involved in order to assign a score

to each category, and to properly weight each indicator according to its importance in determining the risk.

(b) The Fakecare Hot Medicine Tool was designed as a user-friendly application to operationalise the risk matrix developed in the first phase. The tool assesses the product’s falsification risk by using a set of five simple questions. Specifically, users have to select for each indicator (i.e. question) the category of the product under analysis (i.e. answer). The risk index (F1) is calculated by summing the scores assigned to each answer (p_n) properly weighted for each question (x_n) (see formula below).

The results are displayed within a five risk category scale: low risk (green), mid-low risk (yellow), mid-risk (orange), high risk (light red), extreme risk (red).

$$RiskIndex(F_1) = x_{origin} p_1 + x_{ipr} p_2 + x_{typology} p_3 + x_{form} p_4 + x_{accessibility} p_5 = \frac{\sum_{n=1}^5 x_n \cdot p_n}{\sum_{n=1}^5 p_n}$$

Annex A

Country profiles

The research activities of the project were conducted in seven EU Member States (Bulgaria, Germany, France, Italy, Spain, the Netherlands and the United Kingdom). The aim was to gain a complete picture of the online trade in falsified medicinal products in Europe, thus avoiding possible biases deriving from a nationally-based analysis alone. More specifically, the research focused on: the demand side (i.e. who are at-risk customers, their characteristics, their decision-making process, and determinant risk factors), the supply side (i.e. actors involved in the trade and their organisation, the illegal online distribution channels used, and the types of – falsified – medicines most frequently supplied) and the patterns (i.e. the sequence of steps taken by offenders in the crime-commission process) of the online trade in falsified medicinal products. For this purpose, national experts were selected in each of the countries involved in the project:

- **Bulgaria:** Anton Kojouharov (an analyst on criminological and sociological research at the Center for the Study of Democracy);
- **France:** Nacer Lalam (a senior researcher at the Institut National des Hautes Études de la Sécurité et de la Justice);
- **Germany:** Denise Boriero (a research assistant at eCrime and at Teesside University);
- **Italy:** eCrime research group (the coordinator of the project);
- **Spain:** Andrea Gimenez-Salinas and Carmen Jordá Sanz (respectively professor and researcher at Instituto de Ciencias Forenses y de la Seguridad, Universidad Autónoma de Madrid);
- **The Netherlands:** Dina Siegel, Rosa Koenraadt and Maarten Roetenberg (respectively professor, DCGC PhD candidate and student at the Willem Pompe Institute for Criminal Law and Criminology, Utrecht University).
- **United Kingdom:** Teesside University research group (co-beneficiary of the project).

Table A1 – Research questions and methods by research activity. Guidelines for national experts – project Fakecare

| Research activity | Research questions | Methods |
|-------------------|--|---|
| 1. Demand side | Who is at risk of buying falsified medicines online? What are customers' characteristics (i.e. determinant risk factors, most at risk social groups)? What are customers' motivations? What are the most in demand medicines? | Virtual ethnography (For further information, see Section 3.2.1) |
| 2. Supply side | Who are the actors involved in the trade? How are they organised? What are the most popular sites and tactics used to advertise and market falsified medicinal products? What are the medicinal products most regularly supplied in illegal online distribution channels? | Virtual ethnography Script analysis of investigative and judicial cases and news from the press If needed, in depth-interviews with relevant stakeholders (For further information, see Sections 3.2.1, 3.2.2 and 3.2.7) |
| 3. Patterns | What are the activities carried out by offenders before, during and after the online trade in falsified medicinal products? | Script analysis of investigative and judicial cases and news from the press If needed, in depth-interviews with relevant stakeholders (For further information, see Sections 3.2.2 and 3.2.7) |

Source: elaboration by eCrime – project Fakecare

Research by the national experts followed common guidelines provided by the coordinator of the project, and in which both research questions and methods were explained (see Table A.1).

This Annex presents a summary of the nationally-based findings, while Sections 4.1, 4.2 e 4.3 of this report provide a complete picture of the demand side, the supply side, and the patterns in the European Union obtained through merging those findings.

Bulgaria

The demand side

Weight-loss medicines and supplements are widely popular and much advertised online in Bulgaria. Although it is difficult to ascertain which of the advertised products is falsified, potentially suspicious products for weight-loss share certain characteristics in their marketing approach. The virtual ethnography performed in forum discussions and comment sections established that the overwhelming majority of persons engaged in exchanges are female. Furthermore, they may include:

- novice users buying and consuming weight-loss supplements and medications for the first time;
- women and girls with a tendency to gain weight easily, as well as those who struggle with being overweight; a smaller, but noticeable group of information and Internet savvy individuals;
- users who also advertise and market products by participating in discussions and adding links to a product/brand that they recommend or are potentially associated with.

Fitness enhancers and anabolic steroids are being sold online in Bulgaria. Anabolic steroids are offered through a multitude of websites, which usually specialise in that product group, but also in online stores which also offer sexual enhancers and weight-loss products. Increasingly, anabolic steroids are being sold through Facebook. Facebook is heavily used by the target customers of anabolic steroids – young adult males over 15/16 years – and research demonstrates how easy it is for them to be reached and exposed to potentially dangerous substances. Overall, the participants in discussions related to the use of anabolic steroids in online media may generally be divided into the following main groups:

- beginners who are interested in fitness and body-building; fitness and body-building experts (usually males aged 20 to 40) who dominate forum discussions;
- a smaller, but noticeable group of participants purporting to be medical experts interested in fitness and body-building;
- users who also market and advertise products who join discussions and add link to a product/brand that they recommend or potentially work for.

Fitness communities are much more close-knit than those discussing weight-loss, perhaps due to their more clearly defined sub-culture status and shared values. Users tend to know one another very well and follow unwritten rules.

Sexual stimulants are among the most falsified medications worldwide. In Bulgaria, EDs, including Cialis, Viagra and Levitra, can only be sold online to customers with a doctor's prescription. Monitored forum interactions pointed to increased awareness about potentially falsified products, especially when purchased online. However, the overwhelming concerns were not health-related but rather performance-related, and fear and anxiety of performance failure may outweigh fear of health damage. Several groups were identified:

- one-timer young males looking for a thrill;
- recreational users that take the medicines more frequently (usually younger males in their 20s and 30s who enjoy an active sexual life);
- men in their late 30s and older, who begin experiencing erectile dysfunction and are seeking a solution;
- a group of users who need erectile dysfunction products because other substances that they habitually take have adverse effects on their erections; and users who also market and advertise products.

A range of other medicinal products likely to be falsified were found to be in demand online in Bulgaria:

- anti-anxiety and anti-depression medications that are very popular among women in Bulgaria;
- ephedrine and pseudoephedrine are used in the production of both amphetamines and body-building substances;
- medications, such as Ritalin and Adderall, used to treat attention deficit disorders. Some demand was recorded in forums, mostly by teenagers and young adults in their 20s.

The supply side

A number of sites advertising and marketing falsified medicinal products online in Bulgaria were found in operation during the virtual ethnography.

Online pharmacies continue to be almost exclusively the venues for the sale of falsified medicinal products and supplements in Bulgaria. Control by the BDA (the Bulgarian regulatory agency) on online pharmacies has proved to be challenging, thus pharmacies are continually found failing to comply with regulations, particularly those requiring them to ascertain a proper prescription before providing the respective medicines. In 2013, out of 756 inspections of online pharmacies, the BDA (2013) issued 265 warrants for administrative offences, which yields an official non-compliance rate of 35%. Nevertheless, media investigations have demonstrated that 80% of online pharmacies sell POMs without requiring a prescription. The virtual ethnography did not identify any particular group of products being unlawfully sold in online pharmacies. Online users indicate erectile dysfunction medicines, anabolic steroids and other fitness enhancers such as clenbuterol and ephedrine/epinephrine, painkillers, sedatives and antibiotics as being sold without proper control measures in pharmacies in the country. Because of the lax control of online pharmacies, online discussions often end with a specific recommendation for purchase of a prescription medicine/substance from a particular online pharmacy, the location of which is usually communicated through a personal message.

Social media are also used to advertise and market falsified medicinal products in Bulgaria. Many Facebook profiles and pages linked to fitness and bodybuilding are associated with a web-shop offering falsified medicinal products. One key finding of the virtual ethnography was the large number of profiles (not pages representing web-shops or pharmaceutical companies and importers) associated with individuals involved in the distribution of falsified medicinal products, including anabolic steroids. These Facebook profiles utilise the networking power of social media to advertise and sell falsified medicinal products, also posting images and publicly sharing information regarding the origin of the product. On friending and/or following such a page or profile, the user receives invitations to befriend and like a multitude of similar actors. Prices are also given in public posts, and subsequent discussions between buyer and supplier continue via the messaging function.

Discussion forums are popular for placing advertisements and links to falsified medicinal products in Bulgaria. Many forum users refer other users wanting

to purchase a particular medicine to a specific online pharmacy, where they have had experience in purchasing a medicine without prescription or where they know that control and compliance are negligible. Furthermore, besides being arenas for marketing, forums are also used to raise awareness and expose scammers involved in fraud and identity-related crimes.

Online marketplaces and classified boards are used by both low turnover individual retailers and online shops to advertise and offer falsified slimming pills, erectile dysfunction medicines, and steroids in Bulgaria. Payments are completed in cash upon delivery. In many cases, especially if the seller is an individual without the support or association of an online store, a meeting is arranged for the transfer of the goods and payment.

There are both local and foreign companies operating online stores/shops on the Bulgarian market. Internet stores are advertised by means of popular and widely used techniques such as Google AdWords, banners on news sites, forums and torrent sites. Websites selling erectile dysfunction medicines tend to concentrate their marketing efforts on adult-oriented online content, while weight-loss supplements are advertised heavily on the websites and media most visited by their target groups. Payments in local web-stores are mostly in cash, upon delivery by courier. Some foreign sites offer electronic payment by credit cards and PayPal. It is not unusual for a meeting to be arranged for the delivery and transfer of the goods.

Spam email is a feature of online communications for both marketing and cybercrime purposes in Bulgaria, and spam marketing pharmaceutical products has been rated among the top types of spam according to content and intent. There are no available data on the volume and trends of spam targeting end-users in Bulgaria. However, spamming certainly occurs on a massive scale and has been used to market falsified medicinal products. Bulgaria has been noted to be the country of origin of around 0.9% of globally distributed spam. The spam emails, marketing pharmaceutical products, mostly focus on erectile dysfunction and other lifestyle medicines, while the sources are similar to global trends, e.g. Canadian and Russian pharmacies.

The patterns

Data from customs and LEAs interviews, the virtual ethnography, and secondary sources highlighted a number of patterns relating to the trade in falsified medicinal products in Bulgaria.

In terms of geographic flow, falsified medicinal products to treat sexual dysfunction (largely erectile

dysfunction medicines), including bulk raw active ingredients, are being smuggled into Bulgaria via air cargo mainly from China and India. Many generic medicines and legally produced products enter Bulgaria via air cargo from India. Turkey and Moldova are often the countries of origin of falsified medicinal products smuggled into Bulgaria in road vehicles. Air cargoes of anabolic steroids seized in the period 2009-2013 were mostly from China, India, Thailand, Hong Kong and Morocco. A shipment originating from the Maldives was also seized by the authorities during that period. Furthermore, the virtual ethnography also indicated that vehicles are used to smuggle anabolic steroids from Serbia and Macedonia. Weight-loss related substances, including raw bulk active ingredients, are smuggled via air cargo overwhelmingly from China. Consignments of anabolic steroids and the substance clenbuterol intended for further shipment and sale in Western Europe and North America have been seized by the authorities in Bulgaria.

In terms of local production and packaging, several factors point to the eventuality that Bulgaria is used as a drop-ship/(re)packaging centre for falsified erectile dysfunction medicines and supplements. In this scenario, wholesale quantities and/or raw materials are smuggled into the country, mainly from China. They are then transported to 'underground' grey packaging facilities and packaged. The organisers of such operations are often foreign citizens (mostly EU citizens), who are also the financiers of the activities. In these cases, the complicity of packaging companies and facilities is implied. The Report on EU customs enforcement of intellectual property rights (European Commission, 2012) labelled Bulgaria as the Member State of highest provenance of packaging for counterfeit goods found and seized in the EU, with 41.46% of counterfeit articles not released. This seemingly well-developed *modus operandi* of counterfeiting includes the packaging of counterfeit/falsified medicines, which are then sold in other EU countries. For example, Bulgaria has been increasingly identified as a country where counterfeited/falsified erectile dysfunction medicines are being distributed and potentially packaged and/or produced.

Another piece of intelligence supporting the above hypothesis relates to the amounts of raw active substances being smuggled in bulk. Customs have seized air-cargo shipments of Sildenafil in amounts of over 25kg. Data from Bulgarian customs suggest two further hypotheses: 1. that the actual market for erectile dysfunction medicines in Bulgaria is much larger, and a significant portion of it lies in the grey sector; 2. that raw bulk erectile dysfunction substances are being smuggled into Bulgaria, packaged locally, and then sold in other EU states.

There are two mechanisms for selling falsified medicinal products either packaged or smuggled in ready-to-use-form through Bulgaria:

1. the perpetrators may advertise the medicine on a website in a western European country with a website based in that country, while the medicinal products are shipped directly from Bulgaria (the research found one such case where a French website, advertising EDs, delivered directly from Bulgaria);
2. the 'drop-ship method' whereby medicines are smuggled through Bulgaria or other countries, then stored in another western European country, including Switzerland, in which they are to be sold. This method is used both to facilitate logistics and to win the trust of potential customers because online buyers are typically more inclined to buy from local providers over the Internet.

France

The demand side

According to a study carried out by Pfizer Inc. (2010), within 14 European countries, one fifth of respondents – the equivalent of 77 million individuals – admitted to buying medicines usually administered by prescription outside the authorised circuits. In France, 14% of respondents disclosed this information, which equates to 6.9 million people. It is also noteworthy that millions of Internet users buy medicines under prescription on the Internet without knowing that around 50% of medicines sold online are falsified.

However, many French people appear to be aware of the risks that they are taking when they purchase medication unlawfully. Despite a high level of awareness, many purchasers claim that time constraints, financial concerns, and a preference for anonymity encourage people to purchase medications through unconventional methods in spite of the risks. Because the government has announced measures to cut back on the reimbursement of medicines, there may be an incentive for French consumers to buy their medicines outside authorised channels. Moreover, the tendency for self-medication is certainly growing in France, and it is an important contextual element relating to the online demand for medicines. According to the IFDP (Le centre de formation expert dans le domaine pharmaceutique), the growing purchase of medicines on the Internet by French people would be understandable due to the scaling down of a social security system whereby patients claimed the cost of medicines. In recent years, a significant drop has been noted in relation to the trust

of the public in the quality of the healthcare system. Individuals inevitably turn to the Internet to place their orders because it offers freedom and discretion whilst also saving money and time. Consequently, the Internet modifies the interaction of consumers with the health-care system. It is therefore suggested that the Internet encourages patients to self-medicate, thus increasing the potential risk of falsification.

The research on online forums demonstrated that a variety of people seem to be interested in online pharmacies. The anonymity offered by these services is believed to induce consumers to purchase on the Internet because they can avoid any interaction with a medical member of staff. Furthermore, the Internet is a source of information widely exploited by young people who use medicine in 'search of sensations', and it is becoming more commonplace for young people to be targeted by illegal pharmacies; which increasingly use social networks to advertise their products. The number of European 15-24 year olds seeking information about psychoactive substances online has risen from 30% to 64% (The Gallup Organisation, 2011). At the end of 2011, it was estimated that there were some thirty French-language online shops selling Novel Psychoactive Substances (NPS). Most of the online shops selling NPS are run by people based in the United Kingdom or the United States. The servers that host the websites are located in countries where they can evade national regulations.

Overall, the online sale of medicines is not reserved to a specific category of people. It is therefore difficult to draw a precise profile of potential buyers in relation to medicines on the Internet. However, research and observations conducted on the forums showed that cyber-pharmacies seem to target handicapped individuals, those who have no medical or health insurance, individuals who are searching for discretion in relation to their health and the product bought, and those who live far away from a pharmacy; such as residents of rural areas.

The supply side

In France, the sale of falsified medicinal products on the Internet is carried out via either short-lived sites specialised in counterfeiting/falsification ('sites-champignons'), which are directly created by producers to appeal to resellers (Business to business or B2B) and/or final consumers (Business to consumer or B2C); or via platforms enabling the completion of private sales (B2C and consumer to consumer or C2C). Given that a large percentage of online buyers choose 'home deliveries' to receive their products, online purchases are predominantly delivered by express or postal freight.

The Internet certainly furnishes flexibility for criminals by enabling them to easily create or close websites, hide their identity, and situate themselves anywhere in the world.

It can be very difficult to distinguish legitimate virtual pharmacies from bogus ones. Operationally they are able to target countries in which it is easier to run a counterfeit business. For Member States of the EU, differing legislation among countries hinders collective action. Therefore, most illegal online pharmacies targeting France are hosted abroad. To portray themselves as credible, they use local correspondents who aim at 'franchising' the website. People who optimise a website or drop shippers also contribute to the business and the credibility of Internet users: they employ specific computer skills and methods to increase the visibility of their websites and their audiences. To avoid customs seizures, falsified medicinal product actors on the Internet do not circulate their products in defined and direct ways. The counterfeiters hide the original source of their pharmaceutical products by transporting or forwarding deliveries through several countries, which complicates customs investigations.

Spam email and affiliate programs are also widely used in France to market falsified medicinal products online. Today, Internet users are inundated with Spam commercials which encourage the consumption of medicines and which channel individuals to illegal sites. Spam is generally sent to incite Internet users to buy products; in particular, those which treat erectile dysfunction. Spam on Viagra is a very profitable activity because the purchase of online medicine to treat this condition allows consumers to avoid an awkward visit to the doctor. Every person who has an e-mail account has a strong chance of receiving this type of message. There is a wide selection of medicinal products on these sites, and users can select which are of interest to them. If they want to purchase some medicines from a site, the relationship switches from the affiliate – whose task it is to locate customers – to the affiliate program – whose task is to monetise the customers and turn them into capital. At this point, the spammer withdraws and the affiliate program steps in. If the user decides to purchase, the transaction typically takes place via the use of credit cards. The user gives his/her credit card details to the affiliate program and the affiliate program operates much like a business. An upsurge in the volume of unwanted messages demonstrates the increasingly active collaboration between spammers and hackers, now organised as real criminal companies. The activity of the spammers is well structured; they use specific programs to generate and send billions of e-mails every day to Internet users and require a significant investment of time and money. An

average mailing list contains approximately a million messages. The objective is to send a maximum number of messages within a minimum amount of time before the publishers of anti-spam software update signatures to detect the latest types of spam.

The patterns

A number of sources, including cases from the Penal Court of Paris, specifically from the Public Health Division and the Central Office for Coordinating Environmental and Public Health Crime (referred to within France as the Office central de lutte contre les atteintes à l'environnement et à la santé publique or OCLAESP), were investigated as part of the project, and a number of patterns relating to the online trade in falsified medicinal products were identified.

To be noted is that, although France has been relatively spared from the sale of falsified medicinal products despite the spread of the phenomenon within Europe, recent years have seen an increase in the number of seizures; particularly within postal sorting. During the course of the research, it became apparent that the Internet is a perfect hiding place for counterfeiters. Besides providing an international platform for sales, the Internet allows for anonymity and ease of concealment. However, the online trade of falsified medicinal products in France should not be considered a major threat; the social security system and strict control of the legal medicines supply act as protective factors, and there is no evidence of falsified medicinal products within the legitimate supply chain.

As regards online sales of falsified medicinal products, the case studies show that a variety of medicines are affected, but seizures mainly concern doping products, including anabolic steroids, and lifestyle medicines such as erectile dysfunction products, slimming products and food supplements. General information on the prevalence of falsified medicinal products in the domestic market is minimal; customs reports and police seizures reveal that the illicit medicines passing through France are bound for Latin America or Africa. Most of the falsified medicinal products in France are imported from China, India, Pakistan, Thailand, and other Asian countries; with some European countries acting as transit points for medicine smugglers.

Most of the criminal actors involved in the trade in France may be considered as opportunistic because they are already involved in the global health business. It is therefore likely that some sort of criminalisation of certain pharmacists or close professions in France has taken place. However, at the international level, it seems that transnational criminal organisations

also participate widely, and that these organisations are generally very well structured. Supported by other forms of criminality, such as terrorism, the swindlers are mobile and organised in order to appear geographically scattered without a particular pattern in order to avoid detection. Besides criminal organisations, another feature of the traffickers was highlighted during an interview with the OCLAESP: 'white-collar criminals' who in reality are single and secluded individuals. Tempted by the allure of profit and easy money, these solitary individuals are able to organise their small trafficking enterprises thanks to the effortlessness that the Internet offers. Indeed, effective penal risks are low and the online trade in falsified medicinal products yields a wide profit margin to a counterfeiter, especially for lifestyle medicines.

According to French Customs Services, the criminal organisations involved are constructed in two ways: a) direct sale to the end/final customer; and b) more complex logistical circuits with intermediate/transitional structures in France or in Europe; which stock up abroad then resell – with easy and ample profits – their products within the country. Generally, these criminal organisations supply erectile dysfunction-related products, anti-obesity products, anti-cancer medicines, and anabolic steroids. The motivation of counterfeiters is essentially economic. The population's demand for medicines continues to grow, and the production of falsified medicinal products is inexpensive. Consequently, the profits are attractive for counterfeiters, whose low standards of production, distribution and storage considerably reduce their costs. Counterfeiters choose to falsify medicines that bring them the most, or more, profit. They are tempted by two kinds of medicines: those sold in very large quantities or volumes and those with high value.

Germany

The demand side

In the last decade, e-commerce has increased in Germany, and this includes the online sales of medicinal products. It is possible to find on the Internet a large amount of information linked to health, cures and medicinal products, both in specialised websites and in forums or social pages. According to a survey undertaken by Sanofi in 2014, 53% of Germans declared they had bought medicines online, whereas the European average was 18%. This large difference also depends on the diverse legal provisions regulating the matter. However, the German percentage conflicts with those of other EU Member States with similar legislative provisions on the online trade in medicines: for instance,

in the UK only 15% of respondents had bought medicinal products online (Sanofi, 2014).

Furthermore, German citizens seem to be aware of the risks related to the online market in falsified medicinal products, with 80% of individuals having heard about medicine counterfeiting/falsification; whereas in the United Kingdom, only 50% of the respondents were aware of this danger, and the European average was 66% (Sanofi, 2014). The virtual ethnography demonstrated this awareness of the health risks related to medicinal products sold online in Germany. Consumers prefer to give careful and precise suggestions, advising about all the possible dangers. Furthermore, many groups on Facebook posting about lifestyle problems are closed, and the administrators of the page can decide who to admit. They often have the power to check the posts before they appear on the page, or, alternatively, they post reminders about their power in an attempt to prevent improper posts like advertisements.

A high number of individuals use social networks to find suggestions about health problems and cures. This online word of mouth is an important way to obtain more information, but it also provides a platform for sharing certain difficulties with individuals in the same situation. Similarly, discussion forums are other important places to share information, questions, suggestions, reliable websites, and to seek advice before choosing a product and dosage. Even if Germans resort to these new channels, they have not lost trust in doctors and professional experts. Indeed, in Facebook groups they often suggest visiting a doctor or a specialist before using medicines.

The demand side of falsified medicines online depends on various contributing factors. The results from the German virtual ethnography and secondary sources found the following:

- lower prices;
- no prescription;
- anonymity, avoiding shame/embarrassment;
- convenience/comfort (home delivery).

The principal contributing factor in Germany seems to be money-saving (according to Sanofi, 85% of Germans buy online in order to save money). This result has been confirmed by Google Trends statistics that measure the popularity of a word, i.e. how often a particular search-term is entered relative to the total search-volume across time and space. Selecting the category 'Health' in Germany, between 2004 and August 2015, the word 'cheap' was on average more popular than the word 'safe'. However, the discrepancy between the

two terms decreased over time, probably due to greater awareness among citizens of the risks involved in purchasing medicinal products on the Internet. Another key element related specifically to the economic aspect of the decision to purchase a medicinal product on the Internet is the possibility of a reimbursement (e.g. in the case of medicines to treat fertility or sexual dysfunction).

It is difficult to define a precise profile of the purchasers of medicines sold on the Internet. Several studies have tried to classify customers of online pharmacies according to various features. For instance, a report based on a German survey distinguishes four groups of consumers according to their approach to the online trade in medicinal products: enthusiastic experts, risk-averse traditionalists, convenience-oriented rationalists, and inexperienced users (Orsolini et al., 2015). Taken this approach into account, the virtual ethnography showed that there are some social groups in Germany markedly more at risk of buying falsified medicinal products than others:

- users of lifestyle medicinal products (i.e. weight loss, bodybuilding, hair loss, sexual dysfunction);
- recreational drugs users (i.e. opioids, benzodiazepine).

Moreover, researchers found at least four different profiles of people at risk of purchasing falsified medicinal products that related to the specific product in demand:

Weight loss medicines. There are several websites, forums and social network pages on losing weight, most of them followed by women. The majority of them are places where it is possible to share best practices, recipes and suggestions about medicinal products. There are two main types of users of these websites: private individuals seeking help, and people trying to advertise and sell products or services (for example, personal diet and exercise plans). These individuals often criticise other services and products in order to raise their own profile and reach potential consumers. The research showed that Germans principally request natural products and nutritional supplements, but this could be a problem due to the different legislations and systems in various countries. In fact, in Germany some nutritional supplements are regulated by food laws, with specific indications about transport, conservation and dosage. At the same time, these supplements may be considered cosmetic products in the countries from which they are shipped, so that they are less controlled and regulated (see also Lachenmeier et al., 2012). According to Google Trends findings, between 2004 and August 2015 in Germany there was a huge increase in

the popularity of the search-term 'pro-ana blog', in all the regions, concentrated especially in the North and in the West of Germany.

Fitness enhancers and anabolic steroids. These websites are frequently followed by men, often individuals who want to increase muscle mass. Private individuals interested in suggestions and products may include novices and expert-users. These websites seem to be more closed and cohesive, maybe because the members are part of a bodybuilding subculture, familiar with the same gyms or personal trainers. According to Google Trends findings, from 2004 to 2015 there was an increase also in the popularity of the search-terms 'anabolic steroids' and 'buy steroids', but these were more in demand in the south of Germany (Baden-Württemberg and Bayern) together with the city of Berlin and the central part of Germany (Nordrhein-Westfalen, Niedersachsen and Hessen).

Sexual dysfunctions. Most customers are men, but also on occasion women requesting information for their partners. In this case, avoiding shame is a key contributing factor. Also on these websites it is possible to recognise first-time users, more habitual users, and advisers. The analysis of Google Trends statistics showed that customers frequently made online searches for the names of the most common sexual enhancers, for instance Viagra and Cialis, frequently combined with the word 'rezeptfrei', which in German means 'without prescription'.

Recreational drugs users. There are several websites selling psychoactive medicines like 'Benzos' (Benzodiazepines) or opioids. Customers often purchase these medicines from the Deep Web in order to obtain them in complete anonymity. Also easily available on the Web are specific pills to help students concentrate. Many of these users leave positive feedback about the products and their effects. This was confirmed by a secondary source: according to research undertaken in 2013, 1/20 students in Germany use these pills; they are generally very satisfied with the effects, and are less concerned about the health risks (Sattler & Wiegel, 2013).

Finally, another residual category was found during the virtual ethnography in Germany: medicines for stomach ache, rheumatism, flu, antitumor and products to treat hair loss. In this case, it is impossible to profile a specific target consumer because these are general medicines suitable for several situations and pathologies.

The supply side

In Germany, health-related products, including both OTCs and POMs, are widely available online. This has been permitted since 2004 and the well-known judgment of the European Court of Justice, on the 'DocMorris' (C-322/01) case referred by the Regional Civil Court of Frankfurt, which for the first time explicitly allowed the free circulation of medicinal products online in Europe. This high availability also creates major opportunities for criminals, who can sell medicinal products via the Web and penetrate an otherwise stable, widespread, and trusted legal online market.

The virtual ethnography showed that in Germany the online supply of falsified medicinal products is divided into the following types:

Online pharmacies. It is very difficult to recognise a legal pharmacy from an illegal one. In order to find indicators that could help customers to distinguish a legal online pharmacy from an illegal one, researchers analysed 50 online pharmacies chosen among the first results on Google after inserting some keywords in German, for instance 'German online pharmacy', 'cheap online pharmacies Germany'. More than half of the online pharmacies in German language analysed had their servers based in countries outside EU jurisdiction (i.e. Canada, Russian Federation, and USA), that is a significant indicator to recognise illegal websites. The virtual ethnography also demonstrated that the majority of these websites reported one or more telephone numbers, differentiated by the country of the calling customer (principally distinguishing between calls from the USA and Europe, but in some cases there were different numbers for different MS), without considering the different legislations regulating this type of purchasing. When there was a telephone number, it was often presented as a free number, so that customers could call without a charge. Only a few of the pharmacies analysed (less than 1/6) provided a physical address in Germany, and in almost all of these cases the server was also in Germany. In these pharmacies, a named pharmacist was rarely present. The OPs did not always require a prescription for POMs, in contravention of the law, and rarely offered the possibility of an online consultation.

Social media websites. Today social media offer strategic marketing channels to attract potential customers interested in medicinal products, especially lifestyle medicines. The virtual ethnography showed that there are several health-related pages and groups discussing problems to do with lifestyle factors, such as nutrition, physical activity and chronic stress. Some of these pages and groups were associated with online shops selling medicinal products, others with single individu-

als involved in the distribution of medicines. The active virtual ethnography conducted through the creation of various fake social media profiles found members of groups posting and private messaging about pills and other medical treatments, creating a hidden market which directly involved active Facebook users. Nevertheless, Facebook administrators adopted special procedures against this practice, filtering messages or directly cancelling messages when it was not possible to confirm their reliability.

Online wholesalers. There are several online marketplaces offering B2B, B2C and also C2C pathways to (falsified) medicinal products, chemicals and equipment in Germany. Access to these online marketplaces is very direct: it suffices to write in German ‘wholesale, medicinal products, online’ to find several websites offering medicinal products in huge quantities and with bulk discounts, to be sent to a customer’s home and to be paid for in cash. They are ‘customer-oriented’ and they use the same commercial strategies as adopted by all other e-commerce shops, without any difference among types of products or any special attention to these goods. The majority of these websites are based abroad, not in Germany (and principally extra EU), and they are not linked to physical pharmacies. Since the free circulation of goods is allowed only within the EU, and furthermore since in Germany it is compulsory to have a specific authorisation to sell medicinal products online accorded only to individuals who at the same time manage physical pharmacies, these online marketplaces operate illicitly. There are also several websites in which customers can buy POMs directly from the store without a prescription but merely by answering automatic closed questions that are supposed to be read by an independent doctor working directly for the online platform.

The research results showed that it is possible to find also temporary markets, often set up for short periods of time to sell medicinal products. They do not require specific IT-knowledge, and therefore can be easily created and closed down by criminals.

Email and spam. Many websites selling medicinal products request the email addresses of their customers in order to send offers and discounts on medicines, especially lifestyle medicines, to their mail accounts. Spam also plays an important role in the online supply of falsified medicinal products. It is impossible to quantify the amount of email and spam sent every day in Germany, but they are heavily used and relate principally to medicines used to treat sexual dysfunction and weight loss.

Cryptomarkets on the Deep Web. The number of users of the Deep Web has rapidly increased in the past

few years. Among the legal and illegal products sold on these sites, users can also find medicinal products. Our exploratory analysis of Silk Road 3.0, one of the biggest online marketplaces on the Deep Web, showed that all the products declared to be shipped from Germany (144) were drugs and medicines, except for 3 cases relating to counterfeit money and 1 to the supply of a firearm. It is possible to buy, without prescription, antidepressants, sedatives, opioids and stimulants, with low prices and the guarantee of anonymity. Vendors describe their products as genuine, not counterfeit/falsified.

Lastly, the research highlighted a large online market in principally (falsified) lifestyle medicinal products, e.g. medicines to treat erectile dysfunctions, slimming pills/appetite suppressants, anabolic steroids, hair loss medicines, as well as opioids, sedatives, antidepressants, stimulants, and psychiatric medicines. Medicines such as antibiotics and medicines to treat stomach-ache were also in demand online and at risk of being falsified.

The patterns

Since its legalisation in 2004, the online market for medicinal products in Germany has become widespread. However, it is in this context that criminal opportunities to trade in falsified and illicit medicines have also increased. Consequently, the online trade in falsified health-related products is also now widespread in Germany. It is very difficult to estimate the real extent of this illicit market, although it is supposed to be of large-scale: As declared by the DGIM (Deutsche Gesellschaft für Innere Medizin) during the 119th Congress of Deutsche Gesellschaft für Innere Medizin, entitled “Internal Medicine - From the organ to the system” (6th - 9th of April 2013, Wiesbaden), a falsified medicinal product is sold on the Web every second in Germany.⁴⁶ This number, which also relates to a large parallel market (that allows the repackaging and reselling of medicinal products), is estimated via the seizure results available from LEAs and customs, as well as cases reported by customers who experience unexpected side effects after ingesting falsified medicinal products.

The research results, thanks to the analysis of investigative and judicial cases, crime news items and secondary sources, highlighted that Germany is both a destination and a transit country due to its geographi-

⁴⁶ Source: <http://www.welt.de/wirtschaft/article115109953/Jedes-zweite-Medikament-aus-dem-Netz-ist-gefaelscht.html>. Last accessed on: 10 December 2015

cal position in the centre of Europe, and its proximity to Eastern European countries. Falsified medicinal products arriving in Germany are principally produced in China, India and other Asian regions, from where they are shipped by several means of transport (trucks, aircraft, etc.) directly to Germany or to other intermediary countries (usually inside the EU). Besides the importation of falsified medicinal products, there seems to be a developed local market in Germany. Indeed, some production facilities have been found in Germany: underground laboratories, private home basements, farms or courtyards where falsified medicinal products were being manufactured. In other cases, only the active ingredients were imported from abroad to be pressed and packaged, then traded, in Germany. For example, during one investigation, judicial authorities discovered a number of chemical precursors produced in China, then prepared in Germany in hidden laboratories to be sold as steroids and growth hormones to local amateur athletes.

The actors involved in this illicit trade operate principally in groups ranging in size from locally-based couples to larger criminal organisations with international links. The structure of these groups is that of a flexible network, frequently composed of different nationalities operating in several countries. Some organised criminal groups active in Germany also operate in Austria, due to proximity and the common language. Within the groups, connections among members depend on family/ethnic relationships, friendships and/or business links.

According to the findings of the investigative and judicial cases analysed during the research, the sale of falsified medicinal products online occurs through websites, emails and spam. Commonly, online sales are combined with 'offline' ones based on personal links or related to specific subcultural contexts, for instance gym and bodybuilding scenes.

A variety of medicinal products are affected, but the majority of the cases analysed concerned lifestyle products, principally sexual enhancers. Within this category, the leading falsified labels were Viagra, Cialis and Levitra, anabolic steroids, growth hormones and slimming pills. One case related to two products – the anti-epilepsy medicine Luminal and the antipsychotic medicine Truxal, which are extremely dangerous if combined and consumed – sold online to individuals who wanted to commit suicide. In the majority of the cases analysed, the same criminal groups traded different types of medicinal product, and in one case a single group was selling sexual enhancers online alongside narcotics. Similarly, both falsified and counterfeit medicinal products were often sold together.

The risk for customers was very high, and in many cases chemical analysis of the falsified products had shown their dangerousness; some contained different doses of the active ingredients, others more concentrated doses, and in some cases the active ingredients were completely absent.

The trade of falsified medicinal products is an opportunistic crime. In many of the cases considered, the criminals were already linked to the healthcare sector and/or involved in the pharmaceutical industry, managed gyms, shops or online shops. Other findings show that this cross-over with legal business was related to accomplices, who provided falsified prescriptions or chemical materials. These licit links were generally used as facilities for the logistics of the illicit trade, for instance transport and stock, but the existing business could also be used as a front company to hide the illicit sales and the payments. The profits of this market were usually sent to offshore countries, or deposited in current accounts assigned to a friend or a family member.

Italy

The demand side

In Italy, e-commerce is growing year by year. Since 2010 online commerce has increased by more than 50%, and it has become more significant due to the economic crisis. However, it is still lower than in other countries: for instance, the increase in Italy in 2014 was about 8% while in the UK it was about 21% (Casaleggio et al., 2015). The Internet and social networks play a significant role in the health market, both as sources of information and as purchasing channels. Nevertheless, Italians are not very aware of the risks related to the online trade of medicinal products; a trend recently confirmed by Sanofi, whose study found that only 18% of Italians related the word 'counterfeiting' to medicines (Sanofi 2014). In fact, in online forums and dedicated groups, users suggest purchasing medicines on the Internet and share positive experiences and links to offers. It is less common to find negative comments or warnings; otherwise they are referred to the competitors to devalue their products. This trade is not perceived as a danger nor as illegal: groups on social networks promoting medicinal products are open or, even if they are closed, they accept without question all requests to participate. Often users are registered with real names, personal information and email addresses, and they openly admit to buying medicinal products without prescription and to using steroids. Before legislative decree 17/2014, the online trade of medicinal products was prohibited in Italy, and online pharmacies are still awaiting regulations so to start

selling. However, Italians generally lack awareness of the legality of buying and selling medicine online. Some participants in forums ask whether or not it is legal to sell medicinal products on the Web, and they also ask about the possible consequences. They trust other participants – even if they are not professionals – to provide answers to these questions.

The main reasons for purchasing medicinal products on the Internet seem to be lower prices and accessibility. It is often possible to find online products cheaper than in a pharmacy, and illegal virtual pharmacies offer bulk discounts, price reductions and free delivery. Buying online is also convenient because users can be at home, or at work, and receive the products directly and rapidly. Moreover, they can purchase at any time of the day or night without respecting shop opening times and with guaranteed anonymity. Consumers also buy online because they can find on the Web products that are not normally available in Italy. Above all, they can obtain POMs online without a prescription. The majority of illegal OPs sell POMs without requiring a prescription, or by pretending to offer an online consultation that replaces a doctor's examination. Online purchasing of POMs, in fact, may be due to mistrust in professionals. The avoidance of healthcare practitioners and prescriptions is often related to cases of misuse, so that online purchases are made by individuals addicted to alcohol, drugs or psychopharmacological medicines who overuse these products without the control of an expert.

Indeed, this social group, together with users of other lifestyle medicines, is one of those most at risk of consuming falsified medicines in Italy. Normally, these individuals are ashamed to go to the doctor to ask for erectile dysfunction or abortion-inducing medicines, and in some cases they think that these products are not medicines but merely supplementary products or commodities (like some nutritional supplements or energizers). On the other hand, in some social communities, for instance those dedicated to bodybuilding or pro-anorexia, it is easier to find individuals more aware of the wrongfulness of their behaviour, but who purchase the products anyway to fulfil their need to build muscle mass or lose weight, etc.

Within each social category, it is possible to discern among expert users from beginners, more informed and aware individuals from totally or partially unaware ones. On posts and conversations, for instance, doubts, wishes, questions and suggestions from the beginners were found, as well as training and past experiences from experts and sellers. Forums and common social media sites include both experts and beginners.

Young individuals and teenagers are at risk because they are more technologically skilled and more used to ecommerce. At the same time they have more stigma, due also to the fact that they still rely on their families and have less financial means. They are also more likely to consume 'hot medicines', for instance anabolic steroids and weight-loss pills.

The research found that the medicinal products most in demand on the Web in Italy are:

- erectile dysfunction treatments
- anabolic steroids
- weight-loss medicines
- sedatives/psychopharmacological medicines
- contraceptives/abortion-inducing medicines
- hair-loss treatments
- breast/penis growth treatments

The supply side

Despite the prohibition of trading medicinal products on the Web in Italy, it was possible to find various illegal online channels offering these products. The virtual ethnography conducted during the project found the following types of online sites offering (falsified) medicinal products:

Online pharmacies. There is a huge number of illegal Italian online pharmacies on the Internet. An analysis of the first fifty results of a Google search for Italian keywords like "Italian online pharmacy", "Cheap Italian pharmacy" and "buy Viagra online" found that these websites have some common recurring characteristics: no Italian area codes but more telephone numbers for customers calling from different countries (EU and extra EU); no physical address of the pharmacy; the possibility to pay in various currencies (e.g. euro, British pound, US dollar or Canadian dollar). The home page frequently advertises the medicines most purchased on the Internet (i.e. products to treat erectile dysfunction) guaranteeing anonymity, low prices, and not requiring a prescription. The servers are mainly based abroad, both in other EU countries (e.g. Germany, the Netherlands, France) and non-EU ones (the USA and Canada, for instance). These sites seek to gain the trust of clients by offering the possibility of an online-consultation and reporting positive feedback from fake customers. Moreover, they often reproduce official logos. They use marketing strategies offering discounts and special prices. The names, the structures, and the layouts of these websites are frequently similar. In some cases, the illegal pharmacies redirect users to other websites

selling medicinal products, or they contain an external link to an online marketplace.

There are also wholesale online illegal pharmacies. These present themselves as pharmacies, chains of medicine stores shipping single packs and large quantities of pills and medicinal products to different countries. They assure the quality of their products by pretending to buy them directly from the manufacturers. They do not require any prescriptions for POMs but they offer online consultations.

Social media websites. These channels are most regularly used by individuals of different ages and backgrounds. They are used also by criminals to advertise and sell (falsified) medicinal products, mainly lifestyle medicines such as slimming pills and anabolic steroids. On Facebook, for instance, there is a huge quantity of pages, groups and individual traders marketing medicines of this type. In some cases, pages with an Italian name, Italian telephone number and address contain posts in other languages (i.e. Russian). Some groups related to weight loss or anabolic steroids are closed, and it is necessary to become a member. In other cases they are secret and cannot be found without an invitation from an existing member. These groups are very similar to forums: friends share suggestions, doubts and products. The sellers can be related to physical or virtual shops, but they can also be private individuals organised in special structures or working alone. They can sell just one type of medicine or a multitude, posting pictures and prices of the goods or asking to be contacted privately for the details. Vendors also contact individuals directly by private message and may use fake nicknames or their real names.

Discussion Forums. Discussion forums are very common among Internet users. On these sites, individuals ask questions, share doubts and experiences, write feed-back related to the products and the channels through which to purchase them (both positive and negative). In some cases, users do not consult the doctor: they merely ask other users what is good for their health, which medicine, and in what quantity. In these forums there are also links to other websites and online pharmacies.

Online marketplaces. These marketplaces are e-commerce sites where products or service information are provided by multiple third parties, whereas transactions are processed by the marketplace operator. They can be B2B, B2C or C2C and can be managed directly by the owner, use the drop shipping technique, or both. There are some legal platforms offering a plurality of items (i.e. electronics, accessories, clothes, etc.) including medicinal products and active ingredients. It

is also possible to purchase lifestyle treatments (sexual enhancers, slimming pills, breast growth treatments, etc.) presented as “100% natural” but often very risky: the descriptions are automatically translated into Italian with many grammatical and logical mistakes; the products are packaged as medicines and the vendors promise the same effects as the original medicinal products. In other cases, these marketplaces are completely illegal and specialise in only a few medicines, normally steroids or erectile dysfunction treatments. These online marketplaces offer anonymity, fast home delivery, and simple payment by prepaid card or cash on delivery.

Deep Web. The surface web is only a small part of the Internet. The largest, and increasingly utilised, part is the ‘dark web’ or ‘deep web’, where it is possible to find every legal and illegal good thanks to the anonymity guaranteed to the user. Exploratory research has shown that in Silk Road 3.0, one of the biggest virtual shops accessed via the Tor browser, there are no medicinal products explicitly sold from Italy, but there is a large quantity of them destined for Italy shipped from other EU countries (for instance, Germany, the UK, Sweden, the Netherlands) and extra-EU ones (e.g. India, Pakistan, Thailand, the USA and Canada). These medicines are both lifestyle medicines, e.g. Viagra, Kamagra, steroids, and also recreational drugs including cannabis, MDMA, LSD, stimulants, amphetamines, opioids, benzodiazepines and sedatives.

The patterns

The online market of medicinal products in Italy has very particular features. This is due to the fact that until legislative decree 17/2014, adopting Directive 2001/83/CE as modified by Directive 2011/62/EU, the online trade of medical products was not allowed in Italy. Nevertheless, this market is widespread and exploited by criminals, who take advantage of the lack of knowledge and awareness of Italian customers. Moreover, there are also some legal loopholes exploited by criminals.

It is very difficult to state the real size of this trade, and investigations are often responses to reports from consumers or hospitals of health problems caused by medicinal products traded on the Web, which are very risky. The quality of those products can be very poor: in one case analysed, for instance, the treatment for erectile dysfunction contained a minimum quantity of active ingredients together with chalk dust. On other occasions, they contain excessive percentages of active ingredients, higher than the original POMs. Moreover, this trade creates a ‘parallel health service’ where the

sellers and the criminals take the place of the doctors and the experts.

Another problem is caused by dietary supplements, which are frequently sold as natural and harmless but in many cases contain active ingredients, often more than the original medicinal products (for instance, a “natural instant coffee” seized by the authorities contained a percentage of Sildenafil ten times higher than Viagra).

The crime script analysis of five investigative and judicial cases identified some common characteristics in the *modus operandi* of different individuals involved in the trade:

- The principal origin of the falsified medicinal products or the active ingredients was the East: China, Singapore, Thailand, and East Europe (Moldavia, Romania, Hungary), and they often entered Italy through the Balkan route (which is one of the reasons why Italy is both a transit point and an end-user country). The authorities once discovered traffic from South America (Argentina and Paraguay) and from the Canary Islands. In this latter case, the individual apprehended had some contacts in the Canary Islands. On two occasions, the production was based in Italy: a 20-year-old man produced a huge quantity of medicinal products in his garage (the police seized hundreds of kilos of active ingredients and machinery bought online from the Far East); and a man related to bodybuilding who bought active ingredients, packaging, and labels online to produce anabolic steroids at home. It is also possible that the medicinal products sold online are not falsified but stolen from the legal chain of production and sale. This is dangerous because in these cases the criminals do not respect the appropriate conditions of storage and transportation.
- In the majority of the cases analysed, the individuals involved in this illicit trade were in contact with wholesalers based abroad. They bought the products online, on some specialised websites and OPs, or through more direct contacts, for instance private emails.
- All the groups apprehended were organised into networks in which some individuals had particular roles (principally the importation or the production) and others were the retailers (and on some occasions both suppliers and end-users). This trade may sometimes be managed by one or two individuals, as, for instance, in the case of a young producer in Perugia.
- On occasion, legal enterprises can be involved: they already have contacts, channels, machinery and

warehouses. Furthermore, they can hide this illicit operation under their legal ones, so that it is easier to launder the high profits earned in this market.

- The online trade of medicinal products is an opportunistic crime, and criminals are frequently already involved in legal activities related to this trade (for instance a pharmacist's son was convicted for the sale of Viagra and other medicines to be used as recreational drugs to his friends). Very often gyms are the scenarios of this trade, because bodybuilders want to increase their muscle mass, and it is also easy to meet various contacts in gyms.
- Some criminals are specialised and supply one category of medicinal product; others trade more than one. For example, steroids and erectile dysfunction treatments are often sold together.
- The payments are made principally by credit card, prepaid card (for instance Postepay) and Money Transfer via Western Union. In Italy, there is an upper limit for cash payments: for this reason, criminals hide their real identities, use fake documents and the names of family members.

Spain

The demand side

In regard to consumers at risk of buying and consuming falsified medicinal products in Spain, three types of customer profiles were identified on Spanish websites.

Firstly, consumers seeking to improve sexual performance, among whom two types of individuals were identified in forums during the virtual ethnography. 1) Internet users who stated that they had a sexual problem and needed medicine to help them without providing much information. Occasionally, they admitted to being embarrassed or being too lazy to go to a pharmacy. They preferred to buy the product online because of price/quality and in order to remain anonymous. 2) Women sharing the problems of their male partners and describing satisfactory encounters as a result of their partners buying the falsified product online. In both groups, users gave opinions and information regarding: a) psychological needs, b) assistance regarding the best pharmaceutical products for a specific problem, and c) recommendations of websites where the products can be found. Some of the people giving advice identified themselves as doctors and gave their medical board number and named the hospitals in which they worked. If the product was sold in pharmacies, these individuals stated that buying online posed no health risks. The most common products discussed were Viagra, Cialis and Kamagra.

Secondly, consumers seeking to enhance physical and sport performance. This type of consumers seek to enhance physical performance in order to improve physical appearance and to build muscles or gain body mass. Conversations observed among consumers revealed that they used technical terms, although this did not necessarily signify that they knew the meanings of terms and technical prescriptions. The consumers' backgrounds were unknown; therefore, their expertise cannot be assessed. However, judging from the conversations, they seemed very familiar with the components, side effects, recommended dosages, and consumption cycles (stop and new intake) of the products. The most recommended and requested products were steroids, EpisdroL and Gainner. EpisdroL is a very sought-after product, but it was prohibited by the Spanish Agency of Medicines in 2013. This product is desired because of its properties, which increase strength and libido as well as body mass. Forum interactions focused on products used to gain weight and muscle mass, including recommended websites offering the best price.

Thirdly, consumers attempting to treat different diseases, including diabetes, hepatitis, cancer, arthritis, and asthma. This group is less common than the previous two, but there are several webpages which contain information about treatments, natural substances, etc., alongside recommended sites offering falsified medicinal products used to treat the diseases.

Each profile identified had different consumption habits. Sexual performance-related consumers bought online because they were embarrassed to purchase the product in person and in an attempt to avoid having to obtain a legal prescription. Conversely, consumers seeking products to enhance their physical performance needed technical advice, and the service offered tended to be more professional. Nevertheless, even if the websites offered professional and technical assistance, a low sense of risk was apparent, and it was common to find conversations about strategies or products to avoid side effects. Health control and regulation was undervalued, given the attention that consumers paid to the effectiveness of the product, especially if it was legal.

The supply side

In relation to the supply side of falsified medicinal products online, two types of marketing and distribution channels were identified in Spain.

The most common channel is via online pharmacies. In regard to the types of website identified, many online pharmacies uninhibitedly sell products freely and openly. These websites use various strategies to

be accessible online; the most common are illegal pharmacies or those that are most visited and appear in the first result pages of a search. However, less prominent illegal pharmacies use other strategies to become more 'popular' online: they hack into legal websites and introduce the specific word which they need to be present online, ensuring that they show up earlier in the results pages. Another strategy employed in order to initiate contact with possible consumers operates via websites that are not directly accessible, but to which users searching for particular terms are redirected from legal websites; generally websites which are not related to medicines. The legal link is on the Internet, and when it is clicked, the user is automatically redirected to an online pharmacy. Many legal websites such as those of universities, foundations, etc. appear when an individual searches for a particular product (Viagra, Cialis, etc.). Websites of this kind contain incoherent wording to ensure that specific terms related to the products sold are used; thus allowing the webpage to ascend the list of results. It is extremely common to repeatedly include the text "buy Viagra" or "buy Viagra magnus" in order to persuade potential customers to enter the site. In essence, searches conducted via Google can produce legal links which redirect to online pharmacies.

Online pharmacies offering falsified medicinal products in Spanish have a similar structure. Some websites are linked to physical pharmacies, and others have only online products. However, in regard to the sale of performance enhancing products, online sales generally originate from gyms, nutrition shops or other types of physical or legal businesses.

Furthermore, online pharmacies are similar in appearance and share a number of features, such as:

- information about prices, products and purchasing particulars (by telephone, online, etc.);
- guidance, offers and advisory services;
- client testimonials, which are generally positive about the advantages of buying products online and the benefits of certain products;
- occasionally, information about products, health information, nutrition, side effects, etc.;
- information regarding purchase and transportation. In general, they offer a free telephone number for Spain and a UK telephone number. Communications remain private, and confidentiality is guaranteed. They all try to offer a good service in terms of consumer guidance: a helpline, client assistance and punctual delivery of products all attest to this endeavour.

Furthermore, illegal websites attempt to portray themselves as having a good image, sound service, large amounts of information, and as providing swift answers to doubts or queries (several websites contained the same testimonials).

Online pharmacies were accessed with relative ease during the research. These pharmacies are illegal in Spain, but law enforcement have difficulty in investigating and closing them down. When an illegal pharmacy is detected, an authorisation of cessation is requested, but it is also extremely easy for an alternative website to be rapidly created. Consequently, there is a plethora of websites offering a variety of products that can be purchased online.

Forums are also used to offer information about websites or places where products can be purchased. Additionally, forums provide answers to queries and recommendations about websites or specific links to ones where certain products can be found. This information in some cases includes reviews or personal experiences, which seem to be undercover advertising or supplier publicity. The first comments seem to be real because they express genuine doubts about products and side effects, but then there are suspiciously positive comments with recommendations for particular websites, which give the impression that this could be a good way to offer their products and benefits.

In regard to forums on performance-enhancing products, it was found that the most valued information in these online environments concerned products, personal planning, or standard guides for consumption. Users appeared to appreciate the usefulness of this type of information. However, this means that all of these products can be consumed freely, and that the Internet becomes a substitute for a doctor or pharmacist by recommending dosages and medications. It was also noticed that forums were used not only to provide and receive anonymous advice about dosages or products; they were also commonly used to share opinions or 'tips' on how to avoid side effects, or to propose other medicines to counteract such side effects.

Additionally, and according to the investigations, the most common falsified medicinal products sold in the Spanish illegal market fall into the following categories, and are most regularly bought by the following kinds of consumers:

- Doping: consumers are high-performance sportspeople (TATONIL);
- Steroids: consumers seeking to increase muscular mass (gyms or night clubs) (EPISDROL, EPISTANE or HGH/HGC);
- Sexual performance: consumers seeking to increase sexual performance (erotic and pornographic field) (KAMAGRA, LIBIDUS, MAXIDUS);
- Medicines to cure cancer, HIV, arthritis, diabetes and Hepatitis (MMS: sodium chlorite).

The patterns

Data collected from ten police files detailing investigations carried out by the special Consumption, Environment and Doping Unit in the UDEV-CENTRAL, under the auspices of the Comisaría General Policía Judicial of the Spanish National Police, highlighted a number of patterns relating to the online trade in falsified medicinal products in Spain.

Criminal entrepreneurs involved in the online trade of falsified medicinal products in Spain are best understood as horizontal structures, without a clear division of labour, where tasks are interchangeable. Links among members are usually virtual, though individuals of the same family are sometimes involved in the organisations. The latter have on average 15 members, mainly of Spanish origin (70%), with to a lesser extent other nationalities involved, such as Moroccan, Dutch and British. Furthermore, these organisations often include semi-professional; each of them identified had at least one member whose legal profession was of key importance for the operation. Depending on the product being supplied, business persons, athletes or healthcare professionals were the most common, among which: 14% had criminal records, mainly for crimes against public health but also for robbery, fraud or injuries.

Further patterns identified with regard to the criminal organisations involved were:

- the capacity to restructure with ease in the event of website closure or police investigation;
- low use of security measures due to the flexibility of their structure;
- a general lack of violence, both internal and external, and no strict rules;
- use of legal companies in 90% of the operations used for purchasing or producing chemical components or medicinal products (92%), and to sell or to launder money (8%);
- fitness and leisure centres are the most common places to sell falsified medicinal products offline in Spain (41%), although 'online pharmacies' are also frequently used (23%).

The *modus operandi* in Spain can be summarised in three different phases: 1) product acquisition, with China, Thailand, India and Pakistan identified as the main supplier countries of falsified medicinal products to Spanish individuals/organisations involved in the trade. Products can also be acquired from pharmacies using false prescriptions and in general are paid via Western Union or Money Gram; 2) storage in houses, sport shops, cars, shops etc. often in very poor conditions and no respect for hygiene standards; and 3) distribution, which involves suppliers in Spain who deliver products previously acquired online or by telephone via couriers from organisations/producers overseas. In regard to doping products, the transactions are mainly carried out through gyms or other shops, using websites as additional platforms for transactions. Payments are made by wire transfer or in cash to the personal courier on delivery.

The Netherlands

The demand side

Buying goods or services on the Internet has become increasingly popular in the past decade in the Netherlands, and the Internet is also a popular source of health-related information. Research undertaken by Intomart GFK (2009) and commissioned by the Dutch Ministry of Public Health, Welfare and Sports (VWS) analysed the consumers of online medicines and found that 3.3% percent of the Dutch population had bought medicines without a prescription online and another 2.3% of the population had considered doing so. Intomart GFK described the target group on three different variables concerning gender, age and education. In conclusion the large majority of the Dutch population do not buy medicines online and many people are aware of the dangers of falsified medicines.

However, for some people online pharmacies are interesting places to acquire medicines. The type of medicine is strongly related to the buyer's profile and motivation to purchase medicine on the Internet. Motivating factors include shame, the relative ease with which people can order medicines online, and financial reasons. The research found that weight-loss medicines are by far the most popular medicines bought online without a prescription (46%). They are followed by sexual-related products (24%) and (heavy) painkillers and anti-inflammatory agents (19%).

Moreover, the virtual ethnography identified a number of social groups at risk of buying and consuming falsified medicinal products in the Netherlands. Overall,

three groups were identified: (1) members of pro-ana websites; (2) members of bodybuilding communities; (3) members of forums that discuss the use of drugs for recreational purposes.

In regard to the pro-ana communities, this mostly concerns weight-loss medicines. Some websites offer general tips on which medicines should be used and where they are available. Another important issue in this case is that most of the people in this community want to maintain anonymity and secrecy. Since the Internet is a way to acquire medicine in relative anonymity, this specific group is at a greater risk of buying falsified weight-loss medicines.

Bodybuilders constitute another group more likely to be at risk. The biggest Dutch bodybuilding forum dutchbodybuilding.com even has an internet pharmacy as an official sponsor. Although by far the biggest discussions are about androgenic and anabolic steroids, a range of other medicines can also be of interest to bodybuilders.

The last group comprises people using medicines for recreational purposes. Popular forums have specific boards for discussions on pharmaceutical products. They include a large amount of threads about 'benzos' (benzodiazepines). It seems that these are very popular among drug users, although the latter also discuss the dangers of addiction. Opiates are also discussed for recreational use. Again, members are aware of the dangers of falsified medicines and the risks of ordering via the Internet, yet they have an interest in the recreational effects of some medicines and seem willing to risk their health in order to experiment with medicinal products. Therefore, this group will have a higher risk of encountering falsified medicines.

Overall, the anonymity offered by the Internet can be an important factor in the decision to buy medicines online, including those consumers who do not want others to know that they are using a specific type of medicine. Furthermore, although many members of these communities are aware of the risks and dangers involved, some consider buying medicines online regardless, since the option is available and there is no other way to obtain their required medicines.

The supply side

In the Netherlands, health-related products are abundantly available on the Internet. This has increased opportunities for illicit suppliers of falsified medicinal products online. Three main types of online supply of medicines were found during the research in the Netherlands:

Online Pharmacies. There are a large number of on-line pharmacies that sell falsified medicinal products in the Netherlands. Most sites seem to be based in or operate from another country. Although these websites are in Dutch, many offer the option to display their products in other languages. The research also found multiple sites that link to one online pharmacy. Many of these sites offer a specific medicine (e.g. Viagra, Tramadol), with information regarding that medicine. When customers place their orders, the site links to the online pharmacy where they pay for the goods. Illegal online pharmacies in the Netherlands can be identified largely through unofficial certificates of authenticity and the specific products and prices on offer.

Customer to Customer (C2C). 'Local' C2C websites with consumers and vendors based in the Netherlands also act as online sites for suppliers of falsified medicines. C2C websites do not have a specific category for medicines, but when specific search terms for medicinal products are used, the results often fall under the category 'miscellaneous'. It is extremely easy to establish contact with sellers on these sites. Most of them are very eager to sell but remain cautious when referring about the origin of the medicine or whether the medicine is falsified. C2C sites are still an important part of the online supply of medicine because they require no specific IT-knowledge, and fake names and addresses can be used by sellers. Furthermore, spammers are also active on C2C sites and are usually identifiable by poor translation.

Online Black Markets. Researchers found a large amount of vendors and shops offering a wide variety of legal or illegal products and services, including medicines, on the Deep Web using the Tor browser. One of the main features of the Tor network is that it provides additional privacy to its users. Due to its technical features, a user is able to remain anonymous on Tor and it becomes extremely difficult to establish the identity of the user. Alongside the use of digital currencies, this makes Tor an ideal place for selling and buying falsified medicinal products. These sites are gaining in popularity: in 2011, there were around 2,500 people in the Netherlands accessing the Tor Network, while in 2013 the number had already increased to over 20,000 users (Schellevis, 2013). Therefore, the Tor-network and black-market places such as Silk Road 2.0 remain somewhat of a niche, but in the future may become places where falsified medicines are increasingly sold.

The patterns

Six investigative and judicial cases were collected from the Dutch Inspectorate of Health and analysed to identify patterns relating to online sales of falsified medicinal products in the Netherlands. Three cases involved counterfeit medicines traded online. A further three cases either involved the illegal sale of prescription medicines via the Internet or the sale of unlicensed medicines online.

In all three cases of counterfeit medicines, suppliers were involved solely in selling erectile dysfunction medicines via online pharmacies. In two of these cases, the suspects used multiple web domains. They carried out the activities on their own, or in one case as a couple. These cases involved suspects aware that they were conducting an illegal business. They also stockpiled their merchandise, either at their home location or at another address.

Two of the remaining cases, which involved the online sale of illegal and unlicensed medicines, showed different results. Rather than online pharmacies, C2C websites and email were used to market and advertise falsified medicinal products online. Although these methods require limited ICT knowledge, the suspect in one case had a large amount of different medicines in stock and collected large amounts of revenue.

The final case was somewhat unique because the suspect, a Dutch wholesaler of pharmaceutical products, was a legal actor. The company involved had a licence to store, distribute and sell medicines. The medicines, which were legal in Belgium, were automatically registered as a free-to-trade products, but because the medicines were not licensed, the pharmaceutical wholesaler's activities were deemed illegal. The suspect claimed that he was not aware of this and recalled the medicines. This case highlights how variations in regulatory laws across Europe can have an impact on the trade and its legality.

In all cases, concealment of the criminal activity was of utmost importance to illicit suppliers. In regard to payment methods, suspects preferred ones that are difficult to trace. In one case, the suspect used a fake front in the form of an administrative business to cover up his activities. Cases also involved suppliers attempting to conceal their activities by registering web domains using fake identities and different addresses.

Furthermore, although it is likely that sophisticated organised crime groups are active in the online trade of falsified medicinal products, the cases from the Netherlands did not provide evidence. However, this does not

imply that individuals cannot run large-scale, sophisticated operations. One case highlighted substantial profits and an operation using over fifteen web domains. Correspondingly, the amount of fake medicines that were intercepted showed that some of the suspects were running large-scale businesses and had established contacts with large suppliers from China. However, the cases analysed did not furnish further information regarding the origin of falsified medicinal products.

United Kingdom

The demand side

Findings based on the UK-based virtual ethnography and secondary sources found a number of factors contributing to the demand for falsified medicines online.

Firstly evidence of a more informed consumer/patient, where a sort of DIY health care facilitated by the Internet was apparent, with some consumers lacking trust in the NHS and moving online to self-diagnose and prescribe. Web 2.0 also facilitated networking among consumers who discussed their experiences and sites of supply.

Secondly, drug diversion was a common determinant factor both in terms of recreational drug use and drug misuse. In terms of recreational pharmaceutical drug use, unintended methods, combinations and administration techniques contributed to the online demand for falsified medicinal products in the UK. The growth of the night-time economy has further heightened recreational prescription pharmaceutical drug use and opened up opportunities for suppliers of falsified medicinal products online, sometimes because consumers would rather buy online than meet a drug dealer in person. With regard to pharmaceutical drug misuse, there is high misuse potential relating to opioids and sedatives in particular and in this context the research found that online consumers buying falsified medicinal products are often feeding a prescription drug habit, sometimes to top up a prescription from their doctor.

Finally, in the context of the demand for lifestyle medicines, which is the largest market in falsified products found in the UK, with demand largely for erectile dysfunction, slimming, and hair loss medicines, the most common contributing factors in this market were convenience, saving embarrassment, avoiding stigma and searching for cheaper prices.

Overall, the following determinant factors – depending on the medicines being bought – seemed to have pushed UK consumers online for falsified medicinal products:

- Cost, speed, convenience;
- Beauty/cosmetic qualities – slimming, hair loss, muscle gain;
- Sexual dysfunction, those unable to get a prescription or unwilling to ask;
- Those lacking trust in the NHS and self-diagnosing online;
- Misuse, addiction, recreation;
- Recreational prescription drug use.

The consumer demographic highlighting who is at risk included factors relating to socio-economic status, age and gender.

Socio-economic. There was a tendency for higher socio-economic groups to shop for falsified medicinal products online in the UK. The UK consumer is regarded as a prime target by online sellers because they are seen to have a larger amount of disposable income and therefore offer higher returns. Other sources also point to the fact that in the UK online medicines prices are not necessarily cheaper. Therefore, the principal factors seem to be the availability of online medicines and the culturally specific desires/needs of the consumers. However, with the growing availability of credit and increasingly free Internet access, there are growing opportunities for those from less privileged backgrounds to risk consuming falsified medicinal products bought online.

Age. Young people in the UK are more susceptible to buying and consuming falsified medicinal products because they are close to the age of onset of drug abuse, are very active online, seek out the cheaper option and are more willing to risk harm related to the consumption of falsified medicinal products.

Gender. The increase in demand for falsified medicines online in the UK is not gender specific, and the groups at risk depend more on the specific medicine and the intended purpose. This includes women at greater risk of consuming falsified medicinal products designed for lifestyle purposes relating to body weight and cosmetics, as well as fertility medicines; usually turning online to search for a cheaper option because fertility medicines are not subsidised by the NHS. However, in the specific cases of bodybuilding and sports performance and the market in erectile dysfunction medicines, this gender balance shifts to men.

Overall, the research suggests that demographic differences depend on the specific pharmaceuticals and their intended purposes. However, the following social groups in the UK are particularly at risk of consuming falsified medicinal products:

- Problem drug users;
- Recreational drug users;
- Students and teenagers
- Individuals suffering from mental health problems, including depression and anxiety, schizophrenia and eating disorders;
- Those lacking trust in the NHS and self-diagnosing online;
- Prolific and polydrug users;
- Those seeking lifestyle medicines, usually too embarrassed to ask a health professional or using for unintended purpose (e.g. slimming, hair loss, erectile dysfunction, steroids);
- Women having problems conceiving and wanting to cut costs;
- Bodybuilders.

The supply side

For suppliers targeting the UK consumer, the research suggested the following typology of online sites advertising and marketing falsified medicinal products in the UK:

Online pharmacies. OPs first appeared in the UK in 1999 without support from the National Health Service (NHS). Since 2005 the NHS has developed an online prescription service of its own (Fox & Ward, 2006). They also introduced the green cross logo; however, the logo is often plagiarised by illegal OP operators. Out of 1165 OPs monitored by the NCA, 91% had no physical address. The research also suggested that huge profits can be made because of the relative affordability of setting up a website and selling a falsified ‘blockbuster’ medicine.

Social media sites. Facebook, Twitter and Instagram were all found to be sites implicated in the trade. Virtual ‘word of mouth’ was important in this context in terms of verifying a ‘legitimate’ seller rather than those involved in identity-related crimes. Some sellers used social media to bypass criminal brokers and buy direct from online wholesalers, then market and advertise via Facebook to consumers. Information available on these sites showed various networks of production and consumption.

Classified advertising and online wholesalers. Online wholesalers in Asia were found to be supplying large quantities of falsified medicinal products to UK suppliers, as well as classified advertising sites being used to sell smaller quantities.

Email and Spam – use of email, spam and hushmail were all heavily used to market and advertise falsified medicinal products in the UK.

Cryptomarkets on the Deep Web – various sites supplying drugs including falsified medicinal products were also found on the dark net using the Tor browser.

A large market in falsified lifestyle medicines, particularly in erectile dysfunction medicines, hair loss and slimming pills, was found. The research also highlighted a growing market in falsified opioids and sedatives. Overall most pharmaceutical products were on offer from sites that are likely to be selling falsified medicinal products, including:

- 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;
- Psychiatric medicines;
- Fertility medicines;
- Antidepressants;
- Stimulants.

The patterns

There is a large, and growing, online market in falsified medicinal products in the UK, and the country acts as both a transit zone and end-user market. The research found that there is a common misconception that the UK is merely a consumer end zone, when in reality it is used as a popular transit zone because a UK postage stamp can heighten the perceived authenticity of a postal package in other destination countries. Therefore a large amount of the parcels of falsified medicinal products reaching the UK are intended to be stamped before being redirected to other parts of Western Europe and North America. Furthermore, a greater number of small-scale postal packages of falsified medicinal products reaching the UK is now the norm, which is harder to track due to the sheer number of these packages being shipped from overseas.

The research also highlighted the difficulties for law enforcement due to a number of regulatory and legal loopholes hampering the authorities’ ability to tackle

the trade. Most significantly is the issue of parallel trade – of which the UK has the largest EU market – which results in the repackaging and reselling of medicines before they reach the UK. This opens up the market in falsified medicines (both via illegal parallel trade and via the online trade), whilst simultaneously rendering detection more difficult. Furthermore, the transnational nature of the trade also weakens regulation and detection because the UK authorities have no legal jurisdiction over producers and illicit online operators abroad.

Findings based on 6 investigative and judicial case files made available by the MHRA highlighted a number of additional patterns relating to the trade. Firstly, that the majority of UK cases involved the online supply of falsified erectile dysfunction medicines, and that both counterfeit and falsified medicinal products were often sold by the same operation.

Secondly, with regard the social organisation of the operations, connections were often made between friends, business partners and/or family members. Overall, the organisational structures of the actors outlined in the cases were best understood in terms of flexible networks. Some were larger nationally based ‘criminal organisations’ with international links, others small-scale locally based groups or individuals. However, the cases related to UK-based operations, not the wider producers and distributors of falsified medicinal products abroad. Therefore, UK based sellers may be linked to larger OCGs abroad, although they may have only been connected virtually e.g. drop shippers.

Thirdly, all cases of online trade of falsified medicinal products in the UK seem to offer examples of oppor-

tunistic crime. These individuals and groups already had some of the necessary infrastructure in place – businesses, contacts in the pharmaceutical industry, payment facilities – to assist them in the supply of falsified medicinal products. Therefore, suppliers involved in the online trade of falsified medicinal products often see opportunities to sell falsified medicinal products online through their day-to-day business activities and often use infrastructure they already have in place to begin trading. These existing businesses (gyms, shops, online shops) were also used as front companies, and existing payment facilities are used for the illegal sale of medicines.

Fourthly, in terms of payments, e-commerce has simplified the process of buying and selling illicit goods, but also borrowing/renting the bank accounts of friends and family members and setting up offshore banking facilities were commonly used to obscure the paper trail in the context of online trade of falsified medicinal products. Often various online sites and payment facilities were simultaneously used by the same operation to sell falsified medicinal products. Furthermore, all sales were not necessarily completed online, emphasising the blurred distinction between online and offline processes in the context of the online trade of falsified medicinal products in the UK.

Finally, the research found little evidence relating to the production stage or from where and whom the suppliers were buying their products. However, some evidence that China, India and Pakistan are regularly the production zones providing UK-based operations with falsified medicinal products was found.

Annex B

Syllabus for a university course on pharmacrime

This document outlines a proposal for a High Level Training Course designed by the research group eCrime – ICT, law & criminology at the Faculty of Law of the University Trento, in accordance with task 3.8 of the Fakecare project: “Developing course modules for universities on pharmaceutical crime with special attention to the online trade of falsified medicinal products”. The module is addressed to law enforcement officers, judges, professionals from the private sector (e.g. associations, consumer associations, pharmacists, security officers of pharmaceutical companies) and the public sector (e.g. officials of ministries, local authorities, etc.).

Title of the course

Pharmacrime and the Web: Prevention and Tackling Strategies.

Objectives of the course

The course provides participants with advanced and multidisciplinary skills for preventing and combating pharmaceuticals crimes, with particular regard to those that take advantage of new technologies and the Internet. The course aims to provide knowledge and tools to:

1. Recognise situations and/or pharmaceutical products that are most at risk of falsification;
2. Implement strategies for both public and private investigations, which must be innovative and able to exploit the potential of the Internet;
3. Implement and/or strengthen the anti-falsification systems of medicinal products;
4. Effectively communicate the risks associated with falsification and the illegal trade of medicines on the web;
5. Develop forms of collaboration between the public and private sectors.

Beneficiary

The course is intended for public and private actors involved in the pharmaceutical market and/or its con-

trol: law enforcement officers, judges, security officers of pharmaceutical companies, other private operators (e.g. associations, associations to protect consumers, pharmacists) and public officials (e.g. officials of ministries, local authorities).

Access requirements

Access to the course is permitted to those in receipt of:

1. A Bachelor's Degree;
2. An upper-secondary school diploma with relevant documented work experience in the field.

Selection procedures

Participants in the Higher Education Course are selected based on an assessment of:

- Curriculum vitae;
- A letter of request to participate;
- Individual interview (if necessary).

Course outline

The course lasts a total of 100 hours of lectures and 200 estimated hours of individual study. This means that there is an emphasis on independent learning, and students are strongly advised to read widely and prepare thoroughly for all sessions. Support to the students will be provided outside the 'classroom' environment. Online learning resources for the module and an interactive learning environment will enable students to discuss the course material with other students outside the classroom, and maximise the learning experience.

The teaching hours are subdivided into a core module which is compulsory for all participants (60 hours) and an optional module (40 hours), chosen by the participant from the following three paths:

1. Technical investigation;
2. Corporate security;
3. Risk communication.

The aforementioned paths are designed to provide specific training tailored to the skills and needs of different categories of participants. Hours of individual study are dedicated to deepening themes discussed during the course, also through ad hoc materials provided by the teachers, and the preparation of a final paper. In order to facilitate learning and support participants in the drafting of the final paper, an online community service is provided. Students can interact in this online community.

On completion of the course, the University of Trento will award 12 credits to participants who attend at least 80% of teaching hours and receive a positive evaluation of their final paper. Those participants will receive a certificate of participation. There follows a brief description of the teaching hours provided.

The core module

The core module adopts a multidisciplinary approach, providing participants with relevant basic knowledge of criminology, law, pharmacy and pharmacology, and information technology necessary for operators likely to be affected by or encounter criminal cases related to the illegal trade of medicines on the Web. The module lasts 60 hours and is organized into three Sections, as follows (see also Table A2).

Principles of criminology, law, pharmacy, pharmacology and computer science

This Section provides the basics of criminology that afford better understanding of the causes and development of the illegal trade of medicines both online and offline). Special attention is also paid to concepts and techniques that can be used to reduce pharmaceutical crime, as put forward by situational prevention practices.

Besides elements of criminology, also domestic and European legislation relating to online sales of medicines is explained, focusing specifically on aspects of criminal law and pharmaceutical crime, as well as on the procedural aspects of prosecuting such crimes.

Secondly, this Section introduces the principles and techniques of medicines identification and analysis. It assesses the prevalence of falsified and substandard medicines and also their influential factors on the Internet and in domestic and European environments.

Finally, the module presents some basic concepts of information technology and provides notions useful for the understanding of topics discussed in the following Sections and in the three optional modules.

This Section has a duration of 30 hours.

Illegal trade of medicines on the web: crimes, offenders and consumer-victims

In this Section the dynamics of crimes related to the online trade of medicines (statistics, criminal cases, evolution of crimes), as well as characteristics, profiles and motives of illicit suppliers and 'consumer-victims' involved in such crimes, are detailed. The Section draws directly on applied research, case studies, and results of innovative criminological methods applied by the eCrime research group of the University of Trento during the project www.fakecare.com.

The Section has a duration of 20 hours.

Preventing and combating pharmaceutical crime

The last Section of the core module provides an overview of prevention techniques used in the fight against pharmaceutical crime. More precisely, sessions in this Section provide basics on the strategies to prevent and combat pharmaceutical crime employed by various actors (law enforcement agencies, pharmaceutical companies, public/private entities engaged in communications). Moreover, it introduces the theme of public-private cooperation in the fight against illegal online pharmacies.

The Section has a duration of 10 hours.

Optional modules

The optional modules provide a number of advanced concepts characterized by an applied and practical approach. Three separate paths have been designed to best meet the varied skills and interests of the participants (police/judiciary, pharmaceutical companies, trade associations/pharmacists/communication staff). These include the following specialised pathways: 1) Techniques of investigation; 2) Corporate security; 3) Risk communication.

Teaching is divided into three paths, each of which has a duration of 40 hours. Each is briefly presented below and summarized in Tables A3, A4 and A5.

Technical investigation

This module, specifically for police and magistrates, starts with a focus on investigation techniques that take advantage of 'open source' intelligence. It then illustrates the use of investigative software and Internet-based intelligence (e.g. undercover operations and 'virtual' infiltration of criminal organizations dedicated to pharmaceutical crime, and identification of offenders online).

Alongside the techniques of investigation, the Section also provides advanced knowledge on strategies to fight illegal online pharmacies through national and international case studies (e.g. closure of illegal sites).

Moreover, it describes some techniques for investigation of the electronic payment methods used by illegal online pharmacies and/or other distribution channels active on the Web.

Finally, bearing in mind the transnational nature of pharmaceutical crime, 5 hours are dedicated to examining judicial and police cooperation at the EU level. The skills and experiences of national experts of some EU countries (including Italy), as well as significant case studies at the international level, will be drawn upon throughout the module.

Corporate security

This module, specifically designed for security professionals working for pharmaceutical companies, focuses on prevention techniques that enable private firms to

reduce the risk of falsification and/or the illegal trade of their products online. More specifically, the module provides notions on 'crime proofing' products against possible attempts at falsification; the private techniques of investigations; the aims and strategies of public-private cooperation to improve preventive action, and the fight against the falsification and illegal sale of pharmaceutical medicines on the Internet.

Risk communication

This path, designed for private (e.g. associations, pharmacists, communication operators) and public (e.g. officials of ministries, local authorities) operators, focuses on communicating the health risks and the criminal aspects of the trade in falsified medicinal products. In particular, it offers analyses of communication techniques and examples of successful awareness campaigns, as well as tips for the implementation of similar initiatives that could also exploit the potential of the Internet in the wider dissemination of information on the use of medicines and the risks of criminal cases such as those found during the Fakecare project.

Table A2 – Core module

| Principles of criminology, law, pharmacy, pharmacology and computer science (30 hours) | | |
|---|--------------|--|
| Subject of the lecture | Hours | Teacher |
| Introduction | 2 | Criminology researcher, Senior chemist officer |
| Principles of Criminology | 10 | Criminology researchers (2) |
| Principles of Law | 6 | Criminology researcher, Law researcher |
| Principles of Pharmacy and Pharmacology | 6 | Senior chemist officer, Chemist researcher |
| Principles of Information Technology | 6 | ICT Researcher (2) |
| Illegal trade of medicines on the web: crimes, authors and consumer-victims (20 hours) | | |
| Subject of the lecture | Hours | Teacher |
| Medicines sold illegally on the web: numbers and trends | 4 | Criminology researcher |
| Role of illegal online pharmacies | 4 | Criminology researcher |
| Authors and criminal groups involved profiling | 6 | Criminology researcher |
| Consumers-victims motivations and profiling | 6 | Criminology researcher |
| Preventing and combating pharmaceutical crime (10 hours) | | |
| Subject of the lecture | Hours | Teacher |
| Law enforcement agencies' role | 2 | Senior law enforcement officer |
| Pharmaceutical corporations' role | 2 | Senior pharmaceutical officer |
| Risk communication to reduce pharmaceutical crime | 2 | University researcher |
| Private-Public cooperation in the fight against illegal online pharmacies | 4 | Criminology researcher |

Source: elaboration by eCrime – project Fakecare

Table A3 – Optional module ‘Technical investigation’

| Investigations on the online illegal trade of medicines (15 hours) | | |
|---|--------------|--|
| Subject of the lecture | Hours | Teacher |
| Investigation techniques based on “open sources” available online | 4 | Senior officer of a medicines agency in the EU |
| Technical identification of illegal online pharmacies | 6 | ICT researcher (2) |
| Identification techniques of other channels of illegal online sale | 3 | ICT researcher (2) |
| Undercover operations and “virtual” infiltration | 2 | Senior law enforcement officer |
| Closing / fight against illegal online pharmacies (10 hours) | | |
| Subject of the lecture | Hours | Teacher |
| Closing of illegal online pharmacies: Italian case studies | 4 | Senior officer of a medicines agency in the EU |
| Closing of illegal online pharmacies: United Kingdom case studies | 3 | Senior officer of a medicines agency in the EU |
| Closing of illegal online pharmacies: Interpol operation Pangea | 3 | Senior law enforcement officer |
| Investigations on the online methods of payments (10 hours) | | |
| Subject of the lecture | Hours | Teacher |
| Online payment systems and illegal online pharmacies | 4 | Criminology researcher |
| Traceability of online payments in Italy and the EU | 2 | Italian Ministry of Finances Senior officer |
| Investigations techniques on the online methods of payments | 4 | Custom senior officer |
| Police and judicial cooperation (5 hours) | | |
| Subject of the lecture | Hours | Teacher |
| Systems of exchange of judicial and law enforcement information in the EU | 5 | Senior law enforcement officer |

Source: elaboration by eCrime – project Fakecare

Table A4 – Optional module ‘Corporate security’

| Corporate investigations on the illegal online trade of medicines (30 hours) | | |
|---|--------------|--|
| Subject of the lecturer | Hours | Teacher |
| Techniques for the identification of falsified medicinal products sold online | 10 | Criminology researcher |
| Techniques for the identification of illegal online pharmacies | 10 | Criminology researcher |
| Techniques for the identification of other illegal online sales channels | 10 | Criminology researcher |
| Corporate operations against falsification (5 hours) | | |
| Subject of the lecture | Hours | Teacher |
| Product Crime proofing | 5 | Criminology researcher |
| Private and public cooperation (5 hours) | | |
| Subject of the lecture | Hours | Teacher |
| IMPACT-WHO and the private sector | 5 | Senior officer of a medicines agency in the EU |

Source: elaboration by eCrime – project Fakecare

Table A5 – Optional module ‘Risk communication’

| Subject of the lecture | Hours | Teacher |
|--|-------|--|
| Falsified medicinal products: communicate the health risks | 8 | Senior officer of a medicines agency in the EU |
| Falsified medicinal products: communicate aspects of crime-related | 8 | Criminology Researcher |
| Information campaigns: examples of success | 8 | Senior officer of a medicines agency in the EU |
| Communication and Web: potential and strategies | 8 | Senior officer of a medicines agency in the EU |
| How to build an information campaign | 8 | Senior officer of a medicines agency in the EU |

Source: elaboration by eCrime – project Fakecare

Assessment criteria

The assessment criteria are as follows:

70%-100%

An exceptional submission. Presentation is logical, creative and error free. There is accurate use of the referencing system, with evidence of wide reading, a clear grasp of the material, and an in-depth understanding of issues. The work demonstrates the application of theory to practice well supported by relevant research. There is evidence of original insights, and presentation of the student's own arguments. The essay contains a critical reflection comparing and contrasting points of view. The student debates and argues issues, demonstrating an innovative, imaginative and creative approach to the topic.

60%-69%

The submission is very good, logically sequenced, with presentation to a high standard. Good use is made of source material, with careful adherence to an approved referencing system. The work demonstrates an excellent knowledge base, with a clear understanding of the issues being discussed. There is good application of research findings to practice. The work contains comprehensive, critical and analytical application of literature and published research. The student has clearly drawn conclusions, and explains relevant arguments from a variety of sources.

50%-59%

The submission is sound, clearly presented and logically structured. The work shows evidence of an understanding of the topic, and addresses the major issues. The referencing system used is largely acceptable and reflects competent use of source material. There

is evidence of application of theory to practice, with examples of critical reflection. The work contains some discussion and interpretation of relevant perspectives; further development of the arguments presented would be beneficial.

49% and below – fail

The work is poorly presented and contains numerous serious errors, inconsistencies and omissions. The referencing is inadequate, with very limited use of source material. The work displays a weak knowledge base, and a lack of understanding of the topic. There is no evidence of the application of theory to practice. The essay is descriptive, lacking any attempt at analysis or reflection. It contains many unsupported statements, with no attempt to bring issues together.

Assessment feedback

Students will receive written feedback on their essay assessment sheet. Formative feedback will also be provided to any student submitting a draft of the essay if they follow the stated guidelines.

- Email the essay as an attached Word file to the appropriate tutor making sure that the document includes your full name & the essay title;
- Make sure that there are a minimum of 5 working days between sending the email and the appointment;
- Only ONE draft per student will be read.

Number of participants

The course requires a minimum of 40 participants and maximum of 60 participants.

Annex C

The customer's at risk questionnaire (web survey)

The online trade of medicines

We are conducting research on the online trade in pharmaceuticals and we are trying to understand online health practices better. We would very much appreciate if you could spare 10 minutes to answer our questionnaire. All answers are anonymous and your privacy will be protected. Many thanks for your time!

Are you aware that the online trade in counterfeit goods includes pharmaceutical products?

Please choose only one of the following:

- ☐ Yes
- ☐ No

In your opinion, what types of medicines are most at risk of counterfeiting/falsification?

Please choose only one of the following:

- ☐ Prescription medicines
- ☐ Non-prescription or over-the-counter medicines
- ☐ All types of medicines

Do you think there is a widespread tendency among the citizens of your country to self-medicate? [e.g. using medicines or medications to treat self-diagnosed disorders or symptoms without consulting a doctor]

Please choose only one of the following:

- ☐ Yes
- ☐ No

In your opinion, is the tendency to self-medicate in some way linked to the spread of counterfeit/falsified medicines?

Please choose only one of the following:

- ☐ Yes
- ☐ No
- ☐ I don't know

Have you ever bought medicines online?

Please choose only one of the following:

- ☐ Yes
- ☐ No

What were the reason(s) for you to buy medicines online?

Please choose all that apply:

- ☐ Financial (cheaper products online)
- ☐ Convenience (easier to purchase online than in a store)
- ☐ Guaranteed anonymity
- ☐ Facility of buying without a prescription
- ☐ Other (specify_____)

Usually, how do you find an online pharmacy?

Please choose all that apply:

- ☐ I use online search engines (google, yahoo, etc.)
- ☐ I receive recommendations from people I know
- ☐ I read forums/chatrooms related to medicines
- ☐ Other (specify_____)

What types of medicines have you purchased online?

Please choose only one of the following:

- ☐ Non-prescription (over-the-counter) medicines
- ☐ Prescription medicines
- ☐ Both

What kinds of non-prescription (over the-counter) medicines have you bought online?

Please choose all that apply:

- ☐ Analgesic/painkiller [medicines intended to relieve pain by reducing it, without tackling the reasons that have caused it]
- ☐ Gastrointestinal [medicines intended to treat digestive dysfunctions, e.g. antacid, anti-diarrhoea, etc.]
- ☐ Tonic [medicinal preparations intended to improve and strengthen the functioning of the body or increase the feeling of wellbeing]
- ☐ Antipyretic [medicinal product intended to prevent or alleviate fever]
- ☐ Anti-inflammatory [medicines intended to reduce inflammation]

What kinds of prescription medicines have you bought online?

Please choose all that apply:

- ☐ Lifestyle [medicines intended to treat problems which affect a person's quality of life rather than his or her health. E.g. erectile dysfunction; weight loss, hair loss etc.]
- ☐ Psychiatric [medicines intended to treat mental illness, e.g. antidepressants, antipsychotics]
- ☐ Lifesaving [medicines intended to treat serious and potentially lethal diseases]
- ☐ Anabolic Steroids [medicines designed to increase muscle mass and/or speed up muscle recovery]
- ☐ Analgesic/painkiller [medicines intended to relieve pain by reducing it, without tackling the reasons that have caused it]
- ☐ Antibiotics [medicines used to treat, and sometimes prevent, bacterial infections]
- ☐ Stimulants [medicines used to increase activity in the brain, temporarily heightening mood, alertness and awareness]
- ☐ Sedatives [medicines used to induce sedation and reduce irritability and anxiety, including benzodiazepines and non-benzodiazepines]
- ☐ Other (specify_____)

Considering the last medicine that you purchased online, how would you rate your satisfaction with this purchase?

Please choose only one of the following:

- ☐ Very satisfied
- ☐ Moderately/somewhat satisfied
- ☐ A little satisfied
- ☐ Not satisfied

Why are you very/somewhat satisfied?

Please choose all that apply:

- ☐ The medicine did what I purchased it for
- ☐ I had no side effects
- ☐ I avoided medical prescriptions
- ☐ My anonymity was guaranteed
- ☐ I paid less than in a traditional pharmacy
- ☐ Other (specify_____)

Why are you little/not satisfied?

Please choose all that apply:

- ☐ The medicine didn't do what I purchased it for
- ☐ I had side effects
- ☐ I paid more than in a traditional pharmacy
- ☐ I didn't receive the medicine(s) purchased
- ☐ I received medicines other than the ones I requested
- ☐ My personal information was stolen (e.g. credit card, bank account, etc.)

In the past two years, how many times have you purchased medicines online?

Please choose only one of the following:

- ☐ Never
- ☐ 1-2 times
- ☐ 3-5 times
- ☐ 6 times or more

Do you know other people who buy medicines online?

Please choose only one of the following:

- ☐ Yes
- ☐ No

In your opinion, for what reason(s) do people you know buy medicines online?

Please choose all that apply:

- ☐ Financial (cheaper products online)
- ☐ Convenience (easier to purchase online than in a traditional pharmacy)
- ☐ Guaranteed anonymity
- ☐ Facility of buying without a prescription
- ☐ Other (specify_____)

What in your opinion are the most common medicines being purchased online by other people?

Please choose only one of the following:

- ☐ Non-prescription (over-the-counter) medicines
- ☐ Prescription medicines
- ☐ Both

What kind of non-prescription (over the-counter) medicines have they bought online?

Please choose all that apply:

- ☐ Analgesic/painkiller [medicines intended to relieve pain by reducing it, without tackling the reasons that have caused it]
- ☐ Gastrointestinal [medicines intended to treat digestive dysfunctions, e.g. antacid, anti-diarrhoea, etc.]
- ☐ Tonic [medicinal preparation intended to improve and strengthen the functioning of the body or increase the feeling of wellbeing]
- ☐ Antipyretic [medicinal product intended to prevent or alleviate fever].
- ☐ Anti-inflammatory [medicines intended to reduce inflammation]
- ☐ Other (specify_____)

What kind of prescription medicines have they bought online?

Please choose all that apply:

- ☐ Lifestyle [medicines intended to treat problems, which affect a person's quality of life rather than his or her health. E.g. erectile dysfunction; weight loss, hair loss etc.]
- ☐ Psychiatric [medicines intended to treat mental illness, e.g. antidepressants, antipsychotics]
- ☐ Lifesaving [medicines intended to treat serious and potentially lethal diseases]
- ☐ Anabolic Steroids [medicines designed to increase muscle mass and/or speed up muscle recovery]
- ☐ Analgesic/painkiller [medicines intended to relieve pain by reducing it, without tackling the reasons that have caused it]
- ☐ Antibiotics [medicines used to treat, and sometimes prevent, bacterial infections]
- ☐ Stimulants [medicines used to increase activity in the brain, temporarily heightening mood, alertness and awareness]
- ☐ Sedatives [medicines used to induce sedation and reduce irritability and anxiety, including benzodiazepines and non-benzodiazepines]
- ☐ Other (specify_____)

In your opinion, is it legal in your country to purchase medicines on the Internet?

Please choose only one of the following:

- ☐ Yes, but only for medicines available without a prescription
- ☐ Yes, for all types of medicines
- ☐ No, it is illegal to purchase any medicine online
- ☐ I don't know

Are you:

Please choose only one of the following:

- ☐ Male
- ☐ Female

Age:

Please choose only one of the following:

- ☐ <18 years
- ☐ 18-24 years
- ☐ 25-34 years
- ☐ 35-44 years
- ☐ 45-54 years
- ☐ 55-64 years
- ☐ >65 years

Level of education:

Please choose only one of the following:

- ☐ Primary education
- ☐ Lower secondary education
- ☐ (Upper) secondary education
- ☐ Post-secondary non- tertiary education
- ☐ First Stage of tertiary education
- ☐ Second Stage of tertiary education [e.g. Ph.D.]

Country of residence:

Please choose only one of the following:

- ☐ Bulgaria
- ☐ France
- ☐ Germany
- ☐ Italy
- ☐ Spain
- ☐ The Netherlands
- ☐ UK
- ☐ Other (specify_____)

Annex D

Example of crime script analysis scheme

Case 3 (Year of alleged offence: 2003-2007)

Summary

An MHRA investigation made a number of test purchases of counterfeit and unlicensed erectile dysfunction medicines from a UK-based website. It was found that the main suspect was operating a business called 'MSH World Traders' which supplied products to the UK and abroad via the Internet:

1. He operated three linked companies: the online pharmaceutical business, an Indian call centre and a business selling quad bikes;
2. He opened a PO Box and received orders and cheques;
3. He had opened bank accounts in England, Malta and The Isle of Man to receive cheques and credit card payments;
4. He transferred proceeds to various bank accounts overseas;
5. Various payments to pharmaceutical suppliers were found;
6. The falsified medicinal products being sold were manufactured in India;
7. Turnover was calculated at £6,813,155.54 in the period 1.10.03 – 12.11.07;
8. In 2012 the MHRA recovered assets totalling £14.4 million from the suspect – the largest amount in the organisation's history;
9. The suspect had been enjoying a lavish lifestyle and owned holiday homes, property in London, and luxury cars;
10. The suspect pleaded guilty in 2009. His original sentence was 10 months. It was later extended to 2 years to include money laundering charges.

| Case 3 | Function | | | |
|---------|---|-------------------------------------|------------------------------|--|
| | Preparation | Pre-Activity | Activity | Post-Activity |
| Stage | UK India | UK India Isle of Man Malta | UK Isle of Man Malta | UK Internationally (bank accounts) |
| Cast | 1 male suspect, 49 years old | 1 male suspect, 49 years old | 1 male suspect, 49 years old | 1 male suspect, 49 years old |
| Product | Counterfeited erectile dysfunctional medicine: <i>Viagra</i> Illegal erectile dysfunctional medicine: <i>Kamagra</i> | | | |

| Function | Macro-areas (activity/network/context) | Actions (description of the action) |
|----------------------|--|--|
| Preparation | Illicit erectile dysfunction drugs sourced in India. | Making contact with suppliers to obtain merchandise. |
| Pre-activity | Importing/stockpiling of illegal and counterfeit medicine. Establishing contact with customers for delivery and payment. Distributing and profiting from falsified medicinal products. | Suspect obtained large quantities of illegal and/or falsified erectile dysfunctional medicine. Setting up an online pharmacy to market and sell medicines. Set up a PO box and numerous bank accounts to process orders and receive funds. |
| Activity | Selling of counterfeit and illegal erectile dysfunctional medicine on the Internet. Stockpiling a large amount of illegal and falsified medicinal products. | Suspect operated an illegal online pharmacy and also marketed the products via a number of the press releases. He received payments via a number of banking facilities. |
| Post-activity | Money Laundering | His turnover between 2003 and 2007 was over £6 million and over £14.4 million was later recovered. The suspect had laundered a large proportion of his criminal money through his businesses and bank accounts. |

Annex E

Tables and figures

Table A6 – Usually, how do you find an online pharmacy? Percentages (N=130). Results of the web survey

| | |
|---|--------|
| I use online search engines (google, yahoo, etc.) | 69.2% |
| I receive recommendations from people I know | 10.8% |
| I read fora/chat related to medicines | 14.6% |
| Other | 5.4% |
| Total | 100.0% |

Source: elaboration by eCrime - project Fakecare

Table A7 – In the past two years, how many times have you purchased medicines online? Percentages (N=132). Results of the web survey

| | |
|-----------------|--------|
| Never | 8.3% |
| 1-2 times | 50.8% |
| 3-5 times | 25.0% |
| 6 times or more | 15.9% |
| Total | 100.0% |

Source: elaboration by eCrime - project Fakecare

Table A8 – Are you aware that the online trade in counterfeit goods includes pharmaceutical products by buyers/not buyers? Percentages (N=819). Results of the web survey

| | Buyers | Not buyers | Total |
|-------|--------|------------|--------|
| Yes | 90.9% | 85.4% | 86.3% |
| No | 9.1% | 14.6% | 13.7% |
| Total | 100.0% | 100.0% | 100.0% |
| N | 132 | 687 | 819 |

Source: elaboration by eCrime - project Fakecare

Table A9 – Number of visitors by country. Absolute values. Results of the honeypot websites (N= 4,966)

| | |
|-----------------|-------|
| United Kingdom | 1,842 |
| United States | 1,359 |
| Russia | 635 |
| Italy | 523 |
| China | 184 |
| Brazil | 134 |
| Japan | 101 |
| Germany | 88 |
| The Netherlands | 61 |
| India | 49 |
| Ireland | 13 |
| Spain | 7 |
| Total | 4,996 |

Source: elaboration by eCrime - project Fakecare

Table A10 – Have you ever bought medicines online by educational level? Percentages (N=786). Results of the web survey

| | Low | Medium | High | Total |
|-------|--------|--------|--------|--------|
| Yes | 22.9% | 19.9% | 14.7% | 16.2% |
| No | 77.1% | 80.1% | 85.3% | 83.8% |
| Total | 100.0% | 100.0% | 100.0% | 100.0% |
| N | 35 | 171 | 580 | 786 |

Source: elaboration by eCrime - project Fakecare

Table A11 – What type of medicines have you purchased online? Percentages (N=132). Results of the web survey

| | |
|------|-------|
| OTCs | 62.9% |
| POMs | 23.5% |
| Both | 13.6% |

Source: elaboration by eCrime - project Fakecare

Table A12 – What in your opinion are the most common medicines being purchased online by other people? Percentages (N=267). Results of the web survey

| | |
|-------|--------|
| OTCs | 33.3% |
| POMs | 38.2% |
| Both | 28.5% |
| Total | 100.0% |

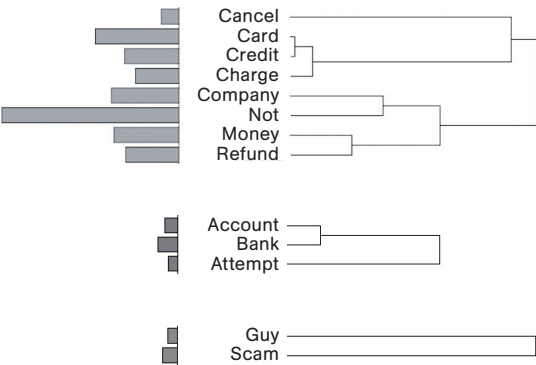
Source: elaboration by eCrime - project Fakecare

Table A13 – Products that customers attempted to purchase. Absolute values. Results of the honeypot websites (N=31)

| Products | Quantity |
|--|----------|
| Kamagra Polo | 8 |
| Valif Jelly | 5 |
| Super Filagra | 5 |
| Orlistat 120 mg | 2 |
| Caverta | 4 |
| Bupropion 150 mg | 2 |
| Chitosan Diet Formula | 1 |
| ABB Adrenalyn Shot | 1 |
| Optimum Natural Amino | 1 |
| Thinkbaby Sunscreen SPF 50 + 6 fl oz (177 mL) | 1 |
| Aveeno Baby Continuous Protection Sunscreen Lotion, SPF 55 | 1 |

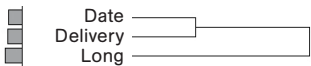
Source: elaboration by eCrime - project Fakecare

Figure A1 – Clusters analysis of ‘fraud’, ‘scam’ and ‘account’ words takeover in negative reviews. Results of the quantitative content analysis of customers’ reviews in illegal/fake online pharmacies



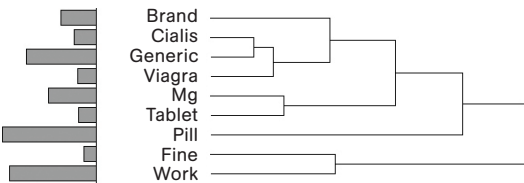
Source: elaboration by eCrime - project Fakecare

Figure A2 – Cluster analysis of ‘long delivery’ word in negative reviews. Results of the quantitative content analysis of customers’ reviews in illegal/fake online pharmacies



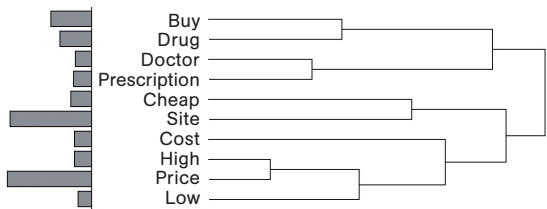
Source: elaboration by eCrime - project Fakecare

Figure A3 – Cluster analysis of ‘pill’ word in positive reviews. Results of the quantitative content analysis of customers’ reviews in illegal/fake online pharmacies



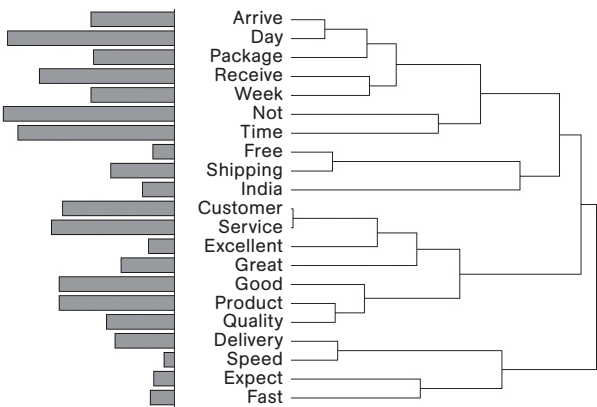
Source: elaboration by eCrime - project Fakecare

Figure A4 – Cluster analysis of ‘prescription’ and ‘price’ words in positive reviews. Results of the quantitative content analysis of customers’ reviews in illegal/fake online pharmacies



Source: elaboration by eCrime - project Fakecare

Figure A5 – Cluster analysis of criteria of choice of a medicinal products in positive reviews. Results of the quantitative content analysis of customers’ reviews in illegal/fake online pharmacies



Source: elaboration by eCrime - project Fakecare

Table A14 – Word frequency first 30 words. Absolute words and percentages. Results of the quantitative content analysis of customers' reviews in illegal/fake online pharmacies

| Positive | | | Negative | | |
|----------------|-----------|---------|---------------|-----------|---------|
| | Frequency | % Cases | | Frequency | % Cases |
| Not | 551 | 36,3% | Day | 192 | 32,2% |
| Day | 538 | 38,8% | Card | 190 | 33,1% |
| Time | 504 | 37,5% | Receive | 174 | 34,7% |
| Receive | 436 | 34,4% | Time | 168 | 29,8% |
| Service | 396 | 33,8% | Call | 163 | 30,1% |
| Good | 372 | 30,8% | Email | 160 | 27,3% |
| Product | 371 | 27,9% | Company | 154 | 30,1% |
| Customer | 361 | 27,5% | Customer | 151 | 28,2% |
| Pharmacy | 340 | 23,1% | Money | 147 | 27,9% |
| Pill | 294 | 16,7% | Pill | 134 | 18,1% |
| Work | 274 | 23,6% | Week | 127 | 25,5% |
| Arrive | 270 | 24,2% | Product | 127 | 24,8% |
| Week | 269 | 23,1% | Credit | 123 | 22,7% |
| Package | 261 | 19,1% | Refund | 122 | 20,9% |
| Price | 258 | 23,4% | Pharmacy | 110 | 22,7% |
| Site | 250 | 19,6% | Never | 109 | 23,9% |
| Online | 249 | 20,5% | Site | 109 | 22,4% |
| Generic | 221 | 18,6% | Service | 106 | 25,2% |
| Quality | 221 | 21,0% | Charge | 100 | 22,1% |
| Call | 220 | 16,0% | Wait | 95 | 19,9% |
| Company | 213 | 15,8% | Number | 93 | 18,4% |
| Shipping | 206 | 18,1% | Contact | 85 | 19,9% |
| Review | 197 | 14,9% | Online | 83 | 18,1% |
| Delivery | 194 | 17,5% | Month | 78 | 18,1% |
| Email | 186 | 13,2% | Fake | 77 | 13,2% |
| Card | 185 | 13,4% | Check | 77 | 12,9% |
| Med | 179 | 12,9% | Chat | 74 | 12,6% |
| Problem | 178 | 15,6% | Pay | 68 | 14,7% |
| Great | 174 | 14,8% | Good | 67 | 17,5% |

Source: elaboration by eCrime - project Fakecare

Table A15 – Co-occurrences with ‘fake’ word in negative reviews. Results of the quantitative content analysis of customers’ reviews in illegal/fake online pharmacies

| Target | Keyword | Co-occurs | Jaccard | Strength |
|-------------|------------|-----------|---------|----------|
| Fake | | | | |
| Fake | Pill | 22 | 0,275 | |
| Fake | Modafinil | 11 | 0,196 | |
| Fake | India | 9 | 0,148 | |
| Fake | Medication | 9 | 0,143 | |
| Fake | Brand | 8 | 0,136 | |
| Fake | Review | 10 | 0,132 | |
| Fake | Product | 14 | 0,127 | |

Source: elaboration by eCrime - project Fakecare

Table A16 – Co-occurrences with ‘medicines’ word. Results of the quantitative content analysis of customers’ reviews in illegal/fake online pharmacies

| Positive | | | | | Negative | | | | |
|-----------------|-----------|-----------|---------|----------|-----------------|------------|-----------|---------|----------|
| Target | Keyword | Co-occurs | Jaccard | Strength | Target | Keyword | Co-occurs | Jaccard | Strength |
| Generic | Cialis | 35 | 0,186 | | Fake | Pill | 22 | 0,275 | |
| Generic | Viagra | 33 | 0,185 | | Generic | Pill | 21 | 0,256 | |
| Pill | Generic | 48 | 0,174 | | Pill | Effect | 14 | 0,215 | |
| Pill | Work | 55 | 0,175 | | Fake | Modafinil | 11 | 0,196 | |
| Good | Pill | 57 | 0,150 | | India | Drug | 8 | 0,154 | |
| Effect | Modafinil | 17 | 0,145 | | Pill | Modafinil | 12 | 0,169 | |
| Pill | Effect | 25 | 0,141 | | Fake | Medication | 9 | 0,143 | |
| Pill | India | 25 | 0,116 | | Fake | Brand | 8 | 0,136 | |
| Free | Pill | 19 | 0,096 | | Generic | Fake | 11 | 0,145 | |
| Pill | Modafinil | 21 | 0,097 | | Fake | Product | 14 | 0,127 | |
| | | | | | Effect | Not | 15 | 0,072 | |

Source: elaboration by eCrime - project Fakecare



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