

United Nations Interregional Crime and Justice Research Institute

# Counterfeit Medicines and Organised Crime



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# TABLE OF CONTENTS

ACKNOWLEDGEMENTS -----

LIST OF ABBREVIATIONS-----

FOREWORD-----

1. COUNTERFEIT MEDICINES: INTRODUCTION-----

1.1 Defining Counterfeit Medicines-----

1.2 Tracking the Magnitude of the Problem. Counterfeit Medicines as a Global Concern ----

1.3 Taking Advantage of the Loopholes: the Introduction of Counterfeit Medicines in the Legitimate Distribution Chain -----

1.3.1 Diversion-----

1.3.2 Parallel Trading-----

1.4 The Victims of Counterfeit Medicines: Patients and Consumers -----

1.4.1 Cases-----

1.4.2 *The Option between Communication and Non-communication: Dangers at the Social Level*-----

1.4.3 *What Consumers Need to Know*-----

1.4.4 *The Other Victims of Counterfeit Medicines: the Industrial Pharmaceutical Sector and National Economies*-----

2. THE WORLDWIDE MARKET-----

2.1 Counterfeit Medicines and Less Developed Countries -----

2.1.1 *Consequences on Patients' Health and Consequences at the Economic and Social Level*-----

2.1.2 *Cases* -----

2.1.3 *The Nigerian Case of Fight Against Counterfeit Drugs* -----

2.1.4 *China and India as Exporters and Consumers of Counterfeit Medicines*-----

2.1.5 *Drawn Conclusions*-----

2.2 The Other Side of the Same Coin: Counterfeit Medicines in Developed Countries -----

2.2.1 *Counterfeit Medicines and the Internet Offer: Legal, Rogue and Fake E-pharmacies*--

3. THE PILOT STUDY ON SPAM AND FAKE E-PHARMACIES -----

3.1 Counterfeit Medicines and Online Advertisement: an Attempt to Understand the Logic of Spamming-----

3.2 Tracking Spam to its Source with Forensic Analysis Methods: a Pilot Study on Spam and Medicines Online -----

4. THE IMPLICATION OF ORGANISED CRIME IN MEDICINES COUNTERFEITING--

4.1 Transnational Organised Groups, Transnational Organised Crimes-----

4.2 A Poorly Sanctioned Organised Crime -----

5. CONCLUSIONS AND PROPOSALS-----

5.1 Understanding of the Problem (What)-----

5.2 Responding to Organised Crime (Who)-----

5.3 Improving the Situation (How)-----

BIBLIOGRAPHY ----- 103

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# **LIST OF ABBREVIATIONS**

AIFA: Agenzia Italiana del Farmaco (Italian Pharmaceutical Agency)

API: Active Pharmaceutical Ingredients

BASCAP: Business Action to Stop Counterfeiting and Piracy

EU: European Union

FDA: United States Food and Drugs Administration

ICE: United States Immigration and Customs Enforcement

IMPACT: International Medical Products Anti-Counterfeiting Task-force

IPR: Intellectual Property Right

ITU: International Telecommunication Union

MHRA: UK Medicines and Healthcare Products Regulatory Agency

NAFDAC: Nigerian National Agency for Food, Drugs Administration and Control

OECD: Organization for Economic Cooperation and Development

R&D: Research and Development

TAXUD: European Commission Taxation and Customs Union

UN: United Nations

UNICRI: United Nations Interregional Crime and Justice Research Institute

UNTOC: United Nations Convention against Transnational Organized Crime

USAID: United States Agency for International Development

WHO: World Health Organization

## FOREWORD

While preparing this report we discussed its content with people of various nationalities, ages and professional statuses. Many of them asked the same question: **“are medicines counterfeited?”** This reveals an important aspect of the phenomenon discussed in this paper. Counterfeiting of medicines rarely enters people’s thoughts; this possibility is usually ignored or considered a distant reality or something that will never occur to them. People actually know about the existence of counterfeit goods -- although they often ignore the dimensions and parameters of the problem -- and they can also admit to have bought a pirated CD or a fake wallet from street vendors. However it is much more difficult for them to see themselves buying counterfeit painkillers, tranquilizers, slimming pills or diabetes treatments. This is mainly due to the fact that no patient would accept a compromise regarding the quality of treatments and would willingly put his/her health and safety at risk by buying a medicine knowing it is a fake. This is also the reason why the production and distribution of counterfeit medicines are illegal activities performed clandestinely. Medicines counterfeiters aim to avoid raising suspicions about the origin and the quality of their products. As a matter of fact they hope to be able to slip past the authorities’ control and, ultimately, deceive consumers. This illegal activity can be so profitable that it has attracted the interest of organised criminal groups. The latter have transformed it into a mass production illegal business which of course exponentially increases the risks for citizens.

Consumers’ vulnerability to this type of crime, organised crime involvement and the consequences counterfeit medicines can have for patients are the main reasons why this report has been prepared. The methodology used relied on a meticulous meta-analysis of reports, studies and information from various sources. Such information has been thoroughly elaborated, examined and analysed with a critical eye in an attempt to render this work comprehensive and easily understandable to laypeople. With this in mind, and in order to thoroughly examine the problem, we have taken various factors into consideration: the means of production and distribution of counterfeit medicines; the peculiarities of the national, regional and international globalised markets; the chain of perpetrators of this type of crime and the involvement of organised criminal groups; the magnitude as well as the geographical spectrum of the phenomenon through a distinction between developed countries and countries with developing economies. In short, we aim to track and trace this ever-changing problem.

This report also examines the internet’s role as an unregulated medicine market, especially the effectiveness of “spam” as a tool for advertising and promoting these products. This component presents the outcomes resulting from a joint initiative carried out as a pilot study by the United Nations Interregional Crime and Research Institute (UNICRI) and the International Telecommunication Union (ITU).

Cooperation is a key to success in all activities aimed at counteracting this emerging crime. This has been demonstrated by the positive results obtained in terms of regulation, enforcement, and information to health professionals and patients from a variety of successful collaboration schemes, including: the International Medical Products Anti Counterfeiting Task-force (IMPACT) launched in 2006 by the World Health Organization (WHO) and other stakeholders; the Council of Europe/EDQM Committee of experts for minimising health risks posed by counterfeit medicines and similar crimes (CMED) active since 2003; and the more relevant national intersectorial networks of “Single Points Of Contacts” in interested public and private stakeholders. Consequently, while preparing this text, we decided to ask for the cooperation of experts from AIFA/IMPACT Italia, one of the most active national networks in Europe and whose representatives are today coordinating key projects of many of the above initiatives.

We hope this work can drive us towards an insightful approach of the phenomenon and provide with an incentive to create a constructive dialogue that will help us understand the importance to the repression and prevention of this crime.

# **1. COUNTERFEIT MEDICINES: INTRODUCTION**



## 1.1 Defining Counterfeit Medicines

Counterfeit medicines<sup>1</sup> are among the counterfeit products with the greatest potential for harming the health of consumers. The production of pharmaceuticals is heavily regulated in order to ensure product compliance with the highest quality and safety standards. All drugs must undergo clinical trials before being marketed in order to test their efficiency, verify their quality and exclude the potential existence of side effects on patients. These institutional and technical measures are meant to work as a safety valve to guarantee the quality of medicines. Counterfeit products do not respect any of these regulations and requirements. Despite the existence of controls, counterfeit products exist in the market, creating consequences ranging from ineffective therapeutic results to severe health problems or death.

Before considering the various elements of the problem, the term “counterfeit drug” should be defined. According to the 1992 World Health Organization (WHO) definition, a counterfeit drug is a pharmaceutical product “which is deliberately and fraudulently mislabeled with respect to identity and/or source.”<sup>2</sup> The WHO further clarifies that this definition applies to both branded and unbranded medicines, the so-called generics, and it includes products “with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.”<sup>3</sup> This definition stresses out the adulteration, inappropriateness, illegality and by extension, the danger of these products.

The 1992 WHO definition of counterfeit medicines falls within the broader concept of “substandard medicine” but the two categories should not be confused<sup>4</sup>. The category of substandard drugs includes medicines that may present an unintentionally incorrect package or that may have an incorrect quantity or ratio of ingredients. The difference with counterfeit medicines is that substandard medicines may not represent an intentional attempt to deceive the consumer but are the result of inaccurate production processes or transport and storage conditions which may represent a problem in those countries where adequate resources and structures may not be available<sup>5</sup>.

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<sup>1</sup> Based on the World Health Organization (WHO) guidelines on counterfeit medicines, the terms “drug”, “medicine” and “pharmaceutical product” will be used interchangeably in this Report. WHO (1999), *Guidelines for the Development of Measures to Combat Counterfeit Drugs*, Department of Essential Drugs and Other Medicines, p.10

<sup>2</sup> WHO, *General Information on Counterfeit Medicines*. Online. Available HTTP: <http://www.who.int/medicines/services/counterfeit/overview/en/>

<sup>3</sup> Ibid. See also REGGI V. (2007), *Counterfeit Medicines: An Intent to Deceive*, International Journal of Risk & Safety in Medicine, IOS Press, no.19 p.105

<sup>4</sup> “It is important to make a distinction between counterfeit medicines and other kinds of substandard medicines: all counterfeit medicines are substandard because they are manufactured and distributed outside of regulatory control and their composition is unpredictable.” Ibid.

<sup>5</sup> “A 1997 study in a Zambian hospital, for example, found that several HIV antibody assays no longer worked effectively because they had been improperly stored or were past their expiration date.” BATE R. (2008), *Making a Killing. The Deadly Implications of the Counterfeit Drug Trade*, AEI Press, Washington D.C., pp.5-6

The meaning associated with “counterfeit medicines” may also incorporate other cases that -- for various reasons -- are ascribable to the adulteration/replication of a product and/or tampering of the packaging<sup>6</sup>:

- products containing the same active ingredients and the same excipients of the original pharmaceutical agent and that are correctly packaged and labelled but which have been illegally imported into a country;
- products containing the same ingredients of the genuine medicine and with genuine packaging but which contain incorrect amounts of ingredients;
- products which -- despite being identical from an external point of view and have genuine packaging -- do not contain any active ingredient;
- products externally similar to the originals and with genuine packaging but that contain harmful substances instead of the correct active ingredients;
- products with counterfeit packaging and correct amounts of active ingredients;
- products with counterfeit packaging but with different amounts of active ingredients;
- products with counterfeit packaging that contain a different active ingredient or harmful substances;
- products with counterfeit packaging that do not contain active ingredients.

Recent attempts at the international level to better specify the definition of counterfeit medicines showed how complex the problem is in reality. This is what happened for example when in 2008 the International Medical Products Anti-Counterfeiting Task-force (IMPACT)<sup>7</sup> tried to redefine the concept of “counterfeit medicines.” The proposed definition, never officially endorsed at an international level, lengthily yet precisely explained what counterfeiting was and was not, stressing the differences between Intellectual Property Rights (IPRs) related issues and public health protection.

The text was longer than the 1992 one, and included four explicative footnotes:

The term counterfeit medical product describes a product with a false representation (1) of its identity (2) and/or source (3).

This applies to the product, its container or other packaging or labelling information.

Counterfeiting can apply to both branded and generic products.

Counterfeits may include products with correct ingredients/components (4), with wrong ingredients/components, without active ingredients, with incorrect amounts of active ingredients, or with fake packaging.

Violations or disputes concerning patents must not be confused with counterfeiting of medical products. Medical products (whether generic or branded) that are not authorised for marketing in a given country but authorised elsewhere are not considered counterfeit.

Substandard batches of or quality defects or non-compliance with Good Manufacturing Practices/Good Distribution Practices (GMP/GDP) in legitimate medical products must not be confused with counterfeiting.

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<sup>6</sup> HARPER J. GELLIE B. (2006), *Counterfeit Medicines Survey Report*, Council of Europe, p.140

<sup>7</sup> Promoted by the WHO and other stakeholders to counteract the threat represented by counterfeit medicines.

The footnotes clarify that:

- (1) Counterfeiting is done fraudulently and deliberately. The criminal intent and/or careless behaviour shall be considered during the legal procedures for the purposes of sanctions imposed.
- (2) This includes any misleading statement with respect to name, composition, strength, or other elements.
- (3) This includes any misleading statement with respect to manufacturer, country of manufacturing, country of origin, marketing authorisation holder or steps of distribution
- (4) This refers to all components of a medical product.

One of the most important issues in this regard is that the discussion at the international level often considers the word “counterfeit” as strictly related to IPRs issues. In reality the fight against counterfeit medicines goes well beyond the mere protection of IPRs and is a struggle aimed at protecting patients and public health while fighting organised criminals profiting from this crime. However, the controversy over the use of the term “counterfeit” still exists and is a very actual issue. For this reason its use was sometimes avoided or well specified in the new regulations proposed at the international level and aimed at protecting public health.

An example of the first case is the Directive of the European Parliament and of the Council amending Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source (2011), which uses the expression “falsified medicine”, defined as follows.

Any medicinal product with a false representation of:

- a) its identity, including its packaging and labelling, name, composition in respect of an of its components including excipients and strength; and/or
- b) its source, including the manufacturer, country of manufacturing, country of origin, marketing authorisation holder; and/or
- c) its history, including the records and documents relating to the distribution channels used.

An example of the second case is the new Council of Europe “MEDICRIME” Convention (opened for signature on 28 October 2011, but not entered into force yet). The full name of the Convention is *Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health* but the use of the term “counterfeit” has been well explained in the Convention itself as well as in its explanatory report. This situation reflects the long negotiation process and points 38, 39 and 40 of the explanatory report clarify that the term has to be considered with a broader meaning than the mere protection of IPRs. Point 38, in particular, affirms that it encompasses any “false” product as well as the “manufacturing of a false product and passing it off as original.”<sup>8</sup> The Convention focuses on the threat to public health posed by medical products that are either

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<sup>8</sup> The explanatory report can be found online. Available HTTP: <http://conventions.coe.int/Treaty/EN/Reports/Html/Medicrime.htm>

counterfeited or manufactured or distributed without proper authorisation and/or in breach of safety standards. The final text is dealing with measures of criminal law aimed at counteracting “Medicrime” in general, i.e. any illegal activity posing at risk public health by the mean of medical products. The Convention does not address the issue of IPRs other than to say that they shall be applied without prejudice to criminal prosecution of their infringement.

Furthermore, the Convention obliges States Parties to criminalise the following intentional acts:

- The manufacturing of counterfeits.
- The supplying, or offering to supply of, and trafficking in counterfeits.
- The falsification of documents.
- The unauthorised manufacturing or supplying of medicinal products, and the placing on the market of medical devices without them being in compliance with the conformity requirements.

Specifying the different activities related to counterfeiting helps elucidate their differences: medicines counterfeiting may also involve products which are initially genuine but whose packaging is modified in order to show that the product has a higher level of active ingredients than the actual amount, thereby allowing for an increase in sales price. Expired drugs may also be placed within packages that report a later expiration date. Given the various practices related to the modification of packages, more complex classifications have been developed<sup>9</sup>.

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<sup>9</sup> A classification of this type was presented, for example, by Jonathan Harper:

1. “Identical copy”: identical formulation with packaging and labeling that are hard to differentiate from original;
2. “Pure counterfeit”: altered/replaced ingredients with familiar packaging (but either no/different/wrong dose, Active Pharmaceutical Ingredient (API) or excipient);
3. “Hybrid counterfeits”: i.) ‘reuse of components/refilling’, for example genuine containers (ampoules, bottles, vials, syringes) or packaging with substitute or no API; ii.) ‘Illegal relabeling/repackaging’: genuine formulated product falsely repackaged/re-labeled as being from the original manufacturer and intended for the same market or diverted to a different market from that intended by the manufacturer (also includes use of fake pricing labels); includes products wrongly claiming to be an original product (e.g. use of well known name or trademark);
4. “Diversion and illegal trade of genuine medicinal products with genuine packaging and labeling” (whether or not through the Internet);
5. “Unpackaged medicinal products”, for example wholesale/retail of medicinal products without the primary packaging;
6. “Placing a non-authorized medicinal product on the market”;
7. “False documentation”, for example granting a certificate of suitability (CoS) by regulatory authorities without the given company being audited, false CoS, incorrect status on import documentation;
8. “False Marketing Authorization Application (MAA)”: entire marketing applications sold and used; their contents do not have any relationship with the actual operations involved in the manufacture of the API or dosage form and;
9. “Waste/expired product” which includes repackaging and relabeling of expired products.

Harper J. (2006), ‘Counterfeit Medicines and Pharmaceutical Crime in Europe: Invisibility, Biohazard and System Failure’, in *Coincidence or Crisis, Prescription Medicine Counterfeiting*, The Stockholm Network, pp.11-12.

There is yet another type of trafficking in addition to counterfeit drugs which often overlaps with the latter. This is the commerce of false active pharmaceutical ingredients, the raw materials by which a pharmaceutical product is made. This trade poses a very high risk for the health and safety of consumers, also considering that the norms regulating the distribution of active ingredients are -- in several countries' legislation -- not characterised by the same severity as those regulating the production and distribution of finished drugs. This is a high-risk factor as fake active ingredients may be used by legitimate manufacturers in good faith<sup>10</sup>.

As we have seen, a proper definition is an important tool for properly identifying and addressing the problem. Unfortunately, only two countries have a clear legal definition of what is a counterfeit medicine: the Philippines and the United States of America. The definition adopted in the United States of America is based on the concept of trademark, the violation of which defines a pharmaceutical product as counterfeit<sup>11</sup>. The definition used in the Philippines focuses more upon the methods through which the product can be faked or the consumer deceived<sup>12</sup> -- it lists several potential cases and seems more consistent with the

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<sup>10</sup> A classification of criminal practices was also implemented with regards to the counterfeiting of Active Pharmaceutical Ingredients (API). These practices are classified as follows:

1. "API procurement from uncontrolled/non Good Manufacturing Practice (GMP) origin": done by some authorised finished medicinal product (FP) manufacturers because uncontrolled API source is cheaper;
2. "Illegal API relabeling/repackaging": unauthorised API material may also be shipped in containers labeled with the name of a different API;
3. "Ghost API manufacturing plant": API (possibly not produced via the registered manufacturing process) not manufactured by the 'registered producer' sold to a FP Marketing Authorization Holder (MAH) (who may be unaware of this fact, as API label mentions only the authorised manufacturer; a broker/trader may play a crucial role in this practice);
4. "Ghost API supplier": MAH purchases API willingly and knowingly from a different manufacturer from that specified in the marketing authorisation (in this case the manufacturing process will normally differ from that described and authorised in the marketing authorisation);
5. "Paper curtain": API manufacture performed through different process from that specified in the marketing authorisation (a double documentation system may be used at the manufacturing site: one hidden set containing the true data and another set containing faked data that comply with authority requirements and regulations. Such documentation system may even be in place at a site where the API is not manufactured at all);
6. "Authorized facades": manufacturer/trader with approved certificate of suitability and drug master file supplies API material from a large number of unauthorised manufacturers (all labelling mentions only the authorised manufacturer. This set-up is believed to be widespread in terms of API material imported from China and possibly also India. In addition forged certificate of analysis and other forged documents will also be used in such situations);
7. "Illicit intermediate production": unauthorised API materials from obscure sources are blended with the registered API material. Harper J. (2006), cited, pp.12-13

<sup>11</sup> Chapter II of the United States of America Federal Food, Drug and Cosmetics Act states the following: "The term 'counterfeit drugs' means a drug which, or the container or labeling of which, without authorisation, bears the trademark, trade name, other identifying mark, imprint, or device or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed or distributed such a drug and which thereby falsely purports, or is falsely represented, to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor." HARPER J. GELLIE B. (2006) cited, p.140

<sup>12</sup> The Philippines Republic Act "Special Law on Counterfeit Drugs", no. 8203 (1996) states the following: "Counterfeit drug/medicine refers to medicinal products with the correct ingredients but not in the amounts as provided hereunder, wrong ingredients, without active ingredients, with sufficient quantity of active ingredient, which results in the reduction of the drug's safety, efficacy, quality, strength or purity. It is a drug which is

“spirit” of the one proposed in 1992 by the WHO. The lack of specific norms in the majority of countries illustrates the preference of numerous legal systems to classify various types of fake products under a general meaning, namely “counterfeit products.” However, to include all the different types of counterfeit products within this single formulation is limiting, particularly when considering the recent developments and the appearance of replicated products in the market, capable of constituting a serious risk for the health and safety of consumers.

In this regard, the upcoming EU Directive and Council of Europe Convention are about to change this situation at least in some countries of the world and, in the coming years, harmonised definitions of falsified/counterfeit medicines are very likely to enter within the European regulations. A mutually agreed-upon definition of counterfeiting would help disparate organisations and people act in concord to fight this emerging danger. No matter the type of falsification or alteration, the common characteristic of counterfeit pharmaceutical products is that they belong to a category of extremely risky goods and that most potential buyers are unaware of their nature or of the risks posed by their use<sup>13</sup>.

## 1.2 Tracking the Magnitude of the Problem. Counterfeit Medicines as a Global Concern

In a 2007 report on counterfeiting and piracy, the Organization for Economic Cooperation and Development (OECD) provided an interesting list with categories of products that are subject to counterfeiting, including pharmaceuticals. This list, without being exhaustive, included medicines used for treating cancer; HIV; malaria; osteoporosis; diabetes; hypertension; cholesterol; cardiovascular disease; obesity; infectious diseases; Alzheimer's disease; prostate disease; erectile dysfunction; asthma and fungal infections; antibiotics; anti-psychotic products; steroids; anti-inflammatory tablets; pain killers; cough medicines;

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*deliberately and fraudulently mislabeled with respect to identity and/or source or with fake packaging, and can apply to both branded and generic products. It shall also refer to:*

*i. the drug itself or the container or labeling thereof or any part of such drug, container or labeling bearing without authorisation the trademark, trade name or other identification mark or imprint or any likeness to that which is owned or registered in the Bureau of Patent, Trademark and Technology Transfer (BPTTT) in the name of another natural or juridical person;*

*ii. a drug product refilled in containers by unauthorized persons if the legitimate labels or marks are used;*

*iii. an unregistered imported drug product, except drugs brought in the country for personal use as confirmed and justified by accompanying medical records;*

*iv. a drug which contains no amount of or a different active ingredient or less than eighty percent (80%) of the active ingredient it purports to possess as distinguished from an adulterated drug including reduction or loss or efficacy due to expiration.* The Philippines Republic Act “Special Law on Counterfeit Drugs”, no. 8203 (1996) Online. Available HTTP: <http://www.wipo.int/wipolex/en/details.jsp?id=9943>

<sup>13</sup> In this regard the new regulations also explicitly request an effort to conduct and promote information campaigns to raise the general public’s awareness on the dangers of fake medicines. This change of the framework must be taken into account when dealing with communication strategies. (See DI GIORGIO D. ed. (2009) (a)“Counterfeit medicines: risk communication” AIFA/EDQM Publishing)

hormones and vitamins; and treatments for hair and weight loss<sup>14</sup>. Literally all kinds of medicines have been or can be counterfeited.

One of the trickiest aspects in the analysis of counterfeit medicines is their level and ways of spreading. Measuring the magnitude of the phenomenon turns out to be extremely complicated, particularly due to various reasons that have to do with the disposable means to detect the trafficking routes, the number and the identity of those involved in the production and distribution processes, and the difficulty in systematising and coordinating the information from the various stakeholders in charge of keeping, collecting and analysing data. This is almost entirely an underground problem and its measurement is very hard, particularly when taking into consideration the difficulties that the authorities and the experts often encounter in distinguishing a counterfeit medicine from an original one. Further problems derive from the ineffective operational capacity of the national regulatory authorities that often do not possess the necessary resources (both economic and human) to identify, collect and analyse data.

Some statistics elaborated by various national and international organisations have tried to propose figures on the exact percentage of counterfeit medicines within the worldwide pharmaceutical market. Their estimations reflect both the magnitude and the volatility of the problem: percentages of counterfeit medicines in different national pharmaceutical markets vary from as high as 50 per cent to as low as 1 per cent with other estimates showing 40 per cent, 30 per cent, 17 per cent, 13 per cent, and 10 per cent of the market<sup>15</sup>. In general, higher percentages refer to less developed countries and economies in transition whereas lower percentages refer to the developed countries. Therefore, it is essential to take into account geographical, economic, legal and social criteria in order to interpret these percentages.

Production and distribution of counterfeit medicines is less spread in more developed countries due to a combination of enhanced legislation, stronger institutions and a more efficient regulatory control. According to the WHO, countries such as the United States of America, Australia, Canada, Japan, New Zealand and those within the European Union (EU) have a very low proportion of counterfeit medicines of no more than 1 per cent of market value<sup>16</sup>. However, the fact that a considerable amount of counterfeit drugs cases are declared on an annual basis by developed countries proves that this problem still affects, to a greater or a lesser extent, both developed and less developed countries. Case studies can illuminate what statistics cannot. An unpublished investigation performed by the Member States of the EU revealed that in the period 2002-2007, 27 cases of counterfeit medicines were recorded in legal distribution chains, while at least 170 cases were recorded in illegal chains<sup>17</sup>. Nevertheless, the situation is more dramatic in less developed countries due to fragile economies, widespread poverty, lack of regulation, difficulties in controlling the system, as

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<sup>14</sup> OECD (2007), *The Economic Impact of Counterfeiting and Piracy*, Directorate for Science, Technology and Industry, Committee on Industry, Innovation and Entrepreneurship, 4 June, p.10

<sup>15</sup> WHO (2006) (a), *Combating Counterfeit Drugs: A Concept Paper for Effective International Co-operation*, Health Technology and Pharmaceuticals Background Document, 27 January, p.3. Online. Available HTTP: <http://www.who.int/medicines/events/FINALBACKPAPER.pdf>

<sup>16</sup> IMPACT (2006), *Counterfeit Medicines: An Update on Estimates*, 15 November. Online. Available HTTP: <http://www.who.int/medicines/services/counterfeit/impact/TheNewEstimatesCounterfeit.pdf>

<sup>17</sup> AEGATE; *Facts and Figures*. Online. Available HTTP: [www.aegate.com/news/facts-and-figures.html](http://www.aegate.com/news/facts-and-figures.html)

well as the difficulties in furthering and enforcing strong legislative measures. Mainly in Africa and partially in Asia and in Latin America, counterfeit medicines' sale ranges from 10 per cent to more than 30 per cent of the national legitimate markets. In the transitional economies of many of the former Soviet Republics there is an estimate of above 20 per cent of market value<sup>18</sup>.

Some data related to different areas of the world may be useful to appreciate the spread of this phenomenon. According to WHO estimations, counterfeit medicines would represent approximately 10 per cent of the entire amount of medicines worldwide. Pfizer estimates that counterfeit Viagra alone causes a loss of 2 billion USD in sales. According to the Centre for Medicine in the Public Interest, based in the United States of America, counterfeit drug sales would generate 75 billion USD globally in 2010, an increase of 92 per cent with respect to 2005. The size of the problem is also confirmed by statistics gathered and elaborated by national health and safety regulatory authorities. Just after a case of fake heparin in 2008, the United States Food and Drug Administration (FDA) issued statistics describing an 800 per cent increase in the incidence of fake drugs within the period 2000-2006. The DG Taxation and Customs Union of the European Commission (TAXUD) announced on 16 December 2008 the results of the MEDI-FAKE action, a two-month operation across the external borders of the EU implemented by the customs services of all the Member States and coordinated by TAXUD: the heads of the action reported tremendous results, with more than 34 million illegal pills<sup>19</sup> seized within these two months, ranging from antibiotics, anti-cancer, anti-malaria and anti-cholesterol medicines to painkillers, and Viagra<sup>20</sup>.

In the Russian Federation, the Federal Service for Health Sphere Supervision (FSHSS) reported that in 2006, 10 per cent of all drugs on the Russian market were counterfeit. However, and according to other estimates, these rates climb up to 20 per cent as there is a growing problem of look-a-like drugs in the Russian market. The situation seems to be even worse in some countries of the ex-Soviet Union. In Ukraine for instance, it is estimated that 40 per cent of the drugs circulating in the country's market may be counterfeit<sup>21</sup>.

According to the Peru's Association of Pharmaceutical Laboratories (ALAFARPE), the sale of counterfeit drugs in Peru has risen from an estimated 40 million USD in 2002 to a 66 million USD in 2006. The General Directorate of Medicines, Supplies and Drugs (DIGEMID) of the Department of Health (MINSA) in Peru seized around 460,000 adulterated and expired

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<sup>18</sup> IMPACT (2006), cited

<sup>19</sup> European Commission (2008), *Customs: Millions of Illegal Medicines Stopped by MEDI-FAKE Action*, Press release, ref.P/08/1980, Brussels, 16 December Online. Available HTTP: <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/08/1980&format=HTML&aged=0&language=en&guiLanguage=en>

<sup>20</sup> TAXUD (2008), *Commission Initiatives for Fighting Counterfeit* (last update 19 December 2008). Online. Available HTTP:

[http://ec.europa.eu/taxation\\_customs/customs/customs\\_controls/counterfeit\\_piracy/commission\\_initiatives/index\\_en.htm](http://ec.europa.eu/taxation_customs/customs/customs_controls/counterfeit_piracy/commission_initiatives/index_en.htm)

<sup>21</sup> The News Today (2006), *Fake Medicines Are Everywhere. On a Daily Basis Many Unknowingly Risk Death*, 11 August. Online. Available HTTP:

<http://www.thenewstoday.info/2006/08/11/fake.medicines.are.everywhere.html>

medicines in 2005 alone<sup>22</sup>. In 2005, the Dominican Republic's Public Health Department reported that 50 per cent of pharmacies in the Dominican Republic operated illegally and 10 per cent of the medicines that arrived in the country were fakes. Some of the medicines found had expired over 10 years before<sup>23</sup>. In Kenya, a random survey by the National Quality Control Laboratories (NQCL) and the Pharmacy and Poisons Board found that almost 30 per cent of the drugs were counterfeit with some of them containing chalk powder and water but being marketed as original products. According to figures from the Kenyan Association of Pharmaceutical Industry, counterfeit pharmaceutical products would account for approximately 130 million USD annually in sales in the country<sup>24</sup>. In 2004, the Ebony State Task Force on Counterfeit and Fake Drugs in Nigeria reported that approximately 48 per cent of various goods and drugs imported into the country were substandard or counterfeit<sup>25</sup>.

Another fact that demonstrates the widespread dimension of the phenomenon is the kind of drugs that can be fraudulently produced and traded. Experience on the phenomenon has shown that there is the possibility to counterfeit every existing medicine, regardless of its kind, composition, form and purpose. What is of great concern is that counterfeiting has found its way into critical drug classes and targets specific consumers' categories by identifying perfectly each market needs and demands. In this case, the market and the target group of consumers for whom the medicines are intended are of great importance<sup>26</sup>. In this light, lifestyle medicines -- such as pharmaceutical products to improve male sexual capacity, substances meant for weight loss, anti-aging products, and steroids -- are prevalent in wealthier countries' markets. In less developed countries counterfeiters are more oriented towards life-saving drugs meant to treat serious diseases such as HIV, malaria and tuberculosis. Nevertheless this does not exclude the presence in developed countries of drugs such as anti-cancer treatments, antibiotics, cholesterol and blood pressure lowering substances, as well as basic painkillers. The differences in counterfeit products produced and distributed within the various national and regional markets reflect a real "marketing strategy" adopted by counterfeiters<sup>27</sup>.

### **1.3 Taking Advantage of the Loopholes: the Introduction of Counterfeit Medicines in the Legitimate Distribution Chain**

As it has already been mentioned, the diffusion of counterfeit medicines and their tremendous consequences are not limited to less developed countries. It is possible to identify clear market strategies operated by counterfeiters, especially in reference to the distribution

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<sup>22</sup> WHO (2006) (b), *Counterfeit Medicines*, Fact sheet no. 275 (last revised in January 2010). Online. Available HTTP: <http://www.who.int/mediacentre/factsheets/fs275/en/>

<sup>23</sup> Ibid.

<sup>24</sup> Ibid.

<sup>25</sup> Ibid.

<sup>26</sup> UNICRI (2007), *Counterfeiting: A Global Spread, a Global Threat*, Turin, p.67

<sup>27</sup> Ibid.

of different categories of medicines in developed and less developed countries. This market differentiation follows the higher demand for specific pharmaceutical products that exist in a given socio-economic context and shows the high level of organisation and the planning capacities owned by the managers of this trade.

Before starting to consider the production-distribution network it is important to avoid the generalisation that it is only Asian countries that are the source of the problem and are flooding other regions of the world. Counterfeit medicines are a global plague potentially affecting every country in the world. In general terms, their production and distribution create a huge web linking together developed and less developed countries. The entire distribution process suffers from a lack of regulation that allows for the creation of a series of “black spots” where unscrupulous criminals may infiltrate their products within the legal supply chain. Regardless of any consideration related to the places where fake medicines are produced, it is important to note that Asian countries are predominantly among the first victims of this problem, as demonstrated by the estimation that 192,000 people are killed in China each year by counterfeit medicines<sup>28</sup>.

The production/manufacturing process of legitimate medicines is relatively complex. This process may, however, be subdivided into two main phases: the primary production phase and the secondary production phase<sup>29</sup>. The first essentially refers to the production of active ingredients which constitute the drug and which allow the desired therapeutic effects to be attained. Secondary production activity refers to the manufacturing of the final product by combining the active ingredients with various excipients that allow the human body to properly absorb these ingredients.

Once the final product is attained, the distribution phase is initiated. Two phases may also be identified here: primary and secondary distribution. The first is entrusted to large wholesale area distributors which receive the product directly from manufacturers and distribute it to retail distributors<sup>30</sup> or directly to pharmacies. The producers themselves may also sell directly to retailers. In this case, the product is intended for exclusive sale to the patient and must not be re-introduced into the distribution chain. The producers may also choose to allocate a part of the production for charitable purposes.

Secondary distribution utilises intermediary parties operating between the major distributors and retailers, often referred to as “brokers.” These distributors vary in size and do not distribute the entire range of products of a pharmaceutical company but operate by acquiring certain products from the major distributors or from sources other than the producer. The products are then re-sold to other large distributors or retailers. These operations are made possible by various circumstances that could potentially benefit the final

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<sup>28</sup> COCKBURN R. et al. (2005), 'The Global Threat of Counterfeit Drugs: Why Industry and Governments Must Communicate the Dangers', in *PLoS Medicine*, issue of April. Online. Available HTTP: <http://www.plosmedicine.org/article/info:doi%2F10.1371%2Fjournal.pmed.0020100>

<sup>29</sup> VANDER BEKEN, T. (ed.) (2007), *The European Pharmaceutical Sector and Crime Vulnerabilities*, Institute for International Research on Criminal Policy (IRCP), pp.36-37

<sup>30</sup> For example, there are three major area distributors in the United States of America; 90 per cent of primary distribution passes through them. United States Food and Drug Administration (2003), *Interim Report*, Counterfeit Drug Task Force, p.7

consumer since they may lead to lower retail prices. For instance, intermediary producers acquire drugs at reduced prices derived from surpluses in production or storage on the part of producers or large distributors and pharmacies respectively -- and therefore they are capable of re-selling the products at lower prices. Their small size allows them to exploit changes in the market and to concentrate on specific drugs that exhibit high demand at specific times and in specific areas; examples include medicines that are used occasionally for targeted vaccination campaigns. Their size grants them a certain flexibility and capacity to respond to changes in demand, thereby allowing them to compensate for warehouse shortages affecting pharmacies or the major distributors in cases of rapid and unexpected increases in the demand for a specific drug<sup>31</sup>. Finally, the existence of significant differences in the sale prices of drugs across different geographical areas creates opportunities for parallel importers; the latter exploit these differences and generate profits by acquiring the product in countries where the price is lower and re-selling it in countries where the sale price is higher.

The problem arises when original pharmaceutical products cross the borders of various countries and numerous importers, retailers and distributors are involved. The repackaging process that takes place throughout the distribution and shipment procedure offers large possibilities of introducing counterfeit medicines to the legal supply channels. This continuous change-hands procedure may be followed to mask counterfeit medicines' provenance, making tracing almost impossible and leaving the question of who makes the counterfeit drugs difficult to answer. The repackaging of medicines and the replacement of prescription instructions are essential in order to ensure that the package and instructions relative to a drug are comprehensible to the final patients and comply with the existing provisions of the legal system of the country where the drugs will be sold. This process may be implemented by the importers themselves -- if granted a special licence -- or by specialised parties authorised to perform such services. This phase is not, however, free from risk. The original package designed by the producer or by a party delegated by the latter, not only fulfills a descriptive function but also guarantees the originality of the drug through anti-counterfeiting features within the packages or labelling. Once the product is opened and repackaged, however, these features may become useless. In addition, the serial numbers of medicines -- which are very useful in the case of a batch recall -- are reprinted, creating the possibility for mistakes in the reprinting phase.

There are additional complications linked to repackaging. Despite the fact that the original packages should be destroyed once they are replaced, they may be re-used by counterfeiters in order to insert non-original products, thereby allowing easier marketing of the fake products. Repackaging may also create several opportunities linked to the adulteration of boxes. Two very common practices of falsification of packages have to do with: 1) the quantity of the Active Pharmaceutical Ingredients (API) -- usually the greater the quantity of active ingredients, the higher the sale price of the drug -- and 2) the change of the expiration date which allows the sale of already expired products. The last two cases pose tangible risks for the distribution chain.

The potential utilisation of rejected hospital material should also be noted. This process is facilitated in cases where the drug package does not include anti-counterfeiting features.

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<sup>31</sup> United States Food and Drug Administration (2003), cited pp.7-8

For instance, cases have been reported in which counterfeiters obtained rejected packages from clinics or hospitals and re-used them by modifying their expiration dates. If the rejected packages still contain the drug it may be marketed again, otherwise the package may serve as a container for a counterfeit product.

The legal framework within which the various players of the distribution chain operate is also interesting to analyse. These players typically operate in accordance with contractual agreements stipulated with the producer as well as licences granted by the legal system. The major distributors operate in compliance with a contract stipulated with the producer (which generally provides for the geographical area of their operations) as well as a licence granted by the national legal system (which outlines the legal framework and the services that the operator is authorised to perform). The licence may also grant authorisation for the distributor to repackage the product, if required. Specific repackaging licences may also be granted to specialised operators that exclusively offer this type of service.

Intermediary and parallel distributors are special entities that operate at the secondary distribution level. Parallel distributors require a licence in order to operate legitimately but do not have any form of agreement with the producer. This is similar to intermediary distributors, who also do not have a stipulated agreement with the producer<sup>32</sup>. Intermediary distributors exploit rapid changes in the demand for a drug as well as incorrect storage levels of goods and contribute to the intensification of exchanges between the various parties; as a result, the drug may be transferred multiple times before reaching the patient. Since these entities operate without commercial agreements with the producer and their business is conducted within the secondary distribution chain, they can acquire drugs at reduced prices in order to re-sell them where demand is higher, thereby attaining a greater profit. The existence of commercial operators that are not subject to specific commercial agreements with the manufacturer adds an element of uncertainty to the system. This element is worsened by various factors. One factor is that intermediary distributors -- operating at the level of the secondary market -- do not receive the goods directly from the producer but simply re-distribute the goods amongst various market players. In reality, it is not possible to know the supply sources of these intermediary distributors and this poses a significant element of risk. Given that these parties are directly involved in the distribution of significant amounts of products, an imprudent purchase on their part from suppliers that are “low cost” but not “safe” could lead to the penetration of counterfeit drugs within the distribution chain. The ramification of the distribution chain and the various transfers of the products would then render it literally impossible to identify the real origin of the medicines in question.

The upcoming Directive of the European Parliament and of the Council (2011), amended Directive 2001/83/EC to include a section on preventing medicinal products falsified in relation to their identity, history or source from entering the legal supply chain. The forthcoming Directive tackles this complexity by defining clear rules for all supply chain operations and creating a framework for controlling legal distribution of medicines. This framework includes enforcing Good Manufacturing Practices in API manufacturing and monitoring actions of brokers and other parties who play no part in the drug’s manufacture. The EU Commission chose this approach because counterfeit products may be inserted into

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<sup>32</sup> HARPER J. (2006), cited, p.19

the distribution chain in multiple ways and at almost all levels. The complexity of the distribution process, potential illegal behaviours, the scarce and rarely implemented controls in the distribution and repackaging phases, and the existence of transportation documents that are easily modified are a few of the factors which weaken the system. The effect of parallel trade and the use of the Internet as a distribution channel also create uncertainties. The excessive complexity of the distribution chain may create vulnerabilities that facilitate the entry of unauthorised or counterfeit products. Due to this complexity, the monitoring of drug movements during their journey from the producer to the patient becomes very difficult. The larger the number of brokers within the distribution chain, the greater the difficulty in monitoring the origin of the product as well as identifying its commercial route.

### ***1.3.1 Diversion***

The term diversion refers to those cases in which a product designed for a specific market or function is re-marketed in violation of the producer's instructions, for example, deliveries of drugs to humanitarian organisations or the supply of free samples to hospitals.

This phenomenon occurs in two forms: it may be limited to the national territory of a country or it may become international in scope. In the first case -- and with regards to pharmaceutical products -- the phenomenon may involve promotional samples for hospitals or clinics, or drugs that are allocated for humanitarian purposes. In both cases, through diversion the products will not reach their intended destination but will be marketed at full price. The motive underlying these operations is the difference in purchase price between a product that is marketed at full price and one that is allocated for specific purposes. This difference allows for the attainment of significant profits.

The diversion implemented on an international scale is driven by the same economic motive. Two primary categories of illegal behaviour -- on the part of entities acquiring drugs directly from the producer -- can be identified within an international diversion. 1) The entity acquires goods which are intended for a market where purchasing power is relatively low in order to sell them in markets where purchasing power is higher; and as a result, the higher the sales price of the good itself, the greater the amount of attainable profit will be. 2) The entity fraudulently acquires the products from the producer, declaring an intention to deliver the drugs for humanitarian purposes but in reality it re-markets the drugs after acquiring them at low cost. These international exchanges are implemented through multiple transfers and involve frequent repackaging of the product, thereby providing opportunities for counterfeit products to penetrate the legal distribution chain. The multiple transfers and repackaging also make the authentication phase very difficult for retailers. Furthermore, this task can be made more complicated by the practice of "layering", which is the mixing in one consignment of original, diverted and counterfeit products. The practice of diversion is strongly linked to the counterfeiting phenomenon given that it facilitates the latter, and the numerous intermediaries who acquire diverted products are not capable of identifying the actual source of the product.

### ***1.3.2 Parallel Trading***

Parallel trading is a legal commercial practice in the EU; however there is an ongoing debate on its actual effect on the penetration of counterfeit goods within the market. Nevertheless, it is necessary to consider several possible ways in which this practice may facilitate counterfeit goods entering the market. These considerations relate essentially to the number of commercial operators through which the product is distributed; the number of “transfers” within the distribution chain and; the number of repackaging opportunities. All these phases may increase and, in the absence of a specific regulatory framework, may facilitate the entry of counterfeit products within the distribution system. With regards to the European regulatory framework, a legislative outline has been established<sup>33</sup> but a complete and harmonious regulation of the subject within EU member states has not yet been attained, even if this is one of the goals of the 2011 Amendment of the 2001/83 EU Directive, also referred to as the *EU pharmaceutical code*.

Parallel trading involves a drug that is sold in a given country, which after having already moved through the various stages of the ordinary distribution chain, is acquired again by the major distributors and is entered into the parallel distribution chain. The product is then transferred to a new and more lucrative market by means of parallel intermediaries/distributors. The times a pharmaceutical product is transferred can be numerous. It is estimated that, on average, a drug which is entered into the parallel market may be subject to 20-30 intermediary transactions.

This extension of the distribution chain creates a problem of verifiability with respect to the source from which each intermediary receives the product. There is no mechanism for verifying the licences of parallel importers; similarly, there is no obligation for the parties involved in the parallel distribution process to record product batch identification numbers. Generally, a proof of authorisation to trade the products is requested; this proof may consist of a licence that is issued at national level and which might be sent by fax from the potential seller to the parallel distributor. The latter will not be able, however, to verify the authenticity of the document by appealing to its own national authorities. If this element of uncertainty is multiplied by the number of transfer points within the parallel distribution chain it obviously becomes impossible to monitor the integrity of the chain and numerous operators are able to act almost anonymously.

This factor is also linked to a lack of international standards requiring the recording of drug batch identification numbers. As a result, it is basically impossible to trace the trade route and origin of a marketed drug by the time it has reached the final consumer. This may

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<sup>33</sup> The basis of the legislative framework is the respect of the free movement of goods within the EU, according to art. 28, 29, and 30 of the Treaty establishing the European Communities. Several sentences of the Court of Justice of the European Communities subsequently specified the characteristics of the legitimate parallel trade regime in the EU (as the principle of *Community wide exhaustion*). Relevant Court decisions in this respect may be found in the cases: *Silhouette v. Hartlauer*, *Hoffmann-La Roche v. Centrafarm*, *Bristol-Myers Squibb and Others v. Paranova*.

create risks for the health of patients even in cases that do not involve counterfeit products. It would be impossible for a pharmaceutical company to recall a batch of medicines that, for whatever reason, should not reach the consumer, because, during the repackaging phase, the batch identification number may have been removed or modified. A change in the country of sale of the drug necessarily implies that the package and prescription instructions will be modified or replaced. The consequence of this requirement is that the parallel importers themselves are often authorised to directly implement the repackaging phase, or alternatively it may be undertaken by another party at any time before the entry into the new market. The repackaging phase can therefore also occur in the exporting country or within one of the countries of transit (where the qualitative standards may be very different from those in the country of final destination).

By exploiting these weak points, a dishonest operator could insert a counterfeit drug into the distribution chain with relative ease, making traceability virtually impossible. These activities are strongly favoured by the external similarity of current counterfeit drugs with respect to the original medicines, thereby making identification difficult even for specialists.

## **1.4 The Victims of Counterfeit Medicines: Patients and Consumers**

The majority of consumers would not voluntarily acquire a counterfeit medical product. The buyers of these products are driven by a diametrically opposed rationale, i.e. they wish to improve their health and not expose themselves to risks or further health problems. Unfortunately, the buyer of a counterfeit drug is not only deceived into acquiring a product which they did not intend to buy but is also exposed to serious risks.

All kinds of medicines can be counterfeited -- branded, generic, prescription-only, over-the-counter <sup>34</sup> drugs -- regardless of whether they were destined to treat a simple headache or serious illnesses such as heart diseases, cancer or malaria. As they are not destined to treat patients but to generate economic gains for their producers, counterfeit medicines are hazardous substances that may have serious impact on the human organism. As efficiency and quality are the last things that matter for drugs counterfeiters, the “final products” can cause serious harm and side effects to unsuspecting consumers. The steady increase in the quantities seized every year by national customs services is a worrying sign that produced amounts of counterfeit medicines are growing, or much spread, that the types of medicines copied are increasing, and that the sophistication of the methods of production and distribution is improving. The message from these assumptions is clear: this danger is present more than ever. Seizures made at the borders checkpoints just before or after the import or the export of thousands of parcels containing counterfeit medicines; verification controls of falsified documents guaranteeing the “authenticity” of doubtful medicines; and

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<sup>34</sup> *Over-the-counter* are called the drugs to which patients can have access without medical prescription. Over-the-counter comprises both branded and generic medicines.

inspections carried out in places suspected of being “laboratories” of counterfeit medicines, seem not to be enough. At the same time, cases of death and other serious damages related to the use of counterfeit medicines are lending credit to the gravity of the problem.

Even when it comes to medicines whose actual ingredients match those on the label, their production, distribution and storage may not comply with the standards set by the drug regulatory authority of the concerned country. There will be no real batch record and any associated defects and inadequacies or adverse reactions will not be easily recognised and monitored, leading also to the impossibility of performing an effective product recall<sup>35</sup>. This means that by the time there is an alert for a specific drug which has turned out to be counterfeit after having been introduced to the market, it is very hard for the competent authorities to detect and seize all the products, as these will have already been scattered in various distribution points and sold. This also implies that it will be particularly hard to establish the links between the medicine in question and the side effects reported subsequently by the victims<sup>36</sup>.

As far as side effects are concerned, it is possible that in some cases they are similar to those of original medicines. However, in the case of counterfeit medicines, the fact that there is no compliance with the officially approved standards and rules of production and packaging, considerably increases the incidence of undesirable and side effects on patients’ health, starting from therapeutic failures.

Side effects can be classified into six main categories with respect to the presence or not -- and if so, to what degree -- of APIs (for example, under-dosed antibiotics present bigger chances for the consumers to develop drug resistance with serious repercussions while total absence of APIs increases the mortality incidence due to complete therapeutic failure); composition-related problems (difference between the APIs contained in the drug and the one illustrated on the package which will undoubtedly lead to under- or over-dose as the type, combination and/or quantity of the substance indicated on the package does not reflect the reality); the presence of toxic, chemical or completely inappropriate microbiological substances that are dangerous for the human organism; stability-related problems that are related to the abusive extension of the expiration date of a medicine which can lead to highly toxic products or to products with considerably decreased therapeutic capacity; excipients’ bioavailability-related problems due to an inefficient control of fabrication or miscalculation of the effects of the mixture of the excipients with the APIs and finally; problems generated by the interaction between the medicines and its container because of the inferior quality of the latter<sup>37</sup>.

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<sup>35</sup> WHO (1999), cited, p.13

<sup>36</sup> LEGRIS C. (2005), *La détection des médicaments contrefaits par investigation de leur authenticité. Etude pilote sur le marché pharmaceutique illicite de Côte d’Ivoire*, Ph.D Thesis defended on 16 December, University Henri Poincaré- Nancy I, School of Pharmacy, pp.35-36. Online. Available HTTP : [http://www.remed.org/these\\_legris](http://www.remed.org/these_legris)

<sup>37</sup> For a more thorough analysis of the side effects that can be generated by the use of counterfeit medicines. LEGRIS C., cited, pp.36-39

Counterfeit antimicrobial drugs are a case that draws particular attention. The WHO estimates that 5 per cent of all antibiotics sold globally are fakes<sup>38</sup>. Admittedly, counterfeit drugs are not the only reason for antimicrobial resistance as the latter can be the result of misuse, improper diagnosis or health personnel's malpractice. However, reported cases of counterfeit or substandard antibiotics show that there is a high incidence of counterfeiting of these drugs. The bacterial infections, which are mainly responsible for human diseases, are also those in which microbial resistance is most evident<sup>39</sup>. When infections become resistant to cheap and effective first-choice or first-line antimicrobials because of counterfeit products, the patient has to receive treatments of second or third-line drugs which are much more expensive and have stronger effects on the human organism. Similarly to cases of counterfeiting of other categories of medicines, prolonged therapeutic failures lead to extended illnesses and increase the risk of death.

Whatever their composition is, counterfeit medicines undoubtedly have a high potential to compromise people's lives as they are nothing more than random cocktails of hazardous substances disregarding all the regulation measures and compliance with the set standards which are indispensable conditions to guarantee the safety of a medicine. It is for these reasons that consumers who are conscious buyers of these products have to realise that by purchasing counterfeit medicines they are not only and not just losing their money but they are putting their lives at risk<sup>40</sup>.

### **1.4.1 Cases**

As the WHO affirmed, while in some countries counterfeit medicines are only "a rare occurrence, in others they are an everyday reality."<sup>41</sup> It is extremely difficult to conduct thorough research with detailed registration and classification of cases in which deaths or serious adverse effects were caused by the consumption of counterfeit pharmaceuticals. This is somewhat regrettable as data such as this would be extremely useful for the implementation of comparative studies and analyses (types of bogus medicines that have been consumed, kinds of substances that have been counterfeited, methods of distribution). The reason for such a gap in information has a great deal to do with the reliability and the verification of the sources or in some cases, with the shortage of means at the disposal of national authorities or international institutions. A common source of this kind of information to date has been the media, although such data has to be carefully considered as it is not always complete and precise. The cases that follow are some of the few confirmed examples

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<sup>38</sup> WHO (2000), *Overcoming Antimicrobial Resistance: WHO Report on Infectious Diseases*. Online. Available HTTP: <http://www.who.int/infectious-disease-report/2000/index.html>

<sup>39</sup> International Council of Nurses (2005), *Nurses for Patient Safety: Targeting Counterfeit and Substandard Medicines*, Information and Action Toolkit, p.18

<sup>40</sup> Remarks made by Dr. ZUCKER H., Assistant Director-General for Health Technology and Pharmaceutical Products, in WHO (2006), *L'OMS et ses partenaires accélèrent la lutte contre les médicaments contrefaits*, press release, 15 November. Online. Available HTTP: <http://www.who.int/mediacentre/news/releases/2006/pr69/fr/index.html>

<sup>41</sup> WHO (2006) (b), cited.

which clearly depict the risks consumers run with regards to counterfeit drugs, as well as the fatal consequences of the phenomenon.

In Yemen a study indicated that between 37 per cent and 50 per cent of all medicines sold at a national level are ineffective or expired drugs, resulting from smuggling activities in the Horn of Africa, India and China. A major issue arose in 2008 when it was found that in Aden about 4,000 local women were about to take capsules for treating fertility issues. The capsules turned out to be extremely dangerous as they contained inappropriate ingredients which could have potentially serious side effects for mothers' health and their ability to bear children<sup>42</sup>.

In May 2008, pharmacies in Hong Kong (China) were closed down after it had been verified they were selling counterfeit male impotency drugs. As a result of taking these drugs, 51 people had to be admitted to hospital -- with two of these patients dying and another two falling into a coma. The drugs were found to contain large doses of glibenclamide, a blood sugar reducing drug found in diabetes medication<sup>43</sup>.

In May 2008, the United States FDA was alerted regarding a pharmaceutical counterfeiting case which revealed that more than 150 people died after having taken fake heparin<sup>44</sup>. The source of the contaminant -- oversulfated chondroitin sulphate -- was traced back to a Chinese supplier of the drug manufacturer.

In 2007, Taiwan's Department of Health announced that, after controls carried out between 2005 and 2007 in 151 various weight loss and herbal-based medicines made in China, 139 (92 per cent) of them failed tests as they were found containing illegal substances<sup>45</sup>.

In 2006, a Canadian woman died from metal poisoning after having ingested a contaminated powerful hypnotic drug not legally permitted in Canada. The autopsy showed "significantly high levels" of metals in her liver, including 15 times the normal level of aluminium. The woman had purchased the medicine via the Internet<sup>46</sup>.

In 2006, over 100 people died in Panama<sup>47</sup> and many more were hospitalised after having consumed contaminated cough syrup, antihistamine tablets, calamine lotion and rash

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<sup>42</sup> Counterfeiting confidential (2008), 'Raids Underline Size of Counterfeit Medicine Market', July, cited in *Business Action to Stop Counterfeit And Piracy (BASCAP) case study database*. Online. Available HTTP: <http://www.icc-ccs.co.uk/bascap/article.php?articleid=780>

<sup>43</sup> The Standard (2008), 'Counterfeit Viagra Vendors May Face Manslaughter Charges', 21 May, cited in *BASCAP case study database*. Online. Available HTTP: <http://www.icc-ccs.co.uk/bascap/article.php?articleid=794>

<sup>44</sup> The Lancet (2008), *Combating Counterfeit Drugs*, (editorial), vol. 371, no. 9624, 10 May

<sup>45</sup> Counterfeiting Confidential (2007), '92% Chinese-made Medicines Contain Banned Drugs', November, cited in *BASCAP case study database*. Online. Available HTTP: <http://www.icc-ccs.co.uk/bascap/article.php?articleid=670>

<sup>46</sup> Counterfeiting Confidential (2007), 'Internet Pills Kill Woman', August, cited in *BASCAP case study database*. Online. Available HTTP: <http://www.icc-ccs.co.uk/bascap/article.php?articleid=684>

<sup>47</sup> EuroPharm Forum (2009), *Framework for a Guide on Counterfeit Medicines for Pharmacists*, May. Online. Available HTTP: [www.europharmforum.org/file/11800](http://www.europharmforum.org/file/11800)

ointment. The tainted medicines all contained diethylene glycol, a substance used to keep glue and cosmetics moist<sup>48</sup>.

In 2000, at least 30 deaths were reported in Cambodia due to fake malaria medicines. The fake drugs were labelled as Mefloquine and Artesunate, which are powerful anti-malaria medicines. The victims were generally of low economic standing, and had resorted to purchasing the cheap drugs in order to save money<sup>49</sup>.

Taking into consideration the geographical magnitude of the counterfeit medicine problem, as well as the high level of danger created by such drugs, it becomes obvious why the WHO qualifies the deliberate production and distribution of counterfeit medicines as a “criminal activity.” Such an argument, though, is often in contradiction with the lack of enforcement and application of the foreseen prevention and repression measures which, sometimes, literally paralyses the effectiveness of the legislation. Moreover, despite the fact that sanctions for the counterfeiting of medicines are normally stricter than those foreseen for other types of counterfeit products, counterfeiters of pharmaceuticals take advantage of existing loopholes within the criminal law and the laws on the protection of Intellectual Property

#### ***1.4.2 The Option between Communication and Non-Communication: Dangers at the Social Level***

At the social level, counterfeit medicines have some particularities which, if mishandled, can have serious negative effects. Being a very sensitive issue it is not always easy to communicate the proper messages in the right way. Health ministries and public authorities that deal with production, regulation, control and distribution-related issues are sometimes reluctant to disseminate extended information to the public. The justification for this behaviour usually lies in the fear that this communication would create great confusion and generalised mistrust towards the safety of the available medicines in the market or on the capacity of the State to effectively tackle the problem.

Public administrations and private stakeholders had to consider how to properly warn patients about the immediate dangers related to counterfeiting in their market and counterfeit medicines in general. In other words, they had to plan reactive and proactive risk communication exercises.

The proactive information (“awareness raising”) and the reactive communication protocol used for new cases of suspected or verified counterfeit medicines are closely related.

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<sup>48</sup> Counterfeiting Intelligence Bureau (2006), ‘Many killed in Panama Due to Fake Pharmaceuticals’, 21 November, cited in *BASCAP case study database*. Online. Available HTTP: <http://www.icc-ccs.co.uk/bascap/article.php?articleid=622>

<sup>49</sup> Counterfeiting Confidential (2000), ‘Fake Malaria Drugs Kill Dozens in Cambodia’, June, cited in *BASCAP case study database*. Online. Available HTTP: <http://www.icc-ccs.co.uk/bascap/article.php?articleid=385>

Both aim to provide information on counterfeit medicines and the associated health risks to consumers.<sup>50</sup>

There are a few differences between the two approaches. The communication protocol for reactive communication defines when, how and who to inform of suspect or verified counterfeit medicines. Its intended use is to follow-up and react after a counterfeit medicine has been detected on the market. The pro-active information aims at making the general public, patients, professionals and partners in the pharmaceutical distribution chain aware of counterfeit medicines before they are detected, contributing to the prevention of harm and future cases.

Appropriate strategies of communication, response/alert mechanisms as well as means and infrastructures can generate this information. In this case, the competent national authorities, although willing, either do not have the necessary means in logistics and/or human resources at their disposal or are simply not able to mobilise existing resources in a quick and effective way. This situation may be more evident in less developed countries although such gaps in organisation and coordination of public information can also be noticed in developed countries. In this regards, law enforcers would certainly benefit from dedicated training/awareness activities, information exercises (also included in publications<sup>51</sup>) as well as dedicated workshops to acquire information and a better understanding on the involvement of organised crime in the issue of counterfeit medicines.

Sometimes the pharmaceutical companies themselves are reluctant to communicate information on copies of their products that have been detected within the distribution chain as they fear consumers will turn down the products of the company. Notwithstanding in which manner parsimonious communication can be justified, the result is that consumers remain unformed about the magnitude of the phenomenon and without proper awareness of the current situation. What really matters is the way and the circumstances under which communication is done rather than the message itself as the aim of informing the public is to increase consumer awareness and vigilance rather than suspicions.

Furthermore, a higher degree of suspicion and reluctance from the public towards the national healthcare system as a whole can be generated -- and somewhat justified -- when and if consumers realise that the presence of counterfeit medicines within the supply chain has been concealed and/or not communicated by the local authorities for various reasons. In this case citizens may become suspicious of the quality of the medicines they buy even from fully legitimate and authorised sources as they fear that bogus pharmaceuticals can break the regulation standards and penetrate the legitimate supply and distribution chain. In addition to that, counterfeit medicines can erode the public confidence in health care professionals and the national health system leading to reluctance towards the use of health care facilities. Such

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<sup>50</sup> DI GIORGIO D. (2011) (a), cited, p. 27

<sup>51</sup> DI GIORGIO D. (2009) (a), *Counterfeit medicines: case studies*, Council of Europe/EDQM publishing; DI GIORGIO D. (2009) (b), p. 5; *Counterfeit medicines: exercises*, Council of Europe/EDQM publishing, p.9; DI GIORGIO D. (2011) (b), *Counterfeit medical products and similar crimes: case studies*, volume II, Council of Europe/EDQM publishing, p. 13.

a situation has the potential to increase the mistrust towards the competences and the efficiency of the national authorities to protect consumers.

### ***1.4.3 What Consumers Need to Know***

The results of a survey conducted in 51 countries by the Gallup Organization and presented during the 3<sup>rd</sup> Global Congress on Counterfeiting and Piracy in January 2007 in Geneva, showed that interviewed consumers who admitted to know or suspected that they had purchased counterfeit products were mainly from countries of the former Soviet Union (Kyrgyzstan, the Russian Federation, the Republic of Moldova, Belarus, Ukraine), Asia (Malaysia, Philippines, Sri Lanka, Viet Nam, Thailand) and Latin America (Haiti, Cuba, Guatemala, El Salvador, Paraguay)<sup>52</sup>.

Counterfeit pharmaceutical products and medicines (not including generics) were among the most frequently bought counterfeit products in the former Soviet Union countries. It is noteworthy that among the most frequently bought counterfeit goods -- soon after branded clothing, footwear and accessories, CDs and DVDs as well as perfumes and cosmetics -- there were also food products, alcoholic beverages, soft drinks and mineral water.

These results support four main assumptions. First of all, counterfeit medicines, seen as a whole with counterfeit food and beverages, are actually very present in the market; secondly, counterfeit medicines are very frequently bought among counterfeit products; thirdly, consumers in many cases know in advance that the product they intend to buy is counterfeit, except when they are purchasing counterfeit drugs; and finally that counterfeit medicines are not easy to detect. In addition, particularities in the ways of production, shipment and distribution as well as in the location of sale points in which they can be found make counterfeit medicines harder to be spotted and identified.

In view of elaborating possible prevention and awareness actions targeting consumers, another interesting element that arises from the Gallup survey are consumers' answers to the question (asked only to consumers in the United States of America) whether or not they would have bought the counterfeit product if they had known what their money was destined to. Negative answers concern almost massively the financing of terrorist groups and organised crime followed by other reasons such as the contribution to the deterioration of national levels of corruption and bribery. A very serious reason that acts as deterrent from buying counterfeit drugs and that was steadily mentioned by consumers is the protection of their health and safety. Arguments such as the losses for the company that produced legitimately the product or the tax evasion figured as less important deterrents, though not

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<sup>52</sup> The survey also included some countries of the EU (Austria, Belgium, Denmark, Estonia, Finland, France, Germany, Greece, Ireland, Italy, Latvia, Lithuania, Luxembourg, The Netherlands, Portugal, Spain, Sweden, the United Kingdom) and the United States of America. No African country was included. The Gallup Organization (2007), *Global Consumer Awareness, Attitudes and Opinions on Counterfeiting and Piracy* presented during the Third Global Congress-Combating Counterfeiting and Piracy, 31 January, Geneva.

meaningless. A recent research on consumers' attitudes towards counterfeit products carried out by Business Action to Stop Counterfeiting and Piracy (BASCAP) in five countries in different regions of the world (Mexico, the Russian Federation, India, the Republic of Korea and the United Kingdom) also revealed that the most important deterrent towards the purchase of a counterfeit is related to the protection of the health and safety of the purchaser and of that of their loved ones. In particular, consumers of all the participating countries, with the exception of the Russian Federation, considered the financing of organised crime as a relevant deterrent<sup>53</sup>.

The common element between the BASCAP and the Gallup researches is that the protection of "health and safety should be the bedrock of any communications efforts [...]" against counterfeiting, to use the words of the Gallup survey organisers. This means that consumers' health and safety may be considered as the first and foremost argument upon which justifying the efforts produced to repress counterfeiting as well as in communicating this message through awareness raising campaigns. This message becomes even more crucial when it comes to pharmaceutical products<sup>54</sup>.

Interesting results were also obtained by a survey conducted by the Italian Ministry of Economic Development<sup>55</sup> -- through the Directorate General for the Fight Against Counterfeiting - Italian Patent and Trademark Office (IPTO) -- with the support of National Consumer Associations. The results showed that on average, about 70 per cent of interviewed consumers know the risks and damages that can arise from using a counterfeit product. About 71 per cent of them, however, are satisfied with counterfeit products and think only people who market and manufactures them should be punished (about 80 per cent). The average consumer purchasing counterfeit medicines seems conscious of its illegality and its dangerousness in general but not of its concrete risks. In particular, consumers do not understand the problem created from a continuous use of falsified medicines. Therefore, it is necessary and important to give appropriate messages to consumers, especially concerning medicines, with specific advices about the negative impact in terms of risks for the public health. This element is essential to directly influence the purchasing attitude of consumers and consequently reduce the level of demand for counterfeit medicines. As analysed in a recent report published by UNICRI<sup>56</sup>, consumers of counterfeit products are certain of the benefits they are obtaining by purchasing non original goods and this certainty is at the basis of their purchasing attitudes. They believe that counterfeit products are a good bargain, fooling producers who market their products at such high prices. However, and as demonstrated also by the previously mentioned Gallup and BASCAP researches, when consumers are made aware of the direct damages and risks that a certain category of counterfeit products may create for them or their loved ones, the assumption that counterfeit products are a good bargain is undermined, with a direct effect on

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<sup>53</sup> BASCAP (2009), *Research Report on Consumers Attitudes and Perceptions on Counterfeiting and Piracy*, November. Online. Available HTTP: [http://www.iccwbo.org/uploadedFiles/BASCAP/Pages/BASCAP-Consumer%20Research%20Report\\_Final.pdf](http://www.iccwbo.org/uploadedFiles/BASCAP/Pages/BASCAP-Consumer%20Research%20Report_Final.pdf)

<sup>54</sup> For more information on this topic, see also: UNICRI (2010), *Strategies for Technical-Judicial Training and Awareness-Raising on Counterfeiting*

<sup>55</sup> Italian Ministry of Economic Development and national Consumers associations (2011), *Counterfeiting in Italy*

<sup>56</sup> UNICRI (2010), cited

the purchasing attitude they will have towards them. Research has also shown that another deterrent towards the purchase of fake goods is constituted by the argument concerning the financing of organised crime or terrorism. When consumers are presented with the possibility that their actions are directly contributing to the activities of organised crime or of terrorist groups, their reaction could directly influence their purchasing attitudes.

#### ***1.4.4 The Other Victims of Counterfeit Medicines: the Industrial Pharmaceutical Sector and National Economies***

The existence of counterfeit medicines in national markets considerably hampers the industrial pharmaceutical sector. Legitimate manufacturers suffer from patent and other IPRs infringement as counterfeiting literally “hijacks” the brand<sup>57</sup>.

According to WHO data, it is estimated that the pharmaceutical industry as a whole undergoes annual losses of approximately 45 millions euros, which represents about 10 per cent of the sector’s annual turnover worldwide<sup>58</sup>. It is undeniable that the sale of counterfeit medicines provides incredible profit margins for perpetrators, which can climb up to 20,000 per cent in cases of very popular products, such as counterfeit Viagra, in specific markets<sup>59</sup>

In 2005, the El Salvador’s Association of Pharmaceutical Companies (INQUIFAR) reported that the national pharmaceutical market was flown by counterfeit medicines which led to a loss of approximately 40 million USD for the country’s national pharmaceutical industry<sup>60</sup>. These percentages are usually higher in African countries as demonstrated by an example in Kenya where the National Association of Pharmaceutical Industry found that sales of counterfeit drugs and other pharmaceutical products reached 130 million USD in 2005<sup>61</sup>. Similar examples and percentages can be found in Angola, Mozambique, Nigeria and India and relatively lower percentages can also be found in Colombia and Mexico. This means that official manufacturers, as well as authorised distributors and dealers, are in a continuous struggle to reduce the massive losses generated by the unlawful production and trade of counterfeit products, consequently reducing potential investments and hampering fields of Research and Development (R&D).

Innovation and growth are the driving forces in the field of R&D especially for pharmaceutical products. The risks created by counterfeiting in the pharmaceutical sector are therefore particularly high in the case of pharmaceutical industries in which R&D costs associated with the study and invention of a new pharmaceutical product are higher by comparison with the costs of producing the designed product<sup>62</sup>. The decrease of the annual turnovers of the pharmaceutical companies means fewer funds available for investments in

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<sup>57</sup> MHRA (2006), *Counterfeit Medicines- Guidance for Pharmacists*, p.2.

<sup>58</sup> WHO (2009). *Santé publique: les dangers de la contrefaçon des médicaments*, minutes of the Symposium held at the French Senate, Paris, 2 April, p.3.

<sup>59</sup> Ibid.

<sup>60</sup> WHO (2006) (b), cited

<sup>61</sup> Ibid.

<sup>62</sup> OECD (2007), cited, p.17

R&D, leading to a situation in which the companies may decide to increase the price of the medicines to recover part of the losses sustained.

The role of pharmaceutical industries and laboratories in the fight against counterfeit medicines is also crucial. Many companies are directly concerned as counterfeiting causes huge profits loss, undermines their R&D efforts, hammers their marketing policies and reduces their credibility. For these reasons, some of them have adopted serious measures towards the fight against production of counterfeit medicines by integrating investigation teams. However, at the same time pharmaceutical companies often choose not to give the issue the necessary limelight as they are afraid of causing panic to the public, thus damaging the turnover of the legitimate trade.

As these products make the government vulnerable from many aspects, another victim of the existence of counterfeit medicines is the State itself. The government is supposed to receive taxes throughout the whole procedure of legitimate distribution, namely from the producers, wholesalers, retailers and various other intermediaries. The launch of counterfeit drugs in the market means that the legitimate change-hands procedure, for which government's control and authorisation are a prerequisite, is actually bypassed. This means that the State involuntarily loses the right of intervention through which it ensures the gathering of taxes, which leads to a loss of taxation revenue ordinarily designated towards the investment in social policies.

In addition, the existence of counterfeit medicines in a national market may discourage or even prevent foreign investments as possible investors see their interests unprotected. This obviously reduces the possibilities of economic development and of the improvement of the national healthcare system of the country where counterfeit medicines are considerably present.

There is also a considerable burden to the social insurance system of the country as social and health services have to cover patients' expenses for drugs that are literally useless, ineffective or even dangerous. Moreover, the national healthcare system is further burdened by providing treatment to patients who have consumed counterfeit medicines and their clinical situation worsened. Finally, health plans for the national health systems might be defrauded and compromised<sup>63</sup>.

It is not difficult to realise that citizens are the most negatively impacted by the effect that counterfeit medicines have on national health infrastructures and economies. They are the final ring of the production-distribution-consumption chain and the final and most vulnerable target of this unscrupulous game.

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<sup>63</sup> MHRA (2006), cited, p.2





## **2. THE WORLDWIDE MARKET**

Integrating pharmaceutical industries and markets has various advantages such as the boost of competition; the securing of the market and the supply chain, in particular through convergence; the achievement of larger capacities in addressing the various needs, demands and offers of medical products in a more comprehensive way; the creation of a more compact and inclusive market power; the control and the better management of the information; and the internationalisation of the activities of the integrated market. Moreover, this model can create benefits in the social field with regard to the access of citizens to better and cheaper medicines. Although, as promising as this may be, it seems that the achievement of harmonisation and further compliance among regionally integrated national markets cannot fully guard against the penetration of counterfeit pharmaceutical ingredients and medicines in the global market. In a global economy, ingredients and excipients for the production of medicines as well as final pharmaceutical products move constantly around the world by being bought and sold many times before they reach their final destination.

According to the WHO estimations, 200,000 of the 1,000,000 malaria deaths annually would be prevented if all the drugs were genuine<sup>64</sup>. As the anti-malaria medicines are almost exclusively destined to less developed countries (the countries most affected by this tropical disease) and as the big majority of them are produced in countries other than the ones of destination, one can easily understand that counterfeiting of these drugs follows the logic and the rules of the market; is based on regional markets' needs and demands and follows the rules of what can be called "a global market of counterfeit medicines."

This global market of counterfeit medicines is entirely similar to its legitimate counterpart and, thanks to the infinite connections and actors it may exploit, it allows a medicine to be produced in a country that is very distant to the place of its final marketing. It exploits the possibility of producing at reduced costs and relies on well established organised criminal networks as well as "favourable environments." This "tactic" or, preferably, this market rule can be especially noticed in cases of counterfeit drugs that are present in the less developed world and particularly in some countries of the African continent. An incident that occurred quite recently in Ghana could be mentioned here as a case in point. On 17 July 2009, a considerable amount of wide-use antimalarials was seized from the market in Ghana, after having been identified as lacking any active ingredient<sup>65</sup>. The operation to trace the fake medicines and recall them from the market started after a citizen notified the Medicines Quality Monitoring Programme which was set up by the United States Agency for International Development (USAID). After the chemical analysis conducted in the laboratories and a subsequent quality control carried out by the Ghana Foods and Drug Board (FDB), the medicine was found to contain zero active ingredients, therefore being entirely useless. According to the results of the two quality tests, the drug in question posed serious risks to human health, since it contributed to the growth of drug resistance in patients towards the non-counterfeited medicine. Officials working on the mentioned programme confirmed

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<sup>64</sup> CLARK E. (2008), cited

<sup>65</sup> United States Pharmacopeia (2009), *Counterfeit Antimalarial Drug Discovered in Ghana with Aid of USP Drug Quality and Information Program. Product Lacked Any Active Ingredient*, press release, 22 July, Online. Available HTTP: <http://vocuspr.vocus.com/vocuspr30/ViewAttachment.aspx?EID=RSVIIQYucB5oeaAqQ+eRWsGX7Qy88vEXkpB6QDmSuOM=>

that the widespread presence of counterfeit medicines is a considerable barrier in improving the public health situation in Ghana, which has been continually challenged by the overwhelming presence of poor quality drugs<sup>66</sup>.

It is commonly admitted that the major part of counterfeiting takes place in South Asia and the Far East, with India and China being the biggest source of production and the initial point of shipment and distribution of many counterfeit pharmaceuticals<sup>67</sup>. While many containers of legitimate medical substances are accompanied by the necessary certification and licence documents, there are also numerous cargos of drugs that pass through various countries, lacking proper paperwork. This implies that counterfeit medical ingredients and drugs can reach every part of the world with almost no difficulty. The globalised financial and trade environment favours cursory exchanges. However, it is this international trade environment that is exploited by counterfeiters to bulk foreign markets with bogus medicines. Documents can be easily falsified while counterfeit pharmaceuticals cross the borders of various countries before reaching their final destination.

A very characteristic example is the abovementioned case of the counterfeit cough syrup that occurred in Panama in 2006. The barrels shipped from China were containing diethylene glycol instead of the glycerin that was claimed by their certificates and shipment documents. The result was that the final product was nothing but poisonous syrup containing diethylene glycol (an industrial solvent and prime ingredient in some antifreeze products) instead of glycerin which is commonly used in medicines, food, toothpaste and other products. The falsely labelled poisonous mixture was approved and shipped two times before reaching its final destination, crossing three different continents: with a Chinese manufacturing company producing the “pharmaceutical excipient”; another Chinese company serving as the first exporting intermediary; a Spanish company serving as stopover and second distribution point; and the Panama State pharmaceutical industry being the final recipient and the country’s markets the final destination for consumption<sup>68</sup>.

In 1996 almost 90 children died in Haiti<sup>69</sup> because of a fever syrup containing diethylene glycol. The United States FDA discovered that the origins of the poisonous medicine could be traced to China<sup>70</sup>. Similar to the case of Panama, the barrels containing the poisonous substance for the production of the fever syrup in Haiti passed through brokering companies in Germany and The Netherlands before reaching the drugs production facilities in Haiti. However, all the investigations that were conducted by the FDA led to a dead-end as most of the records of the shipping and brokering companies were obliterated and almost all paperwork was altered. Similar stories involving the same kind of toxic excipient also occurred in China, Bangladesh, Argentina, Nigeria, and India<sup>71</sup>.

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<sup>66</sup> Ibid.

<sup>67</sup> CLARK E. (2008), cited

<sup>68</sup> BOGDANICH W., HOOKER J. (2007), ‘From China to Panama, a Trail of Poisoned Medicine’, in *The New York Times*, 6 May. Online. Available HTTP: <http://www.nytimes.com/2007/05/06/world/06poison.html>

<sup>69</sup> The number of victims was even higher but it remained unconfirmed because of insufficient registration in hospitals and of children who took the poisonous drug and died without being hospitalised.

<sup>70</sup> BOGDANICH W., HOOKER J. (2007), cited

<sup>71</sup> Ibid.

In several cases national health systems may lack organisation and infrastructure, while patients may have limited or no access to medical facilities, and this impedes cases to be registered and reported. The situation of national health systems however and the possible inefficiency of the state regulatory mechanisms, are not the only causes allowing bogus medicines to enter a national market. In today's increasingly globalised pharmaceutical industry, manufacturers look for cheap ingredients and excipients in order to save production costs, create more affordable and more competitive medical products and make larger deals of distribution, especially in those parts of the world where demand exceeds supply. While fair competition is the basic rule within market economies, problems arise when counterfeiters break the rules and penetrate the production and supply chain as unlawful competitors by introducing unapproved and hazardous pharmaceutical products into the market. While less developed countries are more vulnerable to counterfeit pharmaceuticals, nevertheless, in both the cases of Haiti and Panama the hazardous chemical substance reached its final destination after having passed through European distributors, which means a lot about the potential exposure to the danger of countries with better verification and control systems for pharmaceutical products. Additionally, incidents of counterfeit healthcare products -- such as the case concerning diethylene glycol-mixed toothpaste that was found on the shelves of super markets in many cities of the United States of America -- showed that even small weaknesses and instances of negligence within a sufficiently protected and secure production-repackaging-distribution system can be exploited by medicine counterfeiters, even "in countries where quality control procedures are strictly applied."<sup>72</sup>

In mid-2005, the Spanish police raided six laboratories in the northeastern region of Catalonia and seized some 30 million doses (10 tons) of counterfeit anabolic steroids and hormone-boosting substances as well as cancer drugs<sup>73</sup>. The substances came in various forms including vials, capsules, tablets and doses for injection<sup>74</sup>. The products seized were destined for distribution in various EU countries and considerable amounts had been already exported in Italy, France and Portugal. Transportation and distribution was effected through the use of vans and many of the medicine products discovered were being sold via the Internet or were found on the shelves of health food stores. Even though the production of the bogus substances was taking place in Spain, the authorities concluded that the ingredients used for their production originated from Mexico, Brazil, and Thailand<sup>75</sup>. This case serves to depict the product differentiation strategies adopted by counterfeiters as well as the market-oriented strategies. By choosing to produce fake body mass increasers, a product that appeals particularly to the sporting industry, counterfeiters were able to penetrate markets of developed countries where products of that kind are sold at relatively high prices and can only be purchased in authorised places. It is for that reason that counterfeiters tried to sell those fake products to sports clinics, gyms, fitness clubs, and even directly to athletes, at far lower prices than the normal ones. Moreover, the number and the geographical position of

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<sup>72</sup> BOGDANICH W. (2007), 'FDA Tracked Tainted Drugs Sold in Haiti, but Lost Trail in China', in *The New York Times*. Online. Available HTTP:

<http://www.nytimes.com/2007/06/17/health/17poison.html?pagewanted=all>

<sup>73</sup> The Partnership for Safe Medicines (2005), *Counterfeit Drugs in Europe*. Online. Available HTTP: <http://www.safemedicines.org/resources/europe.pdf>

<sup>74</sup> China Daily (2005), *Spanish police bust six laboratories, arrest 70 in crackdown on sports doping*, 1 June. Online. Available HTTP: <http://www.ergogenics.org/spanjelabs.html>

<sup>75</sup> The Partnership for Safe Medicines (2005), cited

the countries involved, demonstrate the complexity of the production processes and how various supply markets are connected all around the world. However it seems that dubious manufacturers of pharmaceutical APIs and excipients spot their potential buyers in regions where demand for cheap substances is likely to be higher while manufacturers of counterfeit medicines seek, in their turn, buyers for their final “products” in countries where drugs regulations are more relaxed.

The afore mentioned cases revealed the extent to which officially compulsory control and testing procedures can be circumnavigated in order to get cheap ingredients and quick market supply. Moreover, they revealed how existing bureaucracies can often lead to superficial control and approval of the certification documents that accompany pharmaceuticals while rendering the regulation system more rigid and complicated, by requesting the involvement of numerous stakeholders.

The above cases of Haiti and Panama could be considered as “strong” examples. The pharmaceutical manufactures relied on the certificate of analysis provided by the supplier and did not perform full identity tests on the glycerin they used to produce the drug<sup>76</sup>. Most importantly, in both cases the origin of the glycerin was obscured by the distributor to prevent the buyer from dealing with the latter. According to Kevin J. McGlue, a board member of the International Pharmaceutical Excipients Council “where there is loophole in the system, a frailty in the system, it’s the ability of an unscrupulous distributor to take industrial or technical material and pass it off as pharmaceutical grade.”<sup>77</sup> By taking advantage of the prevalent loopholes, counterfeiters introduce bogus medical ingredients and substances into the distribution chain and put counterfeit medical products just beside the original ones.

Moreover, commercial practices adopted and followed by some brokering companies and intermediaries greatly illustrate their deliberate indifference towards fair trade rules. Throughout the whole transport process, the involved distribution brokers and companies will often conceal the names of the previous suppliers on the shipping documents to prevent customers from bypassing them on future purchases. This so-called “neutralisation”<sup>78</sup> is applied by many intermediaries in order to protect their commercial interests and exclude as many competitors as possible from the distribution chain and the business. This practice also conceals the origin of the medicine as any trace that refers back to its provenance disappears making it literally impossible to track the drug or the medical substance. This can lead to disastrous results, as ignorance of the origin of the product also means ignorance as to its quality.

Counterfeiters operating within the global market currently enjoy a general impunity as there is no international authority mandated to conduct investigations and trace the origins of the hazardous pharmaceuticals. This implies that national authorities are the only bodies responsible for the spotting, verifying and tracking down of counterfeit medicines. Investigations rely on the initiatives of the authorities or on report of citizens of countries that

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<sup>76</sup> BOGDANICH W. (2007), cited

<sup>77</sup> Ibid.

<sup>78</sup> Ibid.

have been victims of counterfeit drugs. Such investigations however are usually hindered by a general reluctance to cooperate amongst the various foreign stakeholders (both public and private) involved throughout the whole criminal/distribution chain, or by an abundance of missing and forged documents. Individual countries must conduct their own trace-back investigations as even attempts at bilateral cooperation are usually hampered by uncompromising attitudes, a reluctance to communicate information and evidence, and a general unwillingness to facilitate foreign investigation<sup>79</sup>.

The efficiency of controls and verifications conducted within national territories can often be overcome by the decentralised characteristic of the international trade system. This does not imply however, that ordinary verification and import and export control systems are unimportant or have to be by-passed, but suggests instead that they could be revised and reformed. The need for such reforms is further justified by the magnitude of medical substances transactions that take place within the international market on an ordinary basis. “This is really a global problem, and it needs to be handled in a global way.”<sup>80</sup>

As it has been already mentioned, product differentiation and consumers-targeting strategies are at the basis of medicines counterfeiters’ business choices, as the latter literally draw and implement their unscrupulous activities based on the specificities of each reference market. It is worth analysing how pharmaceutical products are differentiated within the globalised market by making a distinction between drugs that are introduced into the supply chains of less developed countries, and medicines destined to developed countries, and the factors that facilitate the diffusion of counterfeit drugs in each case.

## **2.1 Counterfeit Medicines and Less Developed Countries**

Experience obtained from investigations and raids made in countries of the EU, as well as in the United States of America and Canada, demonstrate that production and distribution of bogus medicines are not an “exclusive business” of the Asian region, or of less developed countries in general. Furthermore, in the same logic, the consumption of counterfeit pharmaceuticals is not confined to only developed or less developed countries respectively. It is, therefore, crucial to avoid any univocal interpretation of this global plague that intends to depict less developed countries only as the source of the problem, whose illicit production is flooding developed countries. The reality is far more complex and the populations of the great majority of less developed countries are those suffering more from the spread of fake life-saving drugs. The international context of the phenomenon (especially when coupled by lack of proper regulations and weak controls at the national level) represents a very favourable environment for the continuing trade of counterfeit medicines and creates an appealing opportunity that modern criminal organisations can not miss.

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<sup>79</sup> Ibid.

<sup>80</sup> Ibid.

In most less developed countries, counterfeit medicines can be found in both popular street markets and legitimate pharmacies belonging to the formal supply chain<sup>81</sup>. The reason for this is that a very well organised network of criminals is usually at the basis of the counterfeit medicines' distribution. Criminals have the intimidating/corruptive power to force/convince supply chain actors to introduce their criminal products into the market while they can also undertake street selling to lure potential victims with low priced drugs. The result is that a patient in these countries can hardly trust the product they are buying and has simply no choice but to purchase them. If they have enough money to buy from the official pharmacies, then they have to hope that the supply procedures and regulations have been respected by all actors and, at the end, that the medicine in their hands is actually genuine. In the case of street/local markets in poorer countries, the diffusion of counterfeit medicines can also be linked to their appealing price that attracts patients with lower financial possibilities. The latter, again, have no choice but to believe that cheap medications are original pharmaceutical products which, for whatever reason have a lower price. There is also a great deal of misinformation or disinformation affecting the potential buyers in this scheme, who do not realise that they are buying low-quality and hazardous products.

High prices of branded pharmaceuticals and the unavailability of generics further contribute, especially in less developed countries, to the creation of opportunities for counterfeiters to bulk the market with low-quality copies of drugs, making huge profits.

There are also other difficulties and problems. In many less developed countries, regulatory bodies are often “an expensive and unaffordable luxury”<sup>82</sup> which means that such mechanisms are not present in all the countries or, in cases where they do exist, they may be too weakly equipped to properly address the problem. Governmental authorities in charge of controlling and regulating the production and distribution of medicines and pharmaceuticals that are either nationally produced or imported may experience difficulties in registering national companies that manufacture APIs, excipients and/or final pharmaceutical products. In addition, many drug storage and sales facilities also fail to comply to governmental authorities' registration lists and procedures. If the first ring of the production-distribution chain is broken, there is a resulting absence of control over brokers and intermediaries who may be involved in distributing counterfeit medicines and supplying the local markets with these products. Several cases concerning illegal manufacturers and unlicensed intermediaries have also shown that those who operate in a more coordinated way and develop large amounts of an ample range of counterfeit pharmaceuticals often try to deceive authorities and customers by acting in an outrageously transparent way. Their main objective is to avoid raising suspicions about the nature and the lawfulness of their activities, as this would lead to controls and the possible discovery of their real activities. Therefore they focus much of their efforts on portraying a legal appearance. Detailed and faultless packages; impeccably forged production and sales licences and certificates; perfect websites advertising affiliations with hospitals or medical centres; even participation in trade shows, are the elements that are crucial to looking trustworthy and reliable. Moreover, other practices are also frequently associated with counterfeiters' activities such as bribery, intimidation, and corruption of borders and customs officials.

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<sup>81</sup> SEWING P. (2007), *Counterfeit Drugs in Africa. Causes, Magnitudes and Impacts*, UNODC, November, p.1

<sup>82</sup> BATE R. (2008), cited, pp.14-24

Additionally, in many less developed countries state mechanisms destined to protect the consumers and enable effective reporting of counterfeiting are almost nonexistent. For instance, in some countries there is only one public office authorised to receive such reports and it is usually located in the capital of the country. This means that citizens from other regions of the country cannot report cases of counterfeiting as there are no regional offices for this purpose. This leads to the practical inapplicability of the right to denounce and to obtain compensation, as civil liability in many less developed countries is literally inactive.<sup>83</sup> Boosted and rigorous civil laws would compensate victims of counterfeit medicines or their relatives for the damage done to their health while, at the same time, they could also deter manufacturers and suppliers from adopting such illegal practices.

The phenomenon of counterfeit medicines is a scourge, and is exacerbated by its global dimensions. Regardless of a substances production location, the industries distribution networks have been designed to cover the entire global market. What is more, counterfeiters have adapted the production and the distribution of their products according to the way of life and the needs of each individual society. This means that societies of developed countries are prosperous markets merely for anticancer, diet and anti-obesity medicines, painkillers and antibiotics whereas societies of the less developed world have become the target for medicines against diseases such as malaria, tuberculosis and HIV. Nonetheless, this does not imply that medicines that are in higher demand in developed countries are excluded from the markets of less developed countries or countries with emerging economies. Antiretrovirals, antibiotics, painkillers, flu drugs, rabies vaccines, birth-control pills, anaesthetics, cardiovascular medicines, anti-diabetics, anti-hypertensives, hormones, anti-asthma and anti-allergic medicines, drugs for skin infections and diseases, cholesterol lowering treatments, psychotropics, anti-impotence treatments and others are also becoming medicines of high demand in less developed countries, particularly as rates of urbanisation increase. According to an article which appeared in the *Manila Times* in 16 August 2005, the top five counterfeit medicines in the Philippines are: antihypertensive drugs; anti-asthma drugs; analgesic medicines; anti-diarrhoea; and vitamins<sup>84</sup>. Although this is only an example, it shows that counterfeiting is very present that it does operate well beyond “traditionally” counterfeited medicines such as antimalarials and antiretrovirals.

### ***2.1.1 Consequences on Patients’ Health and Consequences at the Economic and Social Level***

For poorer people in less developed countries, the medicines that can be found in the local markets are a one-way choice. As Dora Akunyili wrote in an article on the issue “these

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<sup>83</sup> MORRIS J., STEVENS Ph. (2006), cited

<sup>84</sup> Ibid.

people represent an ideal “targeted market” for the marketing strategies of those who take advantage of this kind of illegal market.”<sup>85</sup>

The use of counterfeit medicines can have a tremendous impact on patients’ health, ranging from the development of drug resistance to the cause of serious harm and death. The consequences of bogus pharmaceuticals on health are particularly serious in less developed countries where counterfeit medicines are consumed on a large scale, almost on a daily basis. The enormous spread of fake drugs in less developed countries is due to various factors, including the prevalent lack of adequate social security and public health policies. This means that the purchase of pharmaceuticals is a considerable expense for the budget of most households. Medicines represent a considerable economic challenge for families that have difficulties in affording ordinary basic needs. Specialists warn on the hidden dangers of drug resistance which is behind the consumption of counterfeit medicines that contain insufficient amounts of APIs. Increasing concern has been also expressed for diseases that require a combination therapy, for example malaria, tuberculosis and HIV that are widespread in many less developed countries. In these cases, poor quality drugs risk the spread of drug resistance<sup>86</sup>. According to experts, the high frequency of typhoid antibiotic resistance in Myanmar could have been caused by the high prevalence of substandard *chloramphenicol* and *cotrimoxazole*. The same may be true for other infectious diseases like malaria, with claims that the counterfeit *artesunate*, which contains smaller quantities of the API required, greatly facilitated the spread of *P falciparum* parasites resistant to *artemisinin* derivatives (the group of drugs that treat malaria). Moreover, and as *artesunate* is very commonly used in combination with other substances such as *mefloquine* to avoid the development of *artemisinin*-resistant parasites, it has to be considered that the inefficiency of one or more of the drugs used in a combination treatment for an illness would inevitably lead to therapeutic failures and require time-consuming and expensive processes for the development of new medicines<sup>87</sup>.

Africa is the continent that suffers most from the presence of counterfeit life-saving medicines. It is noteworthy to mention again the extension of fake malaria treatments in the markets of African countries. According to a study in *The Lancet*, up to 40 per cent of *artesunate* products (a medicine to combat resistant malaria today) would contain no active ingredient and therefore have no therapeutic benefits against malaria.

There are various statistics that show the presence of counterfeit medicines in the markets of less developed countries, the same countries which are often already suffering from the presence of lethal diseases in their territory. However, and notwithstanding the presence of these statistics, the importance of the phenomenon is vastly undervalued, especially if one thinks that deaths caused by the use of fake medicines are not negligible<sup>88</sup>. Outlining the problem in less developed countries and in particular in the African continent is

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<sup>85</sup> AKUNYILI D. (2006), 'Lutte contre les médicaments contrefaits en Afrique: l'exemple du Nigeria' in *Diabetes Voice*, vol. 51, no. 3, September. Online. Available HTTP:: [http://www.diabetesvoice.org/files/attachments/article\\_445\\_fr.pdf](http://www.diabetesvoice.org/files/attachments/article_445_fr.pdf)

<sup>86</sup> SEWING P. (2007), cited, p.3

<sup>87</sup> Ibid.

<sup>88</sup> Ibid.

impossible as there is almost no audit in the majority of these countries which could provide a clear understanding of the problem and support the elaboration of trends related to the presence of counterfeit medicines.

As with the counterfeiting of different goods in general, counterfeiting of medicines is a phenomenon that has to be viewed from multiple angles. In this light, particular attention has to be paid to the local level as local markets can be at the heart of the distribution of counterfeit medicines, given that they are the most easily accessible purchase points for the population. Moreover, particular attention has to be paid to the distinction between urban and rural areas as the latter suffers more from the general lack of availability of pharmaceutical products and are therefore more vulnerable to the insertion of counterfeit medicines. Furthermore, in rural areas the problem of underreporting in counterfeit pharmaceuticals cases is even more present than in cities, as the necessary infrastructure, logistics and organisation which would encourage the register of citizens' complaints is often nonexistent.

### **2.1.2 Cases**

From Southeast Asia, to Latin America, to the Middle East and Africa, countless cases of seized counterfeit drugs confirm that bogus pharmaceuticals are an ordinary nightmare for consumers as well as for national and local health and control authorities. The matrix<sup>89</sup> on cases of counterfeit medicines in various less developed countries worldwide, published by the United States Pharmacopeia in cooperation with USAID, reflects the current situation. Without being exhaustive, the following are some striking examples that can be mentioned:

In November 2008, the Pharmacy Affairs Department of Afghanistan announced that it had seized approximately 200 tonnes of counterfeit medicines between May 2007 and November 2008.

In Cambodia, according to *The Phnom Penh Post* of the 23 November 2009, the director of the Municipal Health Department in Phnom Penh said that nine illegal pharmacies would be shut down for selling counterfeit medicines, and 100 more were also facing closure. According to officials, only half of the country's 2,000 pharmacies were registered under the Ministry of Health.

In 2008 in Ouagadougou, the capital of Burkina Faso, 20 per cent of medicines on the market were counterfeit. Those medicines showed no expiration date and required no prescription. In the years between 2005 and 2008, a record 23.6 tones of fake medicines in Ouagadougou were seized by government security forces. According to the National

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<sup>89</sup> The *Matrix of Medicine Quality Reports Affecting USAID-assisted Countries* is a report written and updated on a monthly basis by the United States Pharmacopeia in the framework of the "Promoting the Quality of Medicines" programme and which briefs on cases of seizures of fake pharmaceuticals in all the countries in which the USAID operates. Various online and written sources are used for the information gathered and presented in the United States Pharmacopeia report. For the needs of the present report, the latest up-to-date version of the 10 January 2010 was used. Online. Available HTTP: <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf>

Committee of Drug Control (CNLD), those counterfeits would cost the economy up to USD 4.7 million each year despite laws banning them. Public authorities in Burkina Faso affirm that it is very difficult to break up the nexus of unlicensed wholesalers who are mainly responsible for the imported counterfeit medicines that circulate within the country. Therefore, law enforcers' operations are mainly focused on young vendors who sell these bogus drugs in the streets and in the local markets but who are at the same time, the last ring of this illicit chain.

According to official figures published in 2009, 60 per cent of people in Brazzaville, Congo, used medicines purchased from illegal street vendors to treat malaria instead of the recommended remedy.

During the 3rd Global Forum on Pharmaceutical Anti-counterfeiting held in 2007 in the Czech Republic, in Prague, P. Newton<sup>90</sup> mentioned that samples of tablets taken from the border between Myanmar and Thailand contained only 3-10 mg of artesunate per tablet whereas genuine tablets should contain approximately 50 mg.

In April 2009, Egyptian authorities announced that a large amount of counterfeit drugs were seized during warehouse raids. Counterfeits purporting to treat cancer, diabetes, hyperprolactinaemia, and other diseases were confiscated. According to the authorities, the drugs originated from China and passed through the Syrian Arab Republic before arriving in Egypt. The Ministry of Health and Population estimates that 10 per cent of the pharmaceutical products sold in the country are counterfeit.

A research conducted in Ghana in 2008 showed that 14 out of 17 (82.4 per cent) sampled *artesunate* tablets sold in pharmacies in Kumasi city and destined to treat malaria, failed to meet the active content requirements.

In 2004, the *Daily Nation* newspaper of Kenya reported that antiretrovirals intended for distribution as part of Kenya's AIDS medicine programme against HIV/AIDS were being sold on the black market in Nairobi. The price these drugs were being sold at was less than USD 65 for a monthly cocktail, nearly a quarter of the normal price, and the drugs could be bought without a doctor's prescription. Data and statistics on trade and consumption of counterfeit drugs in Kenya vary but all of them lead unquestionably to the very presence of bogus pharmaceuticals in the country. According to the data provided by the Kenyan Association of Pharmaceutical Industry, approximately 30 per cent of the national drug market would be counterfeit. Translated in financial terms this data would mean a profit of USD 130 million each year for those medicines' counterfeiters. The same assumption can be deducted from the article by S. Mbogo "*Why we are losing the war against fake drugs*" (published on 1 May 2008) according to which Kenyans would spend about USD 64.5 million annually on fake medicines while convicted counterfeiters would face fines of up to only USD 80. According to an article in May 2008, Anyang Nyong'o, the Medical Services Minister, said that up to 80 per cent of the medicines in Kenya would be counterfeit; a large percentage of these drugs being antimalarials.

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<sup>90</sup> Paul N. Newton works at the Centre for Clinical Vaccinology and Tropical Medicine at the Churchill Hospital of the Oxford University.

On 28 July 2007, *The Jakarta Post* communicated that in Indonesia, the Jakarta police confiscated approximately 160,000 drugs that lacked distribution permits and arrested the owners of the two shops raided. Painkillers; throat relievers; anti-allergens; and antibiotics were among the confiscated medicines. Police also seized cosmetic products, such as makeup and face cream that contained high levels of mercury.

On 6 September 2008, *Gulfnews* reported that all 100 samples taken from pharmacies tested by the Iraqi Ministry of Health completely failed to meet the quality standards. Nearly all those medicines were made by companies not registered in Iraq and were sold without being tested for efficacy. According to Adel Mohsin, the Health Ministry's inspector general, there are two state-run pharmaceutical factories in Iraq and 90 per cent of the medicines available in the market are imported.

In October 2007, officials in Mauritania announced that they had seized and destroyed approximately 36,000 bottles of counterfeit drugs. The sources of the drugs were believed to be China, the Syrian Arab Republic and Nigeria.

In February 2007, the *International Herald Tribune* reported that in September 2006, Nigerian authorities discovered USD 25,000 worth of counterfeit antimalarial and blood pressure medicines that were hidden in a shipment of purses originating from China. In December 2008, the Lagos State Task Force on Counterfeit, Fake Drugs, and Unwholesome Processed Foods shut down nine illegal pharmacies, arrested three operators, and confiscated USD 735,000 worth of fake drugs during raids that had been made the months before the end of the year. However, raids did not prevent poisonings and deaths due to the consumption of bogus drugs, as at least 34 children died after using teething syrup tainted with diethylene glycol, commonly found in antifreeze and brake fluid. NAFDAC has shut down the maker of the teething syrup. Publications at the beginning of 2009 increased the death toll to 84, claiming that the tainted teething syrup continued to circulate throughout the country. According to the Vanguard, the Lagos State Task Force on Counterfeit, Fake Drugs, and Unwholesome Processed Foods sealed off seven illegal patent medicine stores and destroyed about USD 394,000 worth of fake medicines in Mushin Local Government Area, in October 2009.

On 30 July 2009, it was reported that the National Bureau of Investigation in the Philippines seized USD 81,800 worth of fake influenza vaccines in San Pedro, Laguna and arrested a former representative of a pharmaceutical firm. The confiscated vaccines contained only distilled water.

On 7 December 2006, in the Philippines, the *Manila Standard Today* communicated that operatives from the National Bureau of Investigation conducted enforcement action against a total of 23 drugstores: 8 in metro Manila, 10 in various areas of Southern Luzon, and 5 in Northern Luzon. Prior to the enforcement action, medicines' samples purchased from the stores in question were confirmed as counterfeit.

In Sierra Leone, the Pharmacy Board destroyed more than USD 492,000 worth of substandard and counterfeit drugs in 2008. Moreover, in January 2009, the Freetown-based

*Concord Times* journal reported that there were more than 1000 border crossing points in the country that were unmanned by customs officials, making drug inspections nearly impossible. The Pharmacy Board had officials at only Queen Elizabeth Quay and Lungi airport. The Ministry of Health increased the 2009 Pharmacy Board's budget to allow them to hire 15 inspectors to monitor the Guinean and Liberian borders. What is more, according to publications issued in November 2009, the Deputy Health and Sanitation Minister, Mohamed Koroma, and the Pharmacy Board have cancelled the licences of over 20 pharmaceutical outlets following investigations proving that the outlets committed various offences, including selling counterfeit and expired medicines.

According to the *British Medical Journal*, South African health authorities in August 2008 withdrew two generic drugs used to treat tuberculosis because of concerns of quality. After being in storage, two combination drugs did not contain the appropriate levels of active pharmaceutical ingredients as stated on their labels.

According to the Tanzanian newspaper *Daily News* of the 8 July 2008, a study by the Confederation of Tanzanian Industries (CTI) revealed that 60 per cent of the medicines imported into the country were counterfeit and that 80 per cent of the medicines used in the country were of foreign origin.

In Thailand, on 14 February 2008, the Bangkok Post reported that Pfizer purchased 217 samples of Viagra in both Bangkok and other provinces and 202 of them were found to be fakes. The counterfeit versions contained between only 17-48 per cent of the active ingredient, but the packaging on most of them was "perfect" and included a hologram.

In October 2008, the *Daily Monitor* reported that the National Drug Authority and the police of Uganda impounded counterfeit medicinal products worth millions of shillings. Only two of the 40 pharmacies sampled during the operation did not possess counterfeit products.

In an article appearing in the journal *Medical News Today* on the 6 June 2007, it was reported that the Zambian government had announced that the alleged HIV/AIDS cure known as "Tetrasil" was found to be a pesticide. Albert Mwangi, a government specialist in HIV/AIDS drugs, reported that Tetrasil is used as a disinfectant for swimming pools.

### ***2.1.3 The Nigerian Case of Fight against Counterfeit Drugs***

In Nigeria, NAFDAC seems to be a pioneer in the fight against the spread of counterfeit drugs in the West African region. Since Dora Akunyili took office in 2001 as Director-General of NAFDAC, almost 80 per cent of the medicines sold within the country were estimated to be bogus or substandard. Counterfeit drugs in Nigeria have been responsible for many deaths, including the intoxication and death of more than 100 children in 1990 -- who had been poisoned after having consumed a painkiller which contained toxic ethylene glycol instead of propylene glycol. Nigeria is particularly prone to counterfeit drugs as its major port of Lagos serves as an import/export gate to the world at both a national and

regional level. According to research carried out by NAFDAC in six major drug markets across the country, the level of compliance to drug registration in 2002 revealed that 68 per cent of medicines were unregistered by the agency. This study was repeated in 2003 revealing an 80 per cent reduction<sup>91</sup>. The decrease in the amount of counterfeit drugs from 41 per cent in 2001 to 16 per cent in 2006 gives support to the argument of the reduction of counterfeit medicines in Nigeria as well as in any other country is possible.

The first measure taken in 2001 to reduce the presence of fake drugs in the country was to restrict pharmaceutical imports to just two airports and two seaports, each staffed by NAFDAC officials. Soon after, the agency discovered several Indian and Chinese drug manufacturers suspected of producing and exporting fake drugs in Nigeria and banned the import of those products. The agency also established independent contacts with authorities in the two countries to regulate their exports to Nigeria. The rigorous work that has been undertaken since 2001, including meticulous borders controls; drafting of prohibition lists regarding substances' import; accompanying certification documents for imported drugs; raids to assess the quality of the medicines produced and distributed; and the boost of the national pharmaceutical industry, both improved the situation within Nigeria, as well as the image of the country abroad. All medicines produced and circulated within the country started carrying a registration number to check their authenticity. NAFDAC began to wield controls to domestic pharmaceutical producers in order to make them comply with good manufacturing practices and to ensure the respect of national rules and directives. Between 2001 and 2006, NAFDAC seized and destroyed bogus pharmaceuticals for a value of USD 109 million<sup>92</sup>.

As the inter-boundary trade that has been established between Nigeria and its neighboring countries has taken the form of parallel trade, other risks arise which endanger the already fragile production-distribution chain -- such as brokering activities carried out by individuals who are not officially authorised to act as intermediaries, or who lack the necessary skills and training, or are led by disloyal and unfair motives. This clearly mirrors the situation in many African countries, with only a few countries (such as South Africa, Nigeria, Ghana, Gambia and Egypt) having some level of systematic drug regulation and drug distribution and acting as exceptions.

#### ***2.1.4 China and India as Exporters and Consumers of Counterfeit Medicines***

Even though China and India are considered as the main exporting countries of fake pharmaceuticals this should not be taken to imply that their internal markets are spared from this scourge, as unfortunately large amounts of bogus medicines are present in their national markets as well. Recently in both countries, legislative reforms foreseeing more inclusive and stricter measures are beginning to advance; public drugs control authorities are becoming

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<sup>91</sup> NAFDAC, *Global Trends*. Online. Available HTTP: <http://www.nafdacnigeria.org/globaltrends.htm>

<sup>92</sup> United States Pharmacopeia (2011), *Media Reports on Medicines Quality: focusing on USAID assisted countries*, Rockville, p. 8

progressively better equipped with technologically improved equipment to conduct full-scale quality control of drugs samples; coordinated raids by law enforcement agencies are occurring more often; illegal drugs storage and sales facilities are closing down; individuals and gangs alleged for counterfeiting pharmaceuticals are being arrested and brought to justice and criminal groups are being broken up. Nevertheless the problem still remains very present.

With regard to the situation in China, *China Daily* reported on 10 May 2006 that a total of 381,000 fake Viagra pills and 1.4 million counterfeit Cialis tablets, worth a combined total of approximately 29 million USD on the market, were seized from workshops at Kangdeli Health Care. According to a release from the court, the counterfeiters were sentenced with 10-year prison term.

Furthermore, throughout 2006 Chinese authorities seized considerable amounts of fake birth control pills containing starch, glucose, and toxic substances and closed down the factory producing them. Following this, the government proceeded by cracking down on manufacturers of fake and poor quality rabies vaccines following reports of several deaths caused by these substandard vaccines. Fake or poor quality bird flu vaccines have also been reported. Shanghai police seized approximately 880 pounds of fake vaccines, worth about 600,000 USD and arrested 13 suspects. The authorities also focused their investigations on the fake vaccine the group had sold via the Internet in Southeast Asia. In 2006, the International Policy Network reported that between 200,000 and 300,000 people die each year in China as a result of substandard or counterfeit drugs. According to a Shanghai-based drug investigator, 22 out of 32 drugstores investigated in Nanjing were selling counterfeit drugs. The investigator further reported that four of the 15 drugstores supported by public medical insurance were selling counterfeit drugs.

In 2007, after 200 Chinese cancer patients had been paralysed or otherwise harmed by contaminated leukaemia drugs, the Chinese State Food and Drug Administration (SFDA) shut down Shanghai Hualian, the maker of *methotrexate*. Officials found that the drug had indeed been contaminated with *vincristine sulfate*, also a cancer drug. Though official numbers were not released, some resources suggested there were at least 193 victims nationwide.

Despite the above mentioned estimations over deaths in China due to counterfeit or substandard medicines, for the cases in which seizures do not clearly prove fraudulence or wilfulness in counterfeiting it is not possible to make the distinction between a counterfeit and a substandard medicine, hence safely attribute deaths to one or the other category of drugs<sup>93</sup>.

As far as the internal pharmaceutical market in India is concerned, according to statistics published on January 2007 by the Associated Chambers of Commerce and Industry of India (ASSOCHAM), 20 per cent of medicines sold in India were fakes. Of those, 60 per cent did not have active ingredients, 19 per cent had incorrect ingredients, and 16 per cent

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<sup>93</sup> MORRIS J., STEVENS Ph. (2006), cited

had either harmful or inappropriate ingredients, like talcum powder. Moreover, approximately 38 per cent of medicines in government hospitals were found to be counterfeit. On 17 May 2007, *Huliq* reported that, according to surveys on medicines bazaars in the country, more than 90 per cent of the medicines were found to be fakes. With only 35 drug inspectors at the national level and slightly more than 1,000 at the state level, there were roughly 500 medicines outlets per inspector.

On 27 July 2008, *The Times of India* reported that the Enforcement of Intellectual Property Rights (EIPR) group and the police seized more than 700,000 counterfeit analgesic tablets.

On April 16, 2009, *The American* reported that fake antidepressants, painkillers, and insulin were found at Danapur Railway Hospital. Following confirmatory testing, India's Drugs Control Agency found that many had 11-12 per cent of the active pharmaceutical ingredient. The same source reported that fake anaesthetics were found at Osmania General Hospital in Hyderabad.

According to an online publication on Securing Pharma website on December 2009, a series of raids conducted in November 2009 by the Indian Authorities in Uttar Pradesh, resulted in the discovery and seizure of approximately USD 222,000 fake and substandard medicines. The raids were conducted over a 15-day period across 14 state districts.

### ***2.1.5 Drawn Conclusions***

The fight to reduce and eventually eliminate counterfeit drugs from national and local markets in less developed countries is inseparable from a proper fight against organised crime's strategies in this field. This means, first of all, that medicines counterfeiting has to be recognised as an organised crime activity, with proper penalties, proper counter-strategies and a proper legislation in place. The scale of the problem also requires an international approach and proper international coordination. Other factors which play a key role in reducing the extent of the problem are: the effectiveness of transparent drug regulatory authorities, political willingness and proper governmental mechanisms, strict border as well as internal controls to stop the smuggling of pharmaceuticals, high public awareness on the issue and vast communication on the risks generated by the use of bogus and deliberately sub-standard medicines.

Furthermore, many less developed countries worldwide suffer from problems that are deeply rooted and that affect the fight against organised crime and fake medicines and the proper control of the legitimate pharmaceutical market. Widespread smuggling activities; opportunities for corruption; shortage of appropriate health facilities and health personnel; lack of training of the said personnel; lack of instructions to the national pharmaceutical associations leading to unsuitable storage of medicines in bulk and under inappropriate conditions; scarcity in government funding of the health sector; the weakness and fragmentation of the drug production and distribution control chain which results in poor

drug production and supply management and; the inefficiency of public awareness on the purchase and consumption of medicines in the majority of the cases, leading to irrational use of drugs are among the principal causes that attribute a persistent character to the problem in the majority of the less developed countries.

This context is not irreversible as there is much margin for the structural changes required for the improvement of the current situation at various levels: social, legal, normative, economic. Future steps to change the situation are inextricably linked with a responsible involvement and commitment of the International community to support changes in these countries and to help their action. Governments and policy makers have to realise that counterfeit medicines “amputate” the populations of many countries as well as their opportunities for human, social and economic development.

## **2.2 The Other Side of the Same Coin: Counterfeit Medicines in Developed Countries**

As stated several times, countries of the developed world are not exempt from the phenomenon. Certainly, meticulously established guidelines regulating the production and distribution of pharmaceuticals; rigorous borders controls; organised and coordinated consumers’ organisations; and empowered national and/or private surveillance services are deterring factors for counterfeiters willing to expand their illegal activities in such well-protected and securitised pharmaceutical markets. Many of these countries have strong national drug regulatory authorities and organised supply chains with highly trained pharmacists<sup>94</sup>. Laws, controls, investigations and reinforced detection capacities may undoubtedly be seen as the security valve for the protection of pharmaceutical markets across Europe, the United States of America, Canada, Australia, Japan, and other countries. It is for these reasons, that the presence of counterfeit medicines within the markets of developed countries is particularly restricted. This fact is confirmed by the statistics of the WHO, which estimates that counterfeit medicines do not exceed 1 per cent of market value in developed countries<sup>95</sup>. The presence of substandard drugs in developed countries’ national markets is also particularly low as the existing prevention mechanisms are quite strong and effective. This means that quality controls are stricter and there is general compliance with national and international goods manufacturing practice guidelines. Furthermore, in the case in which batches of substandard medicines are identified in the market, the great majority of developed countries have established alert mechanisms to recall the dubious batches and warn consumers. In addition, substandard medicines due to improper storage, transportation or negligence in checking the expiration date, are extremely rare. Nonetheless, these markets demonstrate some particularities or weaknesses that allow counterfeiters to infiltrate and exploit new opportunities. People in developed countries seek affordable treatments for various illnesses which are unfortunately too cheap to be true. People with health problems

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<sup>94</sup> BATE R. (2008), cited, p.4

<sup>95</sup> WHO (2006) (b), cited

that are considered taboos such as impotence or mental illnesses are more inclined to seek “discrete” and anonymous -- but inevitably uncontrolled -- sources of medicines. The market of “life-style drugs” is enormous and constitutes real incentives for counterfeiters to expand the criminal nexus of medicines’ counterfeiting.

A striking fact is that even in developed countries, the problem of counterfeit drugs still remains an underreported issue when compared to the actual magnitude of the problem. Most of the countries will only divulge information at national or regional level and according to the WHO, only 5 per cent of its members regularly communicate such information to the Organisation<sup>96</sup>. Moreover, and except for the IMPACT experience, the prevalent lack of an international framework for applied anti-counterfeiting strategies in this field does not help information sharing and communication. The only statistics and data on the issue stem from seizures made at the borders or within national territories. To a lesser extent they are also based on cases of deaths or serious damages which had a proven link with the use of counterfeit pharmaceuticals. Data provided by the European Commission show worrying trends for the years ahead. According to the TAXUD results of the 2008 *Report on EU Customs Enforcement of IPRs*, the number of cases of counterfeit medicines registered by customs’ authorities in 2008 presented a remarkable increase of 57 per cent from the number of cases registered in 2007<sup>97</sup>. The sector of counterfeit medicines had the fourth largest share of customs’ interventions (6.5 per cent), preceded by the textile, jewellery and electrical equipment sectors<sup>98</sup>. There was equally a significant increase not only in terms of customs’ interventions but also in terms of amounts of articles seized as, according to the same statistics, counterfeit medicinal articles presented an increase of 118 per cent in 2008 in comparison to 2007, preceded by CDs and DVDs and followed by cigarettes. Counterfeit medicines “now represent the third largest specific product category in terms of quantities of intercepted articles.”<sup>99</sup> Counterfeit Medicines figure also among the most frequently

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<sup>96</sup> BATE R. (2008), cited, p.5

<sup>97</sup> TAXUD (2009), *Report on EU Customs Enforcement of Intellectual Property Rights. Results at the European Border 2008*, p.11. Online. Available HTTP: [http://ec.europa.eu/taxation\\_customs/resources/documents/customs/customs\\_controls/counterfeit\\_piracy/statistics/2009\\_statistics\\_for\\_2008\\_full\\_report\\_en.pdf](http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/counterfeit_piracy/statistics/2009_statistics_for_2008_full_report_en.pdf)

<sup>98</sup> Ibid.

<sup>99</sup> More in detail, the conclusions of the TAXUD report in regards to the circulation incidence of counterfeit drugs in and out of the European external borders give a clear image of the growing frequency and scope of the problem, literally present in the EU: “*Significant increases were also recorded in this category [of medicines] which was also probably the most controversial product last year. This category, recorded the second greatest increase in articles and cases for different reasons [...]. The action targeted illegal medicines and led to over 32 million medicinal products being stopped by customs, of which more than 15 per cent were suspected of infringing intellectual property rights. Also, during the course of that action, more than 25 million items containing drug precursors were also stopped, equating to the production of 25 million street doses with an estimated value of 50 million euros. 50 per cent of all articles were intercepted in import procedures, 26 per cent in transit and 21 per cent in re-export. More than 93 per cent of all articles were intercepted on the suspicion of a trademark infringement and 6 per cent on the suspicion of a patent infringement [...]. Although 65 per cent of the cases were in postal traffic, these cases accounted for less than 2 per cent of all articles. Most articles were discovered by customs in air transport (more than 50 per cent) and, due to one large case, sea transport represented 36 per cent. The main category of medicines is the so-called life style drugs. In addition to countries of origin included in the top 3 of 2007, such as India and the United Arab Emirates, Syria now becomes the second largest supplier, mainly due to one large case in sea transport*”. TAXUD (2009), *Report*

intercepted products infringing patents, design and models.<sup>100</sup> On the other side of the Atlantic, the FDA considers that counterfeiting of drugs does not exceed 1 per cent of the prescriptions filled in the country every year but officials admit that these figures are simply estimates and are not based on scientific studies<sup>101</sup>.

Despite security measures undertaken to protect the distribution chain, counterfeit drugs are still likely to find ways to enter the legitimate supply chain. Brokers who act as middlemen between manufacturers and distributors have a great share of responsibility as they either intentionally conceal or simply ignore the real origin of the products they trade. The scandal of the counterfeit home diabetes test “OneTouch” strips imported into the U.S. from China in October 2006 is a good example of the obscurity of the role of brokering in the medicines’ distribution chain. Investigations revealed that the phony copies were produced in China without respecting the production quality standards and were then channeled through Canada to the United States of America. Bogus strips had also been found in considerable amounts in 35 other countries worldwide, including Greece, India, Pakistan, the Philippines, Saudi Arabia and Turkey. The defendants -- importers, brokers and wholesalers who were supplying the American pharmacies with the bogus stripes -- claimed that they had distributed the products because they wanted to achieve more competitive prices and that they believed the counterfeit strips were only lower-priced gray market products diverted from normal distribution channels<sup>102</sup>.

In Peru, the Association of Pharmaceutical Laboratories reported that the sale of counterfeit medicines rose from USD 40 million in 2002 to USD 66 million in 2006. In Lima alone, the amount of illegal pharmacies selling counterfeit medicines would have risen from 200 in 2002 to 1800 in 2007. More than 460,000 counterfeit or expired medicines were seized in 2005, according to the General Directorate of Medicines, Supplies, and Drugs.

On March 2007, the Israeli Customs Authority seized 11,820 fake Viagra and 800 fake Cialis pills along with several hundred other unidentified pills. The shipment arrived aboard a container ship which originated in China. If authentic, the seized pills would have been worth approximately USD 248,583<sup>103</sup>.

On February 2008, the police authorities in Singapore arrested a man after they had discovered approximately 2,000 counterfeit anti-impotence drugs in several raids. The value of the seized drugs was estimated at USD 144,000. The drugs contained 45 mg to 100 mg of *glibenclamide* (an anti-diabetic drug), which was several times higher than the normal

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on *EU Customs Enforcement of Intellectual Property Rights. Results at the European Border 2008*, cited, pp. 12-13

<sup>100</sup> TAXUD (2009), cited, p.19

<sup>101</sup> BROWN C. El. (2005), 'Pharmaceutical Fakery. Counterfeit Drugs Threaten Patients' Health', in *LongIsland Press*, 6 September

<sup>102</sup> For further information on the case, see DODDS A., RAPAPORT L. (2007), *China Counterfeit Diabetes Tests Tracked by J&J*, (last updated on 16 August 2007). Online. Available HTTP: <http://www.bloomberg.com/apps/news?pid=20601103&sid=a5XA7.yplw9k&refer=news>

<sup>103</sup> United States Pharmacopeia (2011), cited, p. 44

therapeutic dose of 2.5 mg to 20 mg. At least ten men in Singapore experienced adverse reactions after having taken the drug with one of the men even suffering a stroke<sup>104</sup>.

In summer 2008, customs officials in the Czech Republic seized and destroyed one ton of fake medicines in two towns of the country. Approximately 1 million pills were discovered by way of x-rays that examined incoming packages in the regular post. These packages were most often sent from China and India<sup>105</sup>.

According to the Director-General of Dubai Customs, more than 300 tons of imports containing counterfeit medicines were destroyed in 2007 in the United Arab Emirates. Customs officers in Dubai seized 5 million tablets of counterfeit Viagra and sedatives worth about USD 5,445,000 over the same year. In 9 January 2008, *7Days* reported that the United Arab Emirates was planning to set up a new federal agency to help counter the trafficking of counterfeit drugs. The Chairman of the Brand Owners Protection Group said that this was intended as a precautionary measure to prevent the counterfeit trade from growing, recognising that Dubai had become a “major transit shipment area.” The agency was foreseen to include representatives from health, customs and other authorities.<sup>106</sup>

On 30 October 2009, the Vice President of the Partnership for Safe Medicines in Mexico reported that they had discovered fake versions of Tamiflu being sold by vendors in Tijuana. The packaging mentioned that the product was “generic Tamiflu” but there was no such thing. Besides, the Mexican government possesses all Tamiflu in the country.

### ***2.2.1 Counterfeit Medicines and the Internet Offer: Legal, Rogue and Fake E-pharmacies***<sup>107</sup>

Besides enhancing legitimate production and distribution within the legal supply chain, the existing decentralised global trade system, together with its communication and technological facilities, can also favour illegal activities such as those related to counterfeit medicines. From the perspective of the counterfeiters, the possibility of exploiting a gigantic market characterised by an almost inexhaustible demand is an opportunity that can not be missed. These groups exploit recent developments in communications and new technologies in order to enter the market of medicines and offer their products.

The Internet has completely changed the way people approach their shopping. In e-commerce’s infancy, consumers could buy through websites only, with just a short descriptive text of the item to help them make their decision. Potential buyers often had trouble finding suppliers of the product they wanted on the internet. Many gave all their trust to just one e-company as long as they did not experience problems. Price was less important

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<sup>104</sup> United States Pharmacopeia (2011), cited, p. 54

<sup>105</sup> United States Pharmacopeia (2011), cited, p. 61

<sup>106</sup> United States Pharmacopeia (2011), cited, p. 57

<sup>107</sup> DI GIORGIO D. (2009), ‘E-pharmacies: a new market implies new dangers’ in DI GIORGIO D. (2009) (c) *Counterfeit medicines: facts and practical advice*, AIFA/EDQM Council of Europe publishing

than reliability when making a buying decision. Today fast internet connections are relatively inexpensive and the average consumer can easily access internet shops. Consumers can now buy any product and compare prices without leaving their home. With so many options, loyalty to any one supplier is eroding and price primarily motivates most purchasing decisions. As the Internet has grown in complexity, so have “e-shops.” These days, nearly every product a consumer could want is available online, including medicines. Many seem unaware of the risks of buying medicines online and sometimes approach their purchase as they would buying a CD, DVD or other product with no potential to harm them.

Obtaining data on sales volumes of e-commerce websites is challenging. According to data provided by services as Ranking.com and Alexa, however, the medicines market appears relatively small. The most popular e-pharmacy according to Alexa occupies the 2,000th position overall. The lack of big name suppliers or sites allows for the proliferation of shady brokers, resellers or even “phishers,” who aim to steal buyer credit card information.

The 2009 report “*Counterfeit medicines: facts and practical advice*”<sup>108</sup> accurately and thoroughly classifies the web’s medicinal offerings. The legal pharmacies are overwhelmed in number by rogue pharmacies selling uncontrolled medicines that may not comply with legal standards and regulations. Also sharing this space are fake e-pharmacies that use medicines as a bait for defrauding online buyers (e.g. ID theft and credit card cloning). In summary, legal operators compete with two types of criminal operators: illegal sellers and cyber criminals. According to the figures of the USA accreditation centre LegitScript, the number of legal, licenced e-pharmacies is under 1 per cent of the web offer, in terms of number of sites. The rest of the offer, according to many different independent studies is almost equally divided between fake and rogue websites.

Technological facilities and telecommunication means are playing a very important role and, in recent years, there has been a noticeable increase in the purchase of counterfeit medicines via the Internet, and in particular, lifestyle drugs<sup>109</sup>.

Lifestyle counterfeit medicines have become a scourge for the pharmaceutical markets of developed countries where the targeted consumers are people with a relatively high level of life and satisfactory incomes. However, counterfeit lifesaving drugs, such as treatments against cancer, heart diseases or HIV, are not excluded. Cases involving these products have been registered in relation with purchases from online rogue pharmacies and from other legitimate pharmacies which were completely in good faith.

Reflecting on the aforementioned “market strategy” of counterfeiters, an element that contributes to the difference in the geographical distribution of counterfeit medicines is the different types of diseases that affect developed and less developed countries, and the consequent adaptation by counterfeiters of the medicines they offer to the markets according to the prevalent need and demand. This implies that producers and distributors of counterfeit

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<sup>108</sup> DI GIORGIO D. (2009) (c), cited

<sup>109</sup> This category may include dietetics, anti-age products and treatments, medicines intended to improve the aesthetic appearance (for example anti-cellulite treatments), anabolic steroids and pharmaceuticals to improve male sexuality.

medicines are more “life-saving-oriented” within pharmaceutical markets in less developed countries. Lifestyle products, for instance, would not cause such a stir in less developed countries where priorities are different and concern almost exclusively lifesaving medicines. In recent years the Internet has become largely available also in many less developed countries, especially in those whose economies are experiencing a real boom. As these new technologies become more prevalent all over the world, a growing number of people may be tempted to rely on it to save money and get their medicines easily, often by circumnavigating the necessary verification and control procedures due to the lack of compulsory submission of prescriptions. These people may become an easy prey for the counterfeiters, who conceal their identity behind a well designed website reproducing an online pharmacy, especially if the potential buyer is not aware of the precautions they have to take when buying medicines over the Internet.

As mentioned before, there are by all means online pharmacies that do operate with transparency -- respecting national and international rules, and terms of distribution and sale of medicines, and whose suppliers are reliable pharmaceutical companies. However, this is only one side of the coin as there are many unscrupulous online businesses run by criminals who, hidden behind a well created website, try to fill the medicines market with dubious drugs that do not comply with any national or international standards. The WHO estimates that medicines purchased via the Internet are counterfeit in over 50 per cent of cases in which Internet sites selling the products hide their IP address<sup>110</sup>.

People suffering from several kinds of diseases, especially those illnesses that are seen merely as taboos (for example sexual or psychological problems), may turn to the Internet for medical advice and treatments. Moreover, the Internet offers possibilities of self-diagnosis and self-treatment for patients willing to bypass classic medical control. By consulting general information on illnesses, their principal or possible symptoms and suggested cures, patients may think that the solution to their problem is on the screen of their computer rather than through the consultation of a specialist. Without any prescription requirement and review, or any origin and quality guarantee of the product purchased, patients are defenceless. A characteristic example that shows how the cyber environment may contribute to the spread of counterfeit medicines is represented by an operation conducted by the FDA in which it was found that 85 per cent of the drugs that buyers believed were coming from Canadian pharmacies were actually coming from 27 other countries. In this case, original spam messages (e-mails sent in bulk for advertisement and promotion reasons) were sent from an address licenced to someone in the Russian Federation, the website server the counterfeiters were using was located in China, the credit card payee phone number was in the United Kingdom, the card payment was processed in Australia and the drugs were mailed from Chicago<sup>111</sup>.

In a similar case that took place in Italy, authorities along with the task-force IMPACT Italia asked the UK MHRA to support them in apprehending a shipment of suspect pills shipped by a rogue UK pharmacy. The two organisations eventually identified a complete distribution chain of counterfeit pills. A Swiss company managed the website though it

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<sup>110</sup> IMPACT (2006), cited

<sup>111</sup> CLARK E. (2008), cited

operated from U.S. and Canada servers. The UK address was simply a postbox for the “return to sender” envelopes, shipped from Germany, and containing Indian and Chinese medicines paid through financial transactions in Eastern Europe<sup>112</sup>.

The use of the Internet as a facilitator for the advertisement of counterfeit products has created an independent distribution process which directly targets final users. Ordinary distribution occurs in conjunction with the supply of drugs through the Internet and may result in the entry of illegal products into the legal distribution chain. For example, within the EU, a distributor which acquires goods from an unauthorised online source could become an entry portal for counterfeit medicines which, due to the single market, could then reach any destination within the Union.

Counterfeiters have exploited the Internet as an important channel of offer for products at both the retail and wholesale level. In the former, the consumer is effectively deceived through attractive and convenient prices and a constant stream of spam in their inbox which will link them to a legitimate looking Internet site where they can make their purchases. In the specific case of medicines, the site will not only state that the online pharmacy is authorised and registered in accordance with the law but may also request a regular medical prescription if it is usually required for the drug in question. This only serves to reassure the potential buyer who may then proceed with the purchase even without a medical prescription. Once the purchase is complete, the products will be sent directly to the patient’s home.

In the cases of wholesale sales, counterfeiters penetrate the distribution chain, through exploiting the fact that various distributors are constantly searching for low-cost products to maximise profits. Once the products are acquired by the distributors, they can be marketed as any other drug deriving from an authorised source and it will be almost impossible to trace their origin.

Due to the impersonal nature of online commercial exchanges, the Internet guarantees anonymity. Consequently, the investigations implemented by law enforcement officials are considerably more difficult and, as a result, the risk of being subject to sanctions, seizures of goods or criminal proceedings becomes lower for criminals. Counterfeiters have obviously grasped this opportunity. In 2004, an investigation of various Internet sites and the pharmaceutical distribution chain was implemented by the United States Immigration and Customs Enforcement (ICE). The investigation showed that primary Internet sites could rely upon an additional 650 affiliated sites and that the total value of distributed counterfeit drugs was equal to 25 million USD. Furthermore, an unauthorised distribution network for medicines was discovered that originated in India and extended throughout North America. A similar case occurred within the EU when, in 2001, a criminal group created a network of online rogue pharmacies. The online structure of this network allowed the potential buyer to choose from a large number of links to other sites which offered counterfeit drugs from various pharmaceutical companies. This generated significant business volumes by importing large amounts of counterfeit medicines from Asia in order to retail them in Europe by means of the regular postal service.

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<sup>112</sup> AIFA, unpublished information

Recent researches carried out by different actors, as the ones conducted independently by the Italian Ministry of Economic Development and the Italian Medicines Agency (AIFA), show that consumers have changed how they approach buying medicines online. In the early days, many patients using web pharmacies did not know that the rogue shops they were buying from were set up illegally and they were deceived by rogue sites feigning authenticity by imitating logos and features of legal ones. Today most customers of websites like these understand the site is illegal. However, even if they are aware that they are buying a medicine from an illicit source, these customers are still largely unaware of the risks associated with counterfeit medicines, in particular for what concerns long term side effects caused by impurities, contaminants and improper active ingredients used by “rogue manufacturers.”<sup>113</sup> Information to potential buyers in this regard would certainly support a better understanding of the phenomenon and of the risks it creates.

A general difficulty encountered in estimating the magnitude of -- and the consequences created by -- counterfeit medicines in general lies in the fact that in a considerable number of cases the side effects could be unreported, considering that the adverse reaction or death deriving from the unconscious use of a counterfeit medicine are often not attributed to the real cause. In other cases, shame or embarrassment on the part of the consumer could prevent them from reporting the case to the competent authorities. Furthermore, it is rare that authorities investigate whether a medicine causing side effects was original or not. However, without proper investigations, the side effects caused by a counterfeit medicine would be attributed to the original medicine and not to the fact that the patient used a counterfeit one, further contributing to the “underreporting” of cases.

All this is worsened in cases of distribution through Internet. The International Narcotics Control Board (INCB) -- the United Nations (UN) body entrusted with regulating the circulation of drugs subject to controlled distribution -- recently expressed its concern with regards to the growth of the Internet as a non-regulated market for the distribution of drugs and pharmaceutical products<sup>114</sup>. A recent article on the Internet site [www.medicalnewstoday.com](http://www.medicalnewstoday.com) reported the first death in Canada as a result of the use of counterfeit drugs acquired through an online rogue pharmacy. Clear regulations regarding e-commerce of medicines do not yet exist in most countries. The forthcoming amendment of the EU Directive 2001/83 will change the situation in the European Union countries in the next years. However, a long period of harmonisation may be necessary to create a path to a better structured market.

At the current stage, regulatory authorities find it difficult to standardise this market as it is not localised in a single country. In addition, any limitations on domestic e-pharmacies could be considered hindering the free circulation of goods. The judgments handed down by the European Court of Justice (ECJ) in the *Doc Morris* case (case C-322/01)<sup>115</sup> focused on the need to ensure the safety of medication and regulation of sufficient pharmacy services.

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<sup>113</sup> DI GIORGIO D. (2009) (c), cited p. 107

<sup>114</sup> INCB (2010), *Report of the International Narcotics Control Board on the Availability of Internationally Controlled Drugs: Ensuring Adequate Access for Medical and Scientific Purposes*

<sup>115</sup> DI GIORGIO D. ed. (2011) (c), p. 127, 137

According to the judgments, the running of an e-pharmacy requires the fulfillment of the following health-relevant safety standards as a pre-requisite:

- simultaneous operation of a mail order pharmacy and a community pharmacy;
- quality assurance programme ensuring proper packaging, transport and delivery;
- delivery to the person placing the order or a person designated by them;
- warning that people should consult their general practitioner in case of health problems;
- supply of medicines authorised for market;
- risk reporting system (e.g. by including a note on websites on how risks can best be reported);
- consignment tracking system.

On 5 September 2007, the Committee of Ministers of the Council of Europe adopted the Resolution Res AP (2007) on good practices for distributing medicines via mail order to protect patient safety and the quality of the delivered medicine. This resolution is a major breakthrough to protect patient safety and the quality of the delivered medicine, as no specific quality and safety standards for the mail-order trade in medicines exist. The standards recommended to the Member States for implementation into their national legislation by the Resolution include, among others:

- responsibilities for, and methods of, delivery;
- provision of appropriate counseling and information disseminated to patients;
- mandatory transfer of information regarding adverse effects, interactions, warnings, recalls and quality defects of mail-order medication both to and from the patient;
- supply only of medicinal products authorised in the country of destination;
- exclusion of unsuitable medicines from the mail-order trade;
- marketing and advertising of mail-order services;
- handling of prescriptions for mail-order trading in the case of prescription-only medicines;
- facilitation of international co-operation.

The standards included in the Resolution could be an inspiration for globally applicable “quality tools” to protect patients. However, cooperation among countries of different geographical areas will continue to be of paramount importance. The main reason is that countries that will adopt the Resolution can attempt to apply these standards only to the e-pharmacies located in their area while the majority of pharmacies available on the Internet operate via servers located in the USA or in Asia, leaving to international cooperation still a very important role to play.



### **3. THE PILOT STUDY ON SPAM AND FAKE E-PHARMACIES**



The analysis of criminals' operational patterns is extremely important to better grasp the strategies used to sell counterfeit medicines through illicit online pharmacies and to offer them via spam messages. The AIFA and the Italian Ministry of Economic Development dedicated a study to the first aspect, identifying the various techniques used by the criminal organisations engaging in imitations of e-pharmacies (cybercrime) and rogue e-pharmacies (dealing with illegal trade of medicines and counterfeiting).<sup>116</sup> The results of the first part of this study underlined some peculiar aspects of these organisations:

- the “rogue e-pharmacy” scheme could be seen as a network of specialised organisations, cooperating on a single case basis when mutually beneficial. The study underlined the existence of different specialised activities necessary to the promotion of the market of the rogue e-pharmacies: for instance, the development of “dormant” sites, hidden in the websites of universities and other reliable entities. These inactive websites are developed and left on the web to gain “reputation” on the search engines, before selling products to the targeted organisation. The different activities in this supply chain could be considered as “independent fragments” of the framework: large criminal networks engaging in various illicit activities are not the most reliable model, in fact the most used paradigms are “light cooperation business scheme” facilitated by the web between actors specialised in a single step of the chain (e.g. manufacturing medicines, distributing medicines, developing hidden websites, recruiting and promoting new websites).

- the “fake e-pharmacy” scheme utilises copious amounts of websites, a “spiderweb”, to attract “victims.” The goal is to infect victims' computers with a viral tool (a Trojan file, for instance), in order to steal valuable data (i.e. the ID or the credit card details). These websites can be efficiently promoted through spam campaigns using keywords related to recent health crisis (as in the case of the “swine flu” frenzy in 2010). Cybercriminals looking for new customers use the health crises in a timely and efficient manner, by launching spam campaigns in real time promising the access to the demanded medicines. They may be timely, since for them it is not necessary to manufacture and distribute the medical product requested from the market. Inserting the name of the medicine in the spam mails is enough to attract customers to the “fake websites.”

UNICRI, in collaboration with the International Telecommunication Union (ITU), decided to contribute to the ongoing researches by characterising a specific activity, mostly related to the “fake e-pharmacies”: the SPAM advertising.

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<sup>116</sup> DI GIORGIO D. (2010), *Farmaci contraffatti: il fenomeno e le attività di contrasto*, AIFA-Tecniche Nuove, AIFA/EDQM publishing, p. 182; DI GIORGIO D. ed. (2011) (d), *Counterfeit medicines*, AIFA/EDQM publishing: 2011, p. 145

### **3.1 Counterfeit Medicines and Online Advertisement: an Attempt to Understand the Logic of Spamming**

Nowadays, technology frames almost every activity. Millions of people around the world have at least one mobile phone as well as one computer desktop or laptop, or sometimes even both, and each of these technological devices have connections to the Internet. Due to its worldwide diffusion, the Internet is also becoming one of the main means for criminals to commit illegal activities quickly and easily, with a low probability of being detected. Consequently, since the early 1990s, the number of cyber threats and crimes has grown exponentially.

Seizures conducted worldwide show an increasingly stronger connection between counterfeiting, organised criminal groups and online activities and there are a considerable number of cases in which counterfeiters' profiles perfectly match those of criminals belonging to organised crime. There is little doubt that counterfeiting of any kind of goods is strongly linked with other forms of criminal activities performed by organised criminal groups and the Internet is a major facilitating factor. As we have seen in the previous pages, counterfeiters have exploited the Internet as an important channel of offer for products at both the retail and wholesale level. In the former, the consumer is effectively deceived. Attracted by convenient prices and driven by the constant stream of spam in their inbox, the potential buyer will start browsing an Internet site which is generally structured to appear legitimate.

The Internet has been a veritable evolution for what concerns the diffusion and exchange of information. Among other commercial activities that found a real opportunity for expansion via the Internet, the business of advertisement equally took advantage of the border-free communications and sharing of information that this network could offer. Basic advertising and marketing rules are also applied in the case of online advertisement: the number of people that will be aware of and will eventually buy the advertised product strictly depends on the advertiser's capacity to promote the product as much as possible as well as on their ability to make it easily accessible. As advertisement spots on radio, television, newspapers and public placards are costly, online advertisement has emerged as a quick and no-cost way to advertise a product around the world.

The Internet offers big advantages in terms of free and unlimited access to information and of the spread of the latter. However, this is also connected with the uncontrolled and unverified nature of the information displayed on the computer screen and of what stands behind what is visible to the user. It is undeniable that medicines sales via the Internet multiply the risk of buying bogus pharmaceuticals, as there is very little possibility of quality and source control. According to various estimates, half of the medicines sold online could be counterfeit. In China or in India it costs roughly USD 0.05 to produce sildenafil citrate (sold as Viagra) which can then be sold over the Internet for USD 3.00. This means a profit

of 6,000 per cent which can reach 20,000 per cent if the product is introduced in the regular pharmaceutical circuit<sup>117</sup>.

There are legal online advertisement on one's own webpage, through mailing lists in which users have voluntarily signed up or through newsgroups and newsletters. We can also mention the "affiliate marketing", the process in which a product or service set up by someone is sold by another active seller for a share of profits. The owner of the product normally provides the seller with some marketing material (e.g. sales letter, affiliate link, tracking facility) to ease the diffusion of the information related to the product.

Spam, the method of abusing electronic messaging systems to send unsolicited bulk messages in an indiscriminate way, represents the dark side of online advertisement. Spam plays a crucial role in the advertisement and diffusion of counterfeit medicines. It is about an easy, cheap, anonymous and obscure way of products promotion, especially when the latter are of dubious origin and quality. It is unlikely that dubious Internet sites trade from where they claim to do. The case presented in *paragraph 2.2.1* is relevant to highlight the network behind a spam message received in an e-mail inbox.

Spamming has a great share of responsibility in the trafficking of counterfeit medicines via the Internet because it works as an advertisement and promotion mechanism. These unsolicited e-mails contain identical messages sent in bulk to numerous recipients simultaneously. They have the advantage of little or even no cost in creating and carrying a piece on advertisement online, targeting at the same time a large audience without geographic limits<sup>118</sup>. The ease with which spammers operate together, as well as the high level of impunity that accompanies operations, has meant that spamming has become a large and very profitable advertisement industry run by hackers, spammers, online advertising sites and obscure companies with doubtful products. Although spammers and spam companies work on the promotion of any product or service that can give a profit, there are some products and services that figure in their "preference lists" due to their extreme level of demand and popularity. Medicines and drugs are at the top of this list. Their production, distribution and availability for public consumption are not only extremely sensitive issues but also an appealing lucrative market for counterfeiters and spammers. It is for this reason that counterfeit medicines are among those products that are commonly advertised through spam. This way of advertisement can be equally preferred by organised criminal groups involved in the production and distribution of counterfeit medicines as it offers the secrecy, anonymity and coverage that organised crime needs to minimise the possibilities of detection. Spammers can stem from organised criminal groups or can cooperate with them in the advertisement process. Notwithstanding spammers' status, they may be considered as part of organised criminal activities as long as they are involved in one way or another in advertising counterfeit products. It is not difficult to deduct essential information about the magnitude and the tremendous consequences spamming has in the field of medicines' advertisement and sales. The problem is that spamming is unfortunately omnipresent, littering the e-mail boxes

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<sup>117</sup> Fondation Chirac (2009), *Access to Quality Medication and Healthcare. Mobilisation Campaign against Falsified Medicines*, Actions-2009, p.8

<sup>118</sup> SPAMMER X et al. (2004), *Inside the Spam Cartel: Trade Secrets from the Dark Side*, Syngress Publishing, p. 450

of millions of Internet users worldwide and trying to market dubious products that promise cure of male dysfunction, diet pills, slimming creams, treatments for hepatitis, painkillers and anti-inflammatory treatments and various other doubtful pharmaceutical products promising quick cure for different illnesses or extraordinary results for physical improvements.

Pornographic material and services were originally the most popular spammed material in the early days of the Internet<sup>119</sup>. Nonetheless, things took a new turn by the time Viagra was invented, and it quickly became the most spammed product worldwide. Troubles stemming from Viagra spamming reached such an extent that Pfizer, the authorised manufacturer, announced on 10 February 2005 that it filed 17 parallel lawsuits together with Microsoft against two international pharmacy spam rings operating websites that allegedly were selling illegal, purportedly generic versions of Pfizer's erectile dysfunction medication, Viagra<sup>120</sup>. Other civil lawsuits had been filed by Microsoft against physical persons who were allegedly acting as spammers advertising from those websites while other 10 Uniform Domain-Name Dispute-Resolution Policy (UDRP) actions had been filed by Pfizer against heavily trafficked websites in order to seize names involved in the use of Pfizer's trademark in an unauthorised manner<sup>121</sup>. This was the result of a 7-month investigation operation that the two business entities jointly undertook in an attempt to dismantle illegal online advertisement and distribution rings which were abusing Microsoft's electronic msn® and hotmail® addresses in promoting a product.

The joint action undertaken by these two worldwide leading companies has been a very encouraging sign of the private sector's determination to impede the misuse of Internet for illegal purposes. Nevertheless, there are thousands of other companies that have to deal with spamming on a daily basis who are not able to mobilise all the human, technological and financial resources that are required to track and detect cases of spamming as, for example, Microsoft and Pfizer did. In any case, companies worldwide invest a lot of money on the protection of their IT systems against spamming through "filters" that use complex statistical algorithms (which can analyse received e-mails and block the spam). Nonetheless, while IT security companies and laboratories are trying to invent new and improved versions to counter the phenomenon, spammers will always try to break the anti-spamming systems in place.

But why does spamming seem invincible? Who are those behind this illegal business and in what way is this nexus structured? How do spammers adapt their competencies upon their principals' requests? How are Internet users identified and targeted by spammers? Could we talk about differentiation of spammed products online according to specific characteristics of the recipients of these unsolicited bulky electronic messages? In short, how does the logic of spamming work?

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<sup>119</sup> Ibid.

<sup>120</sup> Information online. Available HTTP:

<http://www.microsoft.com/presspass/press/2005/feb05/02-10mspifizerpr.mspx>

<sup>121</sup> Ibid.

## **3.2 Tracking Spam to its Source with Forensic Analysis Methods: a Pilot Study on Spam and Medicines Online**

### **- The general context of the study**

In an effort to give answers to these questions, among others, UNICRI -- with the support of the ITU and in collaboration with Mediaservice<sup>122</sup> -- implemented a pilot study to analyse spamming with regard to pharmaceutical products that are advertised and can be ordered online. The core purpose of this pilot study was to identify what is behind spamming, and try to understand if there is a nexus between a specifically targeted spam message (namely a person and the entity for which this person works) and the typology of received spam. In a nutshell, the main steps of the study can be summed up in spam data-mining with a view to profiling spammers, which could help to understand the followed business model and the criminal chain through a particular focus on spam typology including online offers and advertisements of medicines and pharmaceuticals. Based on these elements, the objectives of the study were to understand when and why the spam message changes; the frequency with which the spam message is displayed and how the targeted user's e-mail address was found.

If the existence of a veritable strategy behind spamming could be proved, then the entire spamming activity could be read under a different perspective. It would not be a simple and indiscriminating "sending" of good offers to lure a potential purchaser. Rather, it would be the result of a collection of information on the potential buyer allowing the spammer to offer exactly what the potential purchaser is looking for. This also sheds new light on the role of the spammer as an advertiser of a range of illicit goods and services, as this role could be better put in the framework of a wider criminal scheme. Who is rendering the advertised products and services available after the potential consumer has been lured? Most of the time, the reply to this question is organised crime.

The practical idea from which this pilot study emerged was to identify spam messages received by a user and to understand if and in what way spam e-mails could be linked to their receiver -- i.e. whether there are background motivations, user's attitudes and activities and/or company's<sup>123</sup> approaches to IT Security conceived and implemented in an erroneous way. Through this tracking process, the study aspired to uncover the "business model" that is behind the sent spam messages and all the actors -- namely the vendor, the "sales agent" (the spammers themselves) and other intermediaries (hackers and unscrupulous Internet services companies) involved.

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<sup>122</sup> Mediaservice is an IT Advisory Security Company based in Turin, Italy.

<sup>123</sup> As described above, the study was settled on the correlation between an employee-user, the company for which the user works and the type of spam e-mails the user receives. Here the "work entity" is UNICRI which was the tested entity; "user" is selected group of UNICRI's e-mail accounts and; "type of spam e-mails" the messages that had to do with pharmaceutical products.

The research started to verify a specific case study, based on the assumption that spam somehow follows Internet users. For the purposes of the study, employees of the same working entity were considered as the target group, their professional e-mail accounts were tracked and their professional activities were taken into consideration. The main purpose consisted in proving that there was a connection between the employees' professional activities (especially the travels they had to do for work reasons and other issues related to these travels -- i.e. location, logistical arrangements, and purpose of travel) as well as the kind of spam they were receiving before and after these travels.

The methodology used for the implementation of the study was based on variant sources of information. By analysing the user's profile, as well as the spam, the study was able to establish a connection between a certain kind of spam messages and the users who received these messages. Combining the same information on other employees belonging to the same work entity made it possible to develop the first profile-based prototype of a spam tracking model. Although the study was carried out within a relatively short timeframe, the outputs proved that spam e-mails are not (totally) sent on a random basis. Different people working for the same entity began to receive a specific kind of message after they had faced a same experience or after the same event occurred to all of them.

This pilot study revealed that the messages -- and the products/services offered through them -- were progressively changing according to the "profile" of the possible buyer, namely according to the interests, contacts and activities performed. Specific web searches or missions to countries modified the offers and messages received in a way that was clearly linked to what we were doing in our daily work. A mechanism of some sort (spywares or similar) is utilised by spammers to retrieve information on what we do and what we are looking for. The demonstration of this user-message connection and the wide range of products offered is a clear indication that organised criminals are using this means of advertisement to expand their potential market and that, if we think of the criminal organisation as a veritable illicit enterprise, the spammer has a role that is very similar to that of an advertising department in licit enterprises.

In this sense, the outcomes of this pilot study have been particularly interesting and it is hence worthwhile to see how the research was carried out and the consecutive results that this research achieved.

By applying this model to an entire work entity (company, organisation, institute etc.) it could assist in identifying how, and from where, spam is delivered, whether there is a criminal nexus behind it, and which business entities collude in dealing with spammers by pooling information and misusing sources of sensitive data (hotels, travel agencies, conferences organisers, etc).

### **- Outlining spam**

Spamming is undoubtedly one of the most widespread illegal actions committed over the Internet. It would be worthwhile to have a look at some statistics to better demonstrate the magnitude of the problem. According to a *Gartner* research, in 2007, "spam volumes as a

percentage of e-mail will continue to grow, but they will be increasingly erratic as spam campaigns become more concentrated. 85 per cent to 90 per cent of all e-mails that most organisations receive is spam.”<sup>124</sup> According to Steve Ballmer, Microsoft’s chief executive, the company’s chairman Bill Gates receives four million e-mails every day, most of which is spam<sup>125</sup>.

The term “spam” is used to describe the abuse of electronic messaging systems to send unsolicited bulk messages indiscriminately. It is important to note however that this definition is often misinterpreted, because it is not clear that a message has to be both unsolicited and bulk to be classified as spam. “Unsolicited” means that the recipient has not granted verifiable permission for the message to be sent. A message is considered “bulk” when is sent as part of a larger collection of messages, all of them having identical content. An example of unsolicited but legal e-mail could be a first contact enquiry or a job enquiry. A bulk but authorised e-mail could be subscribers’ newsletters or customers’ communications. Therefore spam is a problem of consent, not content. If a message is sent unsolicited and in bulk it does not matter if the content was an advertisement or a so-called “first contact letter” type, it is irrelevant, while the message itself is always marked as “spam.” This is an important element to understand because legislators in many countries spend considerable time as well as human and financial resources in an attempt to regulate the content of e-mail messages, possibly contributing to undermine, in such a way, the freedom of speech<sup>126</sup>.

Spam has been conceived as a very discrete but influential way of advertisement. There is a psychological aspect underneath that makes spam an incontrovertible way of advertisement, especially for some specific products such as medicines against male dysfunction (Viagra, Cialis, etc.). In these cases, the aim of the spammer is to exploit the weaknesses of the consumer-“victim” and to take advantage of his taboos. There is no need to go to a pharmacy in person and experience embarrassing situations when the solution can come from the e-mail box: cheap Viagra that can be bought anonymously via the Internet, accompanied by promises of amazing performances.

Many companies selling products online have an area reserved for those who want to collaborate with the company on advertising. The prospective advertiser has to sign a collaboration contract where it is always clearly stated that “spam is prohibited as a way of doing advertisement” and that “the company will not pay back those customers who will buy its products/services following advertising through spam e-mails.” Nevertheless, in the majority of the cases companies check only partially, or do not check at all, if somebody spammed their products because the company will, more or less explicitly, make money out of this. Hence, all a spammer has to do is to find the company that offers the highest

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<sup>124</sup> FIRSTBROOK P. (2007), ‘Benchmarking Anti-spam Effectiveness, Gartner’, 18 September, in *Securing the Network from Spam, Malware and other Threats. A Strategic Overview Featuring Gartner Content*, 3<sup>rd</sup> issue, Clearswift. Online. Available HTTP: [http://www.clearswift.com/\\_data/assets/pdf\\_file/0020/3674/Clearswift\\_issue3.pdf](http://www.clearswift.com/_data/assets/pdf_file/0020/3674/Clearswift_issue3.pdf)

<sup>125</sup> BBC News, *Bill Gates 'most spammed person'*. Online. Available HTTP: <http://news.bbc.co.uk/2/hi/business/4023667.stm>

<sup>126</sup> Information online. Available HTTP: <http://www.spamhaus.org/>

percentage for every new user that will subscribe to the company's services or buy its products, make a list of e-mail addresses, compose the e-mail, and send it out in bulk.

Following this process, the spammer first chooses the product or service they want to spam: luxury watches, medicines, etc. The next step is to reach an agreement with a website that deals with this kind of products. This is typically done by filling-in an online module that can be found on the advertising company's website. Then, the spammer receives from the company a web address that redirects them to the company's online products catalogue. This web address contains a unique identifier which refers to the spammer and allows the company to know who has to be paid commission for a certain product that was sold. That web address is the one that will be displayed on the spam message. After the product and the online advertisement company have been identified, it is time to decide from where to be provided with the necessary e-mail addresses of the recipients and potential clients of the chosen product. Lists with e-mail addresses are normally sold between crackers and spammers; within a range of USD 100 and USD 1,000 it is possible to buy a package of one or two million e-mail addresses most of which are verified and known to be working. In every group of spammers, there is always at least one person with hacking capacities and "responsibilities." This person is in charge of hacking targeted websites and retrieving users' e-mail addresses from these websites' databases. If this person manages to hack a site that offers medicines and healthcare products for instance, the users that access this website are very likely to buy the products displayed on the spam e-mail. Now, how will the company be able to know who are those who will subscribe to their services thanks to the e-mails that were sent? Each "advertiser" has been assigned with a "track id", for example, 12345. Every time a buyer accesses the website at the URL <http://www.medihealth4u.com/?tid=12345><sup>127</sup> and successfully visits and buys from it, the spammer will receive the agreed percentage.

So, the junk e-mail will be now composed by an image (a pill, a medicine's bottle or a drugs package for example) that will catch the attention and the curiosity of the recipient and which could look like this:

```
<html>
<head>
<title> Would you ignore your well being? </title>
<body>
<img src=http://323.323.323.323/picture.jpg>128
<a href=http://www.medihealth4u.com/?rfid=piu1200> Bet you won't find cheaper. </a>
</body>
</html>
```

---

<sup>127</sup> The URL mentioned here is invented and is used as a case in point.

<sup>128</sup> All the components of the message are intentionally false.

An example of a junk e-mail dealing with medicines could be made up of just an image where all the relevant information is written. By doing so, it is possible to avoid anti-spam filters that identify and prevent spam messages from appearing on the user's screen based on "dirty-word lists." In the case of an image-made e-mail the software detects only an image as the words the user will read are just part of the image. Therefore if the link to which the picture refers is not blacklisted, the e-mail will pass through the anti-spam filters because, just as an example, the word "Viagra" is not part of a text that can be parsed and analysed.



Once the e-mail is composed, the spammer is ready to send it. To deliver the spam they can use a programme like "Dark Mailer."<sup>129</sup> Dark Mailer is commercial software designed for sending unsolicited bulk e-mail. The software taps into a network of zombie computers and is able to send 50,000 e-mail messages per hour from a regular cable modem connection. Near total anonymity is granted. After having sent the mail, the spammer has just to wait for his "victims" to click.

### - A step behind spam: analysing the spam e-mail

An e-mail message is composed by a "header" and a "body." The header contains, among other information, details about the sender, the route and the receiver. From these pieces of information we should be able, in theory, to retrieve the whole route of the e-mail, from the sender's IP address to every e-mail server that managed the communication. Useful header fields are:

<sup>129</sup> Dark Mailer is a controversial [bulk e-mail](#) sending software that relies on [zombie computers](#) to send e-mail messages. Although there is no official website to download the programme, there are many websites where free versions of Dark Mailer can be downloaded but which in most of the cases compromised thus unreliable.

- *From*: the e-mail address and optionally the name of the sender.
- *To*: the e-mail address(es) and optionally the name(s) of the message recipient(s).
- *Subject*: a brief title that describes the content of the message.
- *Received*: the track information generated by e-mail servers that have previously handled a message, but in reverse order (starting from the last handler) and.
- *Date*: the local time and date when the message was sent.

From the analysis of the fields of the e-mail header it could be possible to track the message. This sort of analysis shows how tricky tracking a spam e-mail can be and how easily a message header can be forged leading to the assumption that an e-mail header is unreliable.

Figure 2 contains an example of tracking down a spam e-mail message<sup>130</sup>. It represents a standard forged e-mail header.

**Figure 2: Example of an e-mail forgery**

```

From webpromo@denmark.it.earthlink.net Tue Jul 8 13:05:02 2009

Return-Path: <webpromo@denmark.it.earthlink.net>

From: webpromo@denmark.it.earthlink.net

Received: from denmark.it.earthlink.net (denmark-c.it.earthlink.net [204.119.177.22]) by best.com (SMI-8.6/mail.byaddr) with ESMTP id NAA21506 for <falk@falconer.vip.best.com>; Tue, 8 Jul 2009 13:05:16 -0700

Received: from mail.earthlink.net (1Cust98.Max16.Detroit.MI.MS.UU.NET [153.34.218.226]) by denmark.it.earthlink.net (8.8.5/8.8.5) with SMTP id NAA12436; Tue, 8 Jul 2009 13:00:46 -0700 (PDT)

Received: from healthpromo@earthlink.net by healthpromo@earthlink.net (8.8.5/8.6.5) with SMTP id GAA05239 for <healthpromo@earthlink.net>; Tue, 08 Jul 2009 15:48:51 -0600 (EST)

To: healthpromo@earthlink.net

Message-ID: <199702170025.GAA08056@no-where.net>

Date: Tue, 08 Jul 09 15:48:51 EST

```

<sup>130</sup>E-mail addresses have been changed in Figure 2 to better illustrate an example of forged e-mail that deals with medicines. The initial example is available online: <http://www.rahul.net/falk/mailtrack.html>

Subject: Medi- News!

Reply-To: [healthpromo@earthlink.net](mailto:healthpromo@earthlink.net)

X-PMFLAGS: 12345678 9

X-UIDL: 1234567890x00xyz1x128xyz426x9x9x

Comments: Authenticated sender is <healthpromo@earthlink.net>

Content-Length: 672

X-Lines: 26

Status: RO

- The **To:** line is apparently forged; the actual recipients list was hidden, probably with a blind carbon-copy (Bcc: header).
- The **From: Return-Path:** and **From:** all identify the same e-mail address but may be forged. A solution could be to try to complain for the e-mail received by replying to the e-mail address indicated and check out if the e-mail was delivered or if it bounced because the e-mail address simply does not exist.
- The **To:**, **Reply-To:** and the **Authenticated sender** lines all identify a different account. Again, these may all be forgeries.
- The **Message-ID:** line is obviously falsified.
- The first **Received:** line shows that the mail arrived at the service provider from *Earthlink*. If we decide to trust the service provider this line is almost certainly valid.
- The second **Received:** line though, shows inconsistency:  
... from mail.earthlink.net (1Cust98.Max16.Detroit.MI.MS.UU.NET [153.34.218.226]).

In other words, the machine that delivered the mail to *denmark.it.earthlink.net* identified itself as *mail.earthlink.net* but was actually named *1Cust98.Max16.Detroit.MI.MS.UU.NET*. This is very likely false. However, *Earthlink*<sup>131</sup> rents POPs<sup>132</sup> from *Unet*<sup>133</sup>, so this might be an *Earthlink* customer dialing in from *Unet*.

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<sup>131</sup> *Earthlink* is an Internet Service Provider. Online. Available HTTP:: <http://www.earthlink.net>

<sup>132</sup> *Post Office Protocol* (POP) is an Internet standards used for the retrieval of e-mails from a remote server using a TCP/IP connection. Its earlier versions POP1 and POP2 are practically obsolete and this made POP3 (the latest version) to be the current standard. For further information, see the discussion paper on POP3, available online: <http://www.ietf.org/rfc/rfc1939.txt>

- The third **Received:** line is entirely bogus. If the e-mail had come from a dial-in customer at *Unet* there would not have been any more **Received:** lines. If the e-mail had been relayed from *Unet* this **Received:** line would indicate *Unet*, not *Earthlink*. Finally, this **Received:** line contains e-mail addresses, not machine names.

In other words, this e-mail was forged to look as if it came from *Earthlink* but was actually injected from *Unet*. Whether this was by an *Earthlink* customer or some other *Unet* customer is impossible to tell without co-operation from *Earthlink sysadmins* (system administrators).

From the above it can be deduced that extracting reliable information from e-mail messages' analysis is not as easy as it may seem. Due to the structure of the message and the e-mail protocol it is very easy to forge the information contained in an e-mail header. As the field of an e-mail header is easily forgeable, spammers often do it. Trying, therefore, to track down a spam e-mail is rarely 100 per cent useful since we analyse, most of the times, fake information.

To do a basic statistical analysis we can have a look at the e-mail body which is the real content of the message. After having performed the profiling of the people targeted by the study by analysing the body of the e-mails they received, it is then possible to retrieve useful information such as which kind of spam a person receives after having visited a certain country or attended a certain conference and then compare the spam of their inbox with that of other persons who had been to the same place or to the same conference. By intersecting these results, one is able to tell the source from which the spammer pooled the targeted e-mail addresses. If, for instance, after having been at the same hotel, two people start receiving the same spam messages the database of the hotel probably has some security breaches or the agency that booked the hotel (or somebody related somehow to the hotel) is involved in the spam market.

### **- The pilot study: technical components and outcomes**

This paragraph discusses the technical component of the pilot study focusing mainly on the methodology and the technology that were chosen, the technical details of the programming language used and the database structure.

For a comprehensive statistical analysis of the spam messages, an inverted index of all e-mail bodies was created to perform a *TermFrequency* analysis. This allowed to retrieve the spam typology of every person from a rank of the most common words that were included in the received spam messages. Along with this, all the messages were stored in a database. By combining these two solutions it is possible to first conduct an analysis of the terms and draft

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<sup>133</sup> *Unet* was one the first and largest Internet Service Providers and was the first one to offer this kind of services to business and commercial entities. Today, *Unet* is an internal brand of Verizon Business. Online. Available HTTP: <http://www.uu.net> (the webpage redirects to Verizon Business webpage <http://www.verizonbusiness.com/solutions/wholesale>)

a list of the spam received, and then by using the keywords found, ask the database to match up the data to the users' profiles information. For example, on date X user A went for a conference to State Y. From the *TermFrequency* analysis it is known that the typology of spam messages user A receives is predominantly pharmaceutical and sexual. Therefore, it is possible to check out if this kind of spam started mainly after the date X and identify State Y (and the contacts related to this trip) as the likely source of a certain type of spam for user A.

After having received almost 110,000 e-mail messages, the first step was to write some perl<sup>134</sup> scripts to parse these messages. Each script just splits every message in its two major components, the *header* and the *body*. Hence, for each "message.mail" it creates "message.mail.body" and "message.mail.header." This is because we meant to do a *TermFrequency* analysis only of the content of the messages so it was better to exclude the headers from the index.

The second script parses every message and extracts useful data to fill in a database *MySQL*<sup>135</sup>. This database contains an entry for every e-mail with the following fields:

- ***Id***: auto increment integer, the primary key;
- ***File***: the name of the file (for example, "message.mail");
- ***User\_name***: name of the user who receives the e-mails;
- ***Date***: the date in which the e-mail was sent;
- ***IP\_sender***: sender's IP address (not used for this phase of the study);
- ***IP\_sender\_location***: geographic location of the sender's IP address (not used for this phase of the study);
- ***IP\_1st\_remailer***: first e-mail server IP address (not used in for this phase of the study);
- ***IP\_1st\_remailer\_location***: geographic location of the first e-mail server IP address (not used in for this phase of the study);
- ***Header***: e-mail's header;
- ***Body***: e-mail's body;
- ***Subject***: e-mail's subject;

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<sup>134</sup> *Perl* is a very popular programming language compatible with almost every operating system. Online. Available HTTP: <http://www.perl.org>

<sup>135</sup> *MySQL* is a Relational Database Management System (RDBMS) that runs as a server providing multi-user access to a number of databases. Online. Available HTTP: <http://www.mysql.com>

- **Sender\_address**: sender's e-mail address.

The afore-mentioned research and analysis did not take into consideration image-based spam messages (see Figure 1 of the present chapter) as it is not possible to do a simple text analysis for this kind of messages.

As far as the part of text analysis is concerned, and as previously mentioned, an *inverted index* of all the messages' bodies was created. An *inverted index* is an index data structure storing a mapping from a value such as words or numbers to its location in a database file, in a document or a set of documents, in this case allowing full text search. The following example can better show how an inverted index is made. Let us take these three texts as example:  $T_0 = \text{"it is what it is"}$ ,  $T_1 = \text{"what is it"}$  and  $T_2 = \text{"it is a pill"}$ . An inverted index of these three documents would be:

```
"a":    {2}
"pill": {2}
"is":   {0, 1, 2}
"it":   {0, 1, 2}
"what": {0, 1}
```

A term search for the terms "what", "is" and "it" would give the set:

$$\{0, 1\} \cap \{0, 1, 2\} \cap \{0, 1, 2\} = \{0, 1\}$$

A variation of the above index could be the following full inverted index where the **pairs** are document numbers and local word numbers. Like the document numbers, local word numbers also begin with **zero**. Therefore, "a": {(2, 3)} meaning the word "a" is in the third document ( $T_2$ ), and it is the third word in that document (position 2 since local word numbers begin at zero while to human perception it would appear to be "position 3").

```
"a":    {(2, 2)}
"pill": {(2, 3)}
"is":   {(0, 1), (0, 4), (1, 1), (2, 1)}
"it":   {(0, 0), (0, 3), (1, 2), (2, 0)}
"what": {(0, 2), (1, 0)}
```

If we run a phrase search for "what is it" we get hits for all the words in both document 0 and 1. But the terms occur consecutively only in document 1.

To write the code in order to perform such a task we selected *Java* as the programming language and *Lucene* as the support library.<sup>136</sup>

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<sup>136</sup> “*Apache Lucene*’ is a high-performance, full-featured text search engine library written entirely in Java. It is a technology suitable for nearly any application that requires full-text search. Online. Available HTTP: <http://lucene.apache.org/java/docs/>

With the above analysis in mind we can safely ignore images or other media attached to spam messages since we are interested solely in a text-based analysis.

In order to produce its results, the study was based on the information concerning six people chosen as “target users” (hereafter mentioned as “users”). First of all, we did a profiling of each one of them. The profiles’ information were mainly based on the kind of work (the main areas in which each user is involved), their most recent professional travels, the hotels where they stayed, the process and the websites used to book flights and hotels and the people to whom each user gave contact information. All the users worked for the same organisation and the aim of the research consisted in finding the existence of a correlation between the user’s activity and the kind of spam they received.

The performed *TermFrequency* analysis of the received spam messages gave the following occurrences of the most common relevant words listed by users<sup>137</sup>:

**User A (7,304 e-mails)**

- Price -- 19,735
- Viagra -- 8,820
- Cialis -- 8,653
- Pharmacy -- 2,428
- Pills -- 2,387
- Drugstore -- 2,108
- Rolex -- 1,847

**User B (19,195 e-mails)**

- Price -- 40,327
- Viagra -- 17,389
- Cialis -- 17,372
- Pills -- 8,046
- Pharmacy -- 5 540
- Drugstore -- 4,229
- Rolex -- 3,683

**User C (20,453 e-mails)**

- Price -- 29,205
- Viagra -- 12,776
- Cialis -- 12,717
- Pills -- 4,844
- Pharmacy -- 4,756
- Rolex -- 3,029
- Casino -- 2,450

**User D (8,987 e-mails)**

- Price -- 20,166
- Viagra -- 8,615
- Cialis -- 8,505
- Pills -- 4,168
- Pharmacy -- 2,745
- Drugstore -- 2,121
- Rolex -- 1,606

**User E (12,173 e-mails)**

- Price -- 20,508
- Cialis -- 9,273
- Viagra -- 9,234
- Pills -- 4,168

**User F (11,490 e-mails)**

- Price -- 33,852
- Viagra -- 14,823
- Cialis -- 14,719
- Pharmacy -- 4,039

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<sup>137</sup> For privacy reasons, users are named as “User A”, “User B”, etc.

- Pharmacy -- 3,579
- Drugstore -- 2,680
- Rolex -- 1,912
- Drugstore -- 3,672
- Rolex -- 2,432
- Pills -- 2,281

A quick look at these results allows us to notice that these data are quite the same; they just change in proportion of the total amount of e-mails. What is of importance is that, despite the fact that every user is involved in different thematic areas, they look altogether like a unique target. This is significant, but not terribly surprising as big organisations, like the one all the users work at, are subject to many cyber-threats such as network intrusions, spam, viruses. It is therefore quite possible that some of the hosts inside the network company have been infected by a virus sent through a spam e-mail not caught by the anti-spam filter or through any IM software. In this case, all the e-mail addresses of the company could have already been in the hands of some spammers.

Nonetheless, there is an interesting result that stems from the crossed analysis of two profiles, User A and User B. Both users worked in the same area, both had been in State Y for a professional travel (one in January 2009 and the other in February 2009) and both had stayed at the same hotel. Since we found two users who had similar profiles and received the same kind of spam, it is possible to make some correlations. Basing the test on the Viagra-related e-mails it is possible to know that for User A the total spam messages in our database that had been received before the travel to State Y were 3,042 and those received afterwards are 4,262: almost half before and half after the travel (more precisely 42 per cent and 58 per cent respectively). But if we exclusively focus on the spam related to Viagra, from the final data that include 1,468 Viagra-spam, 1,260 of them were received after the travel in State Y that is exactly 86 per cent.

As far as User B is concerned, the total spam messages they received before the travel to State Y are 4,128 and those they received afterwards are 15,068. Although the majority of the spam e-mails was received after the travel to State Y (22 per cent against 78 per cent respectively), also in this case most of the Viagra-related e-mail have been received after that trip, too. In a total of 3,294 Viagra-related e-mails, 2,876 were sent to User B after the trip (87 per cent). Figure 3 resumes the afore-mentioned assumptions:

	<b>TOTAL SPAM</b>	<b>TOTAL SPAM</b>	<b>VIAGRA SPAM</b>	<b>VIAGRA SPAM</b>
	<b>BEFORE STATE Y</b>	<b>AFTER STATE Y</b>	<b>BEFORE STATE Y</b>	<b>AFTER STATE Y</b>
<b>User A</b>	42 per cent	58 per cent	14 per cent	86 per cent
<b>User B</b>	22 per cent	78 per cent	13 per cent	87 per cent

Figure 3: Results summary

**- Conclusions drawn from the study**

The purpose of this first phase of the study was to demonstrate the potential link between the user's activities and the spam they receive, confirming the existence of a bigger scheme behind the spam e-mails we receive. This idea could be further developed in a bigger and more detailed prospective work. The concept was based on a crossed analysis between different sources of data (users' spam messages, users' profiles, etc.) using different methods. Other than the simple e-mail text *TermFrequency* analysis, other methods could be used to analyse image-based spam e-mails. From the simple results previously discussed it can be deducted that, in terms of percentages, there was the same increase of a certain type of spam after the same occurrence of events happened to two of the users. We could suppose that the reason/source for this kind of messages lie probably there. It could be the hotel, since in order to book their rooms the users had to submit their e-mail addresses or some contacts the users made during their stay there. If the prevalent case is the hotel, the probable scenarios are:

- The hotel is infected by some virus, is part of some botnet(s) or it has security loophole(s) in anyway.
- There is an insider in the hotel who has direct access to customers information and who is involved in the spam market.
- The hotel itself is involved in the spam market as "source" of verified e-mail addresses.

It is clear that with such an analysis many different new ways to track the spam source and understand its course of action were brought to light. The results that stemmed from this first phase of the research could lead, if further explored and developed, to other possible similar research activities:

- Analysis of image-based spam e-mails.
- In case of correlations found as these of the "State Y example" described above, effort to track back the geographic origin of the sender's address.
- Analysis and comparison among different entities (not only one like in the case described here): various organisations and companies located in different countries.
- Analysis led by the core-business of the organisation or company in order to try to build a "generic framework model" and then apply it to different organisations' backgrounds.

Finally, what can undoubtedly be assumed is that hotels' networks or other public Wi-Fi networks such as those of airports are exposed to hacking threats. The insufficiently secured passwords -- or their complete absence in some case -- and the weak firewalls and anti-virus software used, make them an open door for hackers who can break in with an unimagined easiness and steal personal data such as names and other personal information, credit card numbers, passwords and expiration dates. With such sensitive data in their hands hackers can then do everything, from selling them to spammers to frauds involving the misuse of credit cards' information that they have stolen. The outcomes of this pilot study

have been equally confirmed by a recent industry research carried out by TrustWave's Spider Labs<sup>138</sup> which showed that hotel networks were the favourite destination for hackers in 2009, accounting for 38 per cent of all known security breaches, more than the financial services industry (19 per cent) and retail industries (14.2 per cent) combined<sup>139</sup>. The most worrying side of this vicious story is that the hotels whose networks were compromised had not realised the fraud for an average of 156 days, leaving plenty of time to hackers to operate. In addition, they have not yet been able to identify how many customers and locations were affected and thus manage to notify all the customers as to the breach of their personal information<sup>140</sup>.

Nonetheless, and despite the fact that hackers and spammers may seem invincible, hotels, restaurants, coffee shops, airports, municipal squares and other places where free access to Internet is possible, have to be better secured. But it mainly lies within the users' responsibility to be careful and proactive when accessing the Internet. Apart from using up-to-date protection software it is also very important to be vigilant and suspicious towards any strange message and irregularity that may be noticed in their e-mail boxes or their credit cards respectively. Taking all the necessary measures to safeguard personal data and privacy can be the only responsible answer to hackers, spammers and other "e-criminals" who watch out for the right moment to seize.

The list of possible hacking threats above does not only indicate a series of possible means through which our information and preferences can be gathered or stolen. The fact is that these weak points were actually used to shape a sort of purchaser profile of each user participating in the pilot that resulted in an offer of products via spam. This offer matched their preferences or fields of active research on the web (that may be interpreted as preferred needs from the criminal observer ready to offer us what we are looking for) resulting from their daily action on the PC, confirming, at least in a preliminary way, that a real scheme exists behind the spam e-mails we receive and that we are in front of organised crime to advertise their illicit products and services. That said, this study should be merely seen as an original initiative and a driving idea for future projects and prospective studies of the same kind.

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<sup>138</sup> *SpiderLabs* is an advanced security team within *Trustwave* focused on forensics, ethical hacking, and application security testing. Online. Available HTTP: <https://www.trustwave.com/spiderLabs.php>

<sup>139</sup> SMAIL M. (2010), *Hackers Lurking Hotel Networks*, 17 March Online. Available HTTP: <https://www.infosecisland.com/blogview/3348-Hackers-Lurking-in-Hotel-Networks.html>

<sup>140</sup> Ibid.





## **4. THE IMPLICATION OF ORGANISED CRIME IN MEDICINES COUNTERFEITING**



It seems like counterfeiting perpetrators and law enforcement authorities participate in a race against time where organisation, coordination and promptness are the basic factors that make the game rules. In this light, one of the key-issues to be addressed is the profile, motivation and *modus operandi* of those hidden behind the counterfeiting production and distribution chain. Factors contributing to the spread of counterfeit medicines are based on various levels that have to be examined as a whole as they are intrinsically connected and influence each other. These factors vary considerably and range from institutional and legislative issues to matters of economics, production, trade and marketing.

The numerous cases of seizures, alerts and recalls of counterfeit medicines in almost all the regions of the world, corroborate the transnational scope of the phenomenon. This huge market and the level of organisation of the counterfeiting network supports the conclusion that counterfeiting is based on complex and sophisticated structures, often set and maintained by organised criminal groups. Counterfeiting is both a very lucrative and relatively low-risk illegal activity. This leads counterfeiters to act in coordinated ways -- adopting market behaviours, sophisticated methods of production and distribution and enter in the logic of industry and massive production. Counterfeiting is an organised criminal activity to the extent that it is depicted as a complicated network where numerous criminals undertake long-lasting activities in order to make economic profits. There is serious evidence establishing links between counterfeiting and other forms of organised criminal activities such as drugs production and trafficking, trafficking in persons, arms trafficking and money laundering. The knot of this link is obviously economic benefit.

Criminal organisations are well aware of the economic profitability of counterfeiting medicines. According to the pharmaceutical company Pfizer (a company directly concerned about drugs' counterfeiting as it manufactures and licences Viagra, one of the most counterfeited medicines worldwide) the difference in profitability when comparing the production of heroin with that of Viagra is remarkable -- namely, the production of 1 kg of heroin has higher costs and lower street value than the respective costs and profit entailed by the production and distribution of 1 kg of Viagra. In one case investigated by the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom, 100,000 counterfeit pills imported at the price of about 25 pence each were being sold for up to 20 pounds each, thus worth more than 1.6 million pounds in total<sup>141</sup>.

The reasons behind this strict interconnection between counterfeiting and other forms of organised crime can be briefly summed up in the following assumptions. There is a wide range of means and aims used by medicine counterfeiters that are compatible with other types of criminal activities. For example, medicine counterfeiters can use their installations and equipment to produce drugs and *vice versa*. What is more, counterfeiting can finance and be financed by other forms of organised crime and this activity can contribute to the increase of the exploitation of illicit and forced labour. Furthermore, illegal distribution and trafficking routes can be used for many purposes, allowing counterfeiters to avoid spending extra money and time in establishing new distribution networks.

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<sup>141</sup> CLARK E. (2008), 'Counterfeit Medicines: The Pills That Kill', in Telegraph, 5 April. Online. Available HTTP: <http://www.telegraph.co.uk/health/3354135/Counterfeit-medicines-the-pills-that-kill.html>

Nowadays, organised crime is predominantly responsible for the magnitude of counterfeiting worldwide. As technology and sophistication of know-how are growing and becoming more complex in the globalised environment, organised criminal groups are, in turn, constantly endeavouring to find new ways to exploit these new technologies. They use and expand all possible means of information and communication and transform their *modus operandi* by taking advantage of all available technologies and opportunities. Hence, the knot among different criminal groups and their various activities is facilitated by the flows of communication, the boom of technology and the minimisation of physical distances. Like political, economic or social actors, organised criminal groups are “players” within the actual context. Structured in small or larger units and based on more or less flexible decision-making and operational cores, they constantly try to expand their illegal activities by engaging in old and new forms of crime, from trafficking of human beings, drugs and arms to corruption, money laundering, financial frauds, forgery and counterfeiting.

Investigations and cases worldwide have uncovered serious evidence demonstrating that organised criminal groups have expanded their illicit activities into the field of counterfeit medicines. Counterfeiting of medicines has become a highly profitable crime industry run by transnational criminal organisations, and is costing the international community a lot in terms of economic growth, industrial and commercial turnover, social development, improvement of people’s living conditions and human security, and has become part of the “obscure side of globalisation.”<sup>142</sup> Consequently, any efforts to seek realistic solutions to control and reduce the phenomenon of counterfeit medicines would be aimless if the involvement of organised crime is not taken into account.

The constantly narrowing relationship between counterfeiting and organised crime is due to the significant expansion of the latter’s areas of activities. Organised criminal groups have entrenched themselves in so many illicit activities that they can no longer be identified by one type of crime. Apart from that, they have progressively started implementing various types of activities which are often similar to those previously considered as economic crimes<sup>143</sup>, such as counterfeiting.

The globalisation of markets has also had a strong impact on organised crime. Challenged by this market evolution, organised criminal groups that were traditionally local or regional in terms of geographical location and range of operation have intentionally expanded through the creation of links with other criminal groups in other geographical regions in order to better perform their illegal activities. The process of geographical internationalisation followed by a trend of decentralisation or delocalisation of their decision-making and operational cells have given them the opportunity of expanding the activities in which they were traditionally involved while offering them a range of numerous new opportunities through their new links and connections. In order to perform illegal activities such as human trafficking, criminal groups establish alliances with other similar criminal organisations, subdividing operational tasks and creating an actual illegal production/

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<sup>142</sup> UNIFAB (2005), *Rapport Contrefaçon et Criminalité Organisée*, 3<sup>rd</sup> edition, p.12. Online. Available HTTP: <http://www.theworldbusinessorganisation.com/uploadedFiles/BASCAP/Pages/RAPPORT%20-%20UNIFAB.pdf>

<sup>143</sup> UNICRI (2007), cited, p.103

distribution chain<sup>144</sup>. Hence, throughout the shipment of a cargo containing counterfeit products, for instance, the connection of the counterfeiters with criminal groups in each stopover of the cargo until its final destination can facilitate the whole transportation by means of intimidation, extortion and bribery and by using the local connections they have established.

By penetrating financial and regular product markets criminal groups have the opportunity to launder proceeds deriving for other crimes committed or income transferred to them for such purpose<sup>145</sup>. It has been proven that some organised criminal groups such as the Russian mafia, the Chinese triads, the Colombian cocaine traffickers, and the Mexican mafia are involved in counterfeit medicines' production and trafficking. In his report entitled "*Making a Killing*", Roger Bate quotes Francis Burnett of the Caribbean Industrial Research Institute who pointed out that many of those groups switched from narco-trafficking to the counterfeit drug trade due to the potential for high profits, and comparatively low risk (especially where regulations and enforcement are weak and sanctions are clement).<sup>146</sup>

Being a highly profitable crime and a source of big tax-free income, counterfeiting is nothing but one more "feed-gear" for organised criminal groups to receive more "funds" which can be then invested into other illegal activities. Under the same logic, profits generated by other illicit activities may also be used to feed counterfeiting. It is not rare that criminal activities are intermingled as, for instance, the exploitation of illegal immigrants' labour for the production of fake products. Cases exist which have established the link between counterfeit medicines and trafficking of drugs due to similar practices adopted during their production and distribution. This can be particularly true for the production phase as the infrastructure and logistics needed for the production of fake medicines are very similar to those used for the production of drugs under the form of pills. By way of example, we can mention a case in Canada, where in 2008 the police seized a massive quantity of narcotics and counterfeit drugs at an illegal pharmaceutical laboratory in Quebec. The seizure, reported to be worth over 5 million USD, contained hundreds of thousands of ecstasy and methamphetamine pills as well as 35 kg of bulk powder which could be used to manufacture another 160,000 ecstasy pills. Furthermore, 25,000 fake Viagra tablets and 31,000 fake Cialis tablets were also seized during the raid<sup>147</sup>.

A very interesting study conducted by the Institute for International Research on Criminal Policy analysed the vulnerability of the European pharmaceutical sector to the penetration of organised crime by taking into account characteristic elements of the market such as the nature of the product, the conditions for entry into the market and the existence of alternative irregular markets parallel to the principal one<sup>148</sup>. The purpose of the study was to interpret, through the analysis of the combination of elements that characterise the European pharmaceutical market, the motivations of organised criminal groups in infiltrating the

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<sup>144</sup> ZUCCARELLI F. (2006), *The Phenomenon of Trademark Counterfeiting and Organized Crime. Domestic and International Investigations for Contrasting Illegal Replication Activities*, p.2

<sup>145</sup> UNICRI (2007), cited, p. 103

<sup>146</sup> BATE R. (2008), cited, p.35

<sup>147</sup> UNICRI Database on Counterfeiting and Piracy/ Cases including the involvement of organized crime, Online. Available HTTP: <http://counterfeiting.unicri.it/database.php?sec =C&c =5>

<sup>148</sup> VANDER BEKEN T. (2007), cited

market as well as the “assets” the sector offers for the expansion of illegal activities. The outcome of this research underlined the degree of vulnerability of medicines to counterfeiting. This vulnerability would be essentially related to the fact that a medicine is a product that can be easily reproduced with a high level of external likeness to the original counterpart, even if it bears none of its therapeutic virtues. Furthermore, medicines are small-size products thus easy to transport and, as they are generally not temporary and superfluous products, their demand is continuous and steady with sharp increases in cases when illnesses switch to epidemics. The outcomes referring to the conditions for entry into the market were basically based on the specificities of the European market such as the existing legislation that regulates the entry into the market of new operators and the implementation of trading; the complexity and the very technical nature of such legislation which complicate controls; the low level of harmonisation of legislation among the States members of the single market and; the oligopolistic, even monopolistic, nature of this kind of trade. If such elements are seen as shortages and loopholes that favour the penetration of organised crime in the European single market one can imagine the possibilities offered to criminals at the international level, where there is a general lack of unanimous and harmonised regulations with regards to the trade, export, import and distribution of pharmaceuticals. Finally, a component of the study focused on the existence of irregular markets that represent alternative options offered to consumers to circumvent the standard methods through which a medicine can be purchased. The Internet, in the case of irregular on-line pharmacies, offers an example *par excellence* of an alternative irregular market for medicines.

Investigations and seizures of cargos of counterfeit medicines have proved that counterfeiters use technological equipment able to produce big amounts of apparently identical copies of the original products in a very short time. This leads to the conclusion that the medicines’ counterfeiting network has become a veritable mass production industry<sup>149</sup>. Mass production and mass distribution of fake medicines, together with the level of resemblance these copies have reached, show that this illegal activity is no longer undertaken just by individual offenders but has instead become a business of well organised and co-ordinated criminals. Production and transportation techniques, distribution networks and the practices used by counterfeiters and traffickers to waive controls and to co-ordinate their actions and communicate, show that production and distribution of counterfeit medicines cannot be classified as anything but an organised criminal activity in the majority of cases.

Since one of the main aims of counterfeiters is to make the final fake product look like the original one (so as to look reliable and to dupe the consumer), counterfeiters will invest a lot in technological means to assure this similarity. Legitimacy of medical products is usually assumed after just a quick glance at look-a-like products. In the case of counterfeit drugs, what is important is to make the packaging of the product look identical to the original one. The quality of the packaging boxes, blister packs, bottles, tubes, etc. that contain the drugs is the most convincing element for the consumer. Criminals know that consumers will trust a product based on what they first see and in case of medicines the first thing a consumer sees is the packaging. It is for this reason that they focus their attention on making fake packaging look as genuine and authentic as the original one. Raids and investigations at premises and warehouses where bogus drugs were produced revealed that these are often equipped with

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<sup>149</sup> UNIFAB (2005), cited, p.10

highly accurate printing and packaging machines while the rooms where “excipients” and “pharmaceutical ingredients” are produced do not meet even the minimum hygiene conditions.

Unscrupulous practices are applied not only in the production phase but also during the transportation phase. Things are much simpler for criminals when they are only seeking to infiltrate the local or national markets with their counterfeit products, as there will not be any border controls. However, many counterfeit drugs are intended for exportation to other countries. In this case, the criminal organisations involved in the transportation process normally prefer to make shipments with more than one stopover before the fakes reach their final destination. By doing so, detection, traceability and verification of data related to the shipped product, the dates of shipment and the final destination become extremely difficult as the long itinerary and all the intermediaries involved strongly complicate the follow-up process. Throughout the multiple stopovers before their final destination, fake medicines pass through various intermediaries and their accompanying documents are subjected to various modifications with respect to dates of transportation, transported quantities, kinds of substances being shipped, names of shipping companies and persons involved.

Transportation of counterfeit medicines becomes even easier when it does not refer to the final product transported but only to components of it. Part of its components can, for instance, originate from one country and others from a different one while the fabrication of the final product can be made in a third country which is the final destination of the transported substances. Another practice of transportation used equally in the case of medicines is the separate shipment of medicines and of their packages in order to avoid the identification of the product<sup>150</sup>. Understandably, such practices adopted by counterfeiters and intermediaries of the transportation process, aimed to subdivide and minimise the risks, greatly hinder any efforts to trace, detect and identify the products at border control points.

In addition, criminal organisations’ routes change continuously, depending on the established networks in various countries and the severity of controls and inspections. Finally, counterfeit medicines can be channelled into the market of various countries, in parallel to or through networks used for other illegal activities such as arms and drugs trafficking, trafficking of human beings, money laundering and so on.

Even if it can be affirmed that the problem is particularly present in some countries,<sup>151</sup> the transnational criminal networks are facilitating a rapid spread of the problem in every region of the world in order to boost their business. Furthermore, some areas of the world has been often tagged as big producers of counterfeit medicines, however, this does not imply that the national markets of these countries are spared from the problem of fake medicines. In August 2007, 17 gang members were arrested in Northern China after authorities uncovered a counterfeit pharmaceutical operation and confiscated 67 different types of counterfeit medication including rabies vaccinations. The imitation rabies vaccination were said to have

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<sup>150</sup> UNICRI (2007), cited, p.107

<sup>151</sup> Among others, see MORRIS J., STEVENS Ph. (2006), *Counterfeit Medicines in Less Developed Countries. Problems and Solutions*, International Policy Network, pp.3-4. also DELVAL P., ZILBERSTEIN G.(2008), *La contrefaçon, un crime organisé*, Jean- Claude Gawsewitch (editions), Paris, pp.115-118

been manufactured from starch and water, had been given to 227 people, all of whom were put immediately under close observation by the local health departments. This case was particularly serious as rabies is one of China's deadliest infectious diseases which, according to official figures, killed over 2,000 people in 2006 alone<sup>152</sup>. In addition to 10,000 doses of the rabies vaccine, 20,250 bottles of medicine used to treat cardiovascular diseases and 211 bottles of blood protein were also confiscated.

## 4.1 Transnational Organised Groups, Transnational Organised Crimes

Either destined for exportation or for consumption within the national borders, the sales of bogus pharmaceuticals seem to follow the existing market practices. Depending on the market structures and the marketing strategies, counterfeit medicines can appear in local dispensaries or online rogue pharmacies. Nonetheless, counterfeit medicines' distribution for sale both in wholesale and retail depends very much on the existing connection and established networks among counterfeiters, distributors and traders. Counterfeiters have been known to use intimidation and blackmail practices to generate fear amongst retailers and preventing them from reacting and taking legal action. However, in the case of counterfeit medicines, which belong to the category of counterfeit products that pose a serious threat to consumers' health and safety, criminal groups usually attempt to penetrate the legal distribution system at a higher level by operating as an actual distributor<sup>153</sup>. There are many cases in which wholesalers, distributors and retailers do not belong to a criminal network but become involuntarily part of it. Attracted by the appealing prices, they buy these pharmaceuticals ignoring the fact that they are fake, convinced that they made a great deal in terms of prices and quantities purchased. Despite their good faith, distributors and retailers acting in this way do have a degree of responsibility. When they do not follow this responsibility, such legitimate purchasing entities grant organised criminal groups the power and the capacity to penetrate the legitimate supply chain. For example, in summer 2004, a considerable amount of counterfeit contact lenses that were neither sterilised nor corrective was seized at the Roissy airport in France by Customs officers. These products were destined for French consumers and had been ordered by authorised opticians, who were convinced that they had bought legitimately discontinued products from a legal source<sup>154</sup>.

Apart from the production of fake pharmaceuticals, organised criminal groups also hijack authentic medicines -- smuggling, repackaging and altering their expiring dates. The final purpose is to make these products re-sellable and re-introduce them into the market. Instead of being destroyed, expired (and thus useless and ineffective) drugs find their way

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<sup>152</sup> UNICRI Database on Counterfeiting and Piracy/ Cases including the involvement of organized crime. Online. Available HTTP:: <http://counterfeiting.unicri.it/database.php?sec =C&c =5>

<sup>153</sup> UNICRI (2007), cited, p.114

<sup>154</sup> UNIFAB (2005), cited, p.15

into the markets and criminals receive large profits for very little effort. Products for diseases such as malaria are unfortunately particularly attractive for counterfeiters of pharmaceuticals. According to the WHO, half of the world's population is at risk of malaria, and an estimated 243 million cases led to an estimated 863,000 deaths in 2008. When malaria is diagnosed, the only solution for the patient to recover is to undertake an appropriate treatment. The magnitude of the disease; the high prices of treatments in comparison to the revenue of people who require such treatments; and the availability of discounted or free medicines for humanitarian purposes that can be illegally diverted, all make these type of medicines an appealing and very promising market for organised crime. It is not overly difficult for counterfeiters to infiltrate the markets of affected countries with bogus choloquine, mefloquine or tetracycline-based treatments as border controls are not always systematic and rigorous. Furthermore counterfeiters have substantial capital to invest in corruption and bribery, which can break down even the most well-designed border controls.

Together with corruption, organised criminal groups also use practices of extortion, intimidation, blackmail, and violence against public officials who deal with the repression of the phenomenon. Tactics of violence are quite usual when organised counterfeiters see their activities threatened by decisive actions undertaken by public authorities to counter the phenomenon. For instance, the attacks by counterfeiters on Dora Akunyili, the Director of the Nigerian National Agency for Food and Drugs Administration and Control (NAFDAC), after she adopted the anti-counterfeiting policies to reduce the problem in her country, leave little space for doubt on the extreme actions that organised criminal groups are willing to resort to when their interests are under imminent threat.

## 4.2 A Poorly Sanctioned Organised Crime

One of the most basic problems encouraging the production and distribution of counterfeit medicines is the lack of appropriate drug legislation and regulation implementation<sup>155</sup>. Unfortunately, apart from the WHO taskforce IMPACT -- which showed the importance of such a cooperation scheme, encouraging dialogue among the stakeholders of different countries and supporting the adoption of commonly agreed instruments to fight the threat of counterfeit medicines<sup>156</sup> -- there is no other coordinated effort on an international level and directives promulgated at a national or regional level are not fostered enough to deter the production and distribution of counterfeit medicines. What is more, criminal organisations know that they can proceed with their illegal activities by taking advantage and exploiting existing legislation loopholes. The trafficking of counterfeit medicines is a particularly complicated issue for both national and international law enforcement agencies due to its decentralised character. In addition, the complexity of

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<sup>155</sup> DI GIORGIO D., REGGI V., *Combating Counterfeit Drugs* (Acts of the AIFA-WHO International Conference, Rome, 2006), p.20.

<sup>156</sup> DI GIORGIO D. ed. (2011) (c), *IMPACT (International Medical Products Anti-Counterfeiting Taskforce) - The Handbook*, cited, p. 18.

national regulatory systems and mechanisms that involve various incumbent institutions, organisations and authorities poses serious enforcement challenges. In some cases the problem can be equally aggravated by lack of strong political commitment and will, corruption and bribery among the various stakeholders and conflicts of interest<sup>157</sup>.

In the majority of the countries, sanctions foreseen by national criminal laws are far from being a deterrent for counterfeiters<sup>158</sup>. Enforcement of legislation to force organised crime to refrain from illicit activities such as drugs production and trafficking made them switch to other activities less regulated and legally enforced such as the production and trafficking of counterfeit medicines. Many national legal systems do not distinguish counterfeiting of medicines (or even of beverages, food, pesticides and all those products the consumption of which directly endangers consumers' health and safety) from counterfeiting of other industrial products and, most importantly, do not link counterfeiting to organised crime. Sentences usually vary from light fines to short-term imprisonments. In mid-May 2001, investigators from Colombia's National Institute for the Supervision of Medications & Foods (Invima) discovered a thriving drug operation in a poor neighborhood of Bogotá with a production capacity of more than 20,000 counterfeit tablets daily of flu drug Dristan<sup>159</sup>. The 10 people arrested were freed on bail within a few days<sup>160</sup>.

Apart from the minor penalties imposed in such cases, it is noteworthy that not all the instances of medicines' counterfeiting are brought before the court and in the majority of cases that do get brought it is difficult to establish the link between the use of a counterfeit medicine and the damage that has been caused to the patient<sup>161</sup>.

The recognition of organised crime involvement and of counterfeiting as an organised crime activity should constitute the basis for a prevention strategy and an increase in the severities of sanctions. Such an approach is needed if laws are to act as real deterrents. The international community should also support the adoption of proper penalties and needs to push towards the recognition of counterfeiting as an emerging organised crime. This is extremely important to avoid that this route is followed only by a limited number of countries, since, in this case, their action would remain limited in scope and effectiveness.

In this view, the United Nations Convention against Transnational Organized Crime (UNTOC) -- which opened for signatures by Member States in Palermo (Italy) on 12-15 December 2000 -- may play a crucial role to enhance the fight against medicines' counterfeiters. Medicines counterfeiting is clearly an activity that is conducted on a large

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<sup>157</sup> WHO. Online, cited

<sup>158</sup> For example, Law 8/1996 of Romania on the Protection of IPRs foresees prison sentences from five to 15 years for cases of copyright infringement in which organised criminal groups are involved whereas for other types of perpetrators fines or lighter prison sentences are foreseen. Sanctioned with longer prison sentences is also the infringement of copyright and industrial property rights when the commercial purpose is proven. However, no distinction is made for particular or more "sensitive" categories of products such as medicines.

<sup>159</sup> Business Week Online (2001), *What's in That Pill? In Latin America, Fake Drugs are as Lucrative as Cocaine*, 18 June. Online. Available HTTP: [http://www.businessweek.com/magazine/content/01\\_25/b3737153.htm](http://www.businessweek.com/magazine/content/01_25/b3737153.htm)

<sup>160</sup> BATE R. (2008), cited, p.36

<sup>161</sup> Ibid.

scale, with a clear involvement by organised criminals, and involving perpetrators that are often connected and operate in different countries

The existence of these elements leaves little or no doubt as to the possible applicability of the UNTOC to the majority of cases concerning the counterfeiting of medicines. It is very clear that the Convention is intended to ensure its widest application to every form of organised crime and not only to those that are expressly mentioned in the body of the Treaty. In his foreword to the publication of the texts of the UNTOC and of its Protocols, the former UN Secretary General Kofi Annan affirmed the importance of the UNTOC as an instrument to combat organised crime as a global problem -- one that has no boundaries and which is exploiting all the opportunities that globalisation is creating. Thus, the UNTOC has the potential to be a common and powerful instrument setting the basis for enhanced cooperation among Member States to fight organised crime and the various activities it manages<sup>162</sup>. This is reinforced by the fact that as at November 2010 the Convention had been ratified by 158 United Nations Member States<sup>163</sup>, which demonstrates that this Treaty has a very large international acceptance, and consequently the potential for widespread global application.

Article 3 of the Convention identifies the scope of applicability of the UNTOC, affirming that it shall apply -- apart from the other forms of crime specifically mentioned -- to offences that are transnational in nature and involve an organised criminal group<sup>164</sup> as well as to "serious crimes"<sup>165</sup> thus potentially covering all the activities carried out by organised

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<sup>162</sup> "With the signing of the United Nations Convention against Transnational Organized Crime in Palermo, Italy, in December 2000, the international community demonstrated the political will to answer a global challenge with a global response. If crime crosses borders, so must law enforcement. If the rule of law is undermined not only in one country, but in many, then those who defend it cannot limit themselves to purely national means. If the enemies of progress and human rights seek to exploit the openness and opportunities of globalisation for their purposes, then we must exploit those very same factors to defend human rights and defeat the forces of crime, corruption and trafficking in human beings. Terrorists, criminals, drug dealers, traffickers in people [...] take advantage of the open borders, free markets and technological advances that bring so many benefits to the world's people. They thrive in countries with weak institutions, and they show no scruple about resorting to intimidation or violence. Their ruthlessness is the very antithesis of all we regard as civil. They are powerful, representing entrenched interests and the clout of a global enterprise worth billions of dollars, but they are not invincible. [...] Criminal groups have wasted no time in embracing today's globalised economy and the sophisticated technology that goes with it. But our efforts to combat them have remained up to now very fragmented and our weapons almost obsolete. The Convention gives us a new tool to address the scourge of crime as a global problem. With enhanced international cooperation, we can have a real impact on the ability of international criminals to operate successfully and can help citizens everywhere in their often bitter struggle for safety and dignity in their homes and communities." UNODC (2004), *The United Nations Convention Against Transnational Organized Crime and the Protocols thereto*, pp. Iii-iv

<sup>163</sup> Constantly updated information on the status of ratifications is provided in the UNODC website at [http://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg\\_no=XVIII-12&chapter=18&lang=en](http://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=XVIII-12&chapter=18&lang=en)

<sup>164</sup> The organised criminal group is defined by art. 2 (a) of the UNTOC as "...a structured group of three or more persons, existing for a period of time and acting in concert with the aim of committing one or more serious crimes or offence established in accordance with this Convention, in order to obtain directly or indirectly a financial or other material benefit". It has to be noted that many countries already have in their legislative framework this -- or a similar -- definition of organised crime. If the involvement of organised criminals in medicines counterfeiting will be investigated, this that may favor a wider cooperation in this field.

<sup>165</sup> Article 2, b of the UNTOC states that "Serious crime shall mean conduct constituting an offence punishable by a maximum deprivation of liberty of at least four years or a more serious penalty".

crime. Furthermore, article 5 of the UNTOC also criminalises the participation in an organised criminal group and its related activities<sup>166</sup>.

These considerations lead us to affirm that investigating organised crime involvement in medicines counterfeiting would allow for the use of a series of potentially powerful instruments that the Convention and the national laws of its Parties provide for the purpose of enhancing the response to transnational organised crimes. The UNTOC contains several articles aimed at setting the basic standards for a series of very important matters related to organised crime investigation and prosecution.

It is worth noticing that in this respect, specific provisions are dedicated to:

- Prosecution, adjudications and sanctions of the crimes indicated in the convention -- among which, we have to remember, is the participation in an organised criminal group -- (Art. 11).
- Confiscation and seizure of: the proceeds of crime, the instruments and equipments used to commit such crimes, of the property into which proceeds of crime have been transformed or converted, income or benefits derived from proceeds of crime (Art. 12).
- Extradition (Art. 16).
- Mutual legal assistance (Art. 18).
- Protection of witnesses (Art. 24).
- Law enforcement cooperation (Art. 27).
- Prevention of crime through the development of national projects and best practices.

These provisions also have the potential to enhance the effectiveness of the national and international response to the problem of counterfeit medicines. What is needed is the recognition that the counterfeiting of medicines is a crime, and that it has to be properly investigated as a part of the wider strategies put in place by organised criminals.

Apart from the EU Directive 2001/83, an interesting initiative is the Council of Europe MEDICRIME Convention, which specifically addresses the problem of counterfeit medical products by giving police forces, customs and prosecutors a comprehensive set of “tools” to counteract this criminal phenomenon.

The practical implementation of the Council of Europe MEDICRIME Convention was agreed on at an international conference co-organised between the Council of Europe and the Swiss Agency for Therapeutic Products (Swissmedic) under the aegis of the Swiss Chairmanship of the Council of Europe Committee of Ministers in Basel on 15-16 April 2010.

In October 2011, the text was opened to the signature of Member States, and 13 Member States signed it up to December 2011. As for other Council of Europe conventions,

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<sup>166</sup>It is interesting to note that article 5 also covers the "Organizing, directing, aiding, abetting, facilitating or counseling the commission of serious crimes involving an organized criminal group".

and given the global dimension of pharmaceutical crimes, this Convention could be open to participation by non-Member States, potentially giving the Convention a universal vocation.

As already mentioned, the Convention focuses on the public health threat posed by counterfeit medical products and medical products that are manufactured or distributed without proper authorisation and/or are in breach of safety standards. Once entered into force, the Convention would also provide a framework for international co-operation, measures for co-ordination at the national level, preventive measures and protection of victims and witnesses. Also predicted by the Convention is the establishment of a monitoring body to oversee its own implementation by the signatories.



## **5. CONCLUSIONS AND PROPOSALS**



The information, data and real cases collected and analysed in this research leaves no doubt as to the extreme gravity of the medicines counterfeiting problem. Many of the same data and information also leave no doubt as to the involvement of organised crime in this deadly but extremely profitable trade. If the consequences are, to a certain extent, visible and recognisable, the same unfortunately cannot be said for the various elements that contribute to prevent medicines counterfeiting. The approach to identify some countries or geographical areas upon which to place the burden of responsibility for the diffusion of the phenomenon is misleading because counterfeit medicines are a global problem affecting every country in the world. The solution to such a threat must consequently come from a shared and responsible approach that would allow the international community to join forces and render each country part of the solution.

To shape this approach and concretely prevent and respond to the problem, it is important to know more on the phenomenon and clearly identify and analyse several peculiar elements that are still not widely recognised or properly considered. It is necessary to set a clear understanding of what counterfeit medicines really are; who are the managers of this deadly trade; and how to better respond to such a plague.

Counterfeit medicines need to be fought against as a serious crime that is global in scope and that fits within the strategies put in place by organised criminals to maximise their profit. Once these aspects of the problem are recognised by the national authorities of the various countries, it will be possible to investigate and prosecute counterfeit medicines as an organised criminal activity, rendering applicable a series of powerful instruments provided by both national and international legal frameworks specifically developed to fight criminal organisations.

In this view, the United Nations Convention against Transnational Organized Crime and the Council of Europe MEDICRIME Convention have the potential to represent a basis from which to enhance the national and international responses against criminals who are involved in producing counterfeit medicines and who are flooding the markets of developed and less developed countries with their bogus products. Being an international instruments dedicated to combat transnational organised crime, there is little doubt as to the fact that, in principle, these regulations could be applied to the acts of counterfeiting of medicines which are being managed by organised criminals. What will be needed, however, are deeper investigations that follow the lead of the criminal business and which will unmask those who are managing it and obtaining profits by putting consumers' lives at risk.

## **5.1 Understanding the Problem (What)**

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This brief introduction contains one of the most important steps that the international community should perform if we are serious about changing the actual situation, namely: the recognition of the global nature of medicines counterfeiting.

**Counterfeit medicines are a deadly trade affecting every region in the world. Recognising this element is of fundamental importance to building a shared strategy that will allow various actors to work together towards a single goal.**

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At a first glance the problem of counterfeit medicines may appear only as an illicit trade violating IPRs. The reality is different. If we think that the lives of hundreds or thousands of people are at risk, we may realise that, in reality, counterfeit medicines are much more than this. Risks for patients' health and safety are the most serious consequence of a crime that creates a variety of consequences for all society. Being an illicit trade, taxes and revenues are not collected by governments, damaging their budgets and financial possibilities. In countries with developing economies, this situation may also hamper the possibilities for investments and sustainable development. Research and development activities by legitimate producers (as well as licit profits for the products developed and marketed) are reduced because of the reduced market share resulting from the presence of counterfeit products. This situation may also cause a reduction of the activities of legitimate producers which may lead in turn to losses of job positions. All these elements clearly show the extreme seriousness of the problem. The situation could change in the near future thanks also to the adoption of specific international instruments dedicated to the production and trade of counterfeit medicines, as in the case of the Council of Europe "MEDICRIME" Convention, once it will be entered into force.

**Taking into consideration the consequences deriving from their marketing and use, counterfeit medicines should be considered as a serious criminal activity and proper legislation and remedies should be put in place. The latter should include appropriate sanctions and provide the possibility to investigate the connections with criminal organisations. In addition to this, the various countries should strengthen their cooperation to address the problem. Being a global problem affecting every country in the world, and being managed by transnational organised crime, international coordination in the fight against counterfeit medicines is extremely important. The UNTOC and the MEDICRIME -- although the latter has not entered into force yet -- may play a fundamental role in this respect, enhancing and facilitating the creation of a common approach against organised crime involved in these illicit activities. The application of the UNTOC and the MEDICRIME could also lead to a better harmonisation of sanctions for criminals that are producing and selling counterfeit medicines. The recognition of its applicability in the case of counterfeit medicines would also allow for the use of powerful instruments that are dedicated to the fight against organised crime and that are present in both the national and international legal frameworks. The forthcoming Council of Europe "MEDICRIME" Convention also has the potential to play an important role to support efforts dedicated to the fight against counterfeit medicines.**

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One of the most important aspects to consider is the distribution phase of counterfeit medicines. This phase may vary considerably in the case of developed and less developed

countries, while better knowledge on the distribution and marketing methods would improve the responses of national authorities.

**Specific analysis should be dedicated to the insertion of counterfeit medicines into the legitimate distribution channels or/and to the methods used by criminals to render these products available to consumers. The use of licit practices (such as parallel trade in the EU) that may favour this illicit trade is of particular interest, since better knowledge on this aspect would allow legislators to close some of the gaps that are favouring these illicit activities.**

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The role of the Internet as an involuntarily facilitator of the trade in counterfeit medicines has, as of today, not been explored enough. There are many aspects and practices linked to the Internet that deserve proper attention and thorough analysis. In this light, the role of spam in the advertisement of counterfeit medicines seems of particular interest. While spammers are acting more and more as an advertisement department for criminal enterprises, these elements are not discussed enough nor properly investigated in researches and reports.

While spam emerges as a problem linked to advertisement, the Internet emerges as a problem linked more to distribution, particularly when taking into account the use of fake and rogue online pharmacies used to lure patients into purchasing counterfeit medicines.

**Efforts should be dedicated to research methods to certify legitimate online pharmacies and render them more transparent and safer for consumers, while more analysis is needed regarding the use of the Internet as a distribution method, particularly the use of spam which advertises fake products and lures consumers. The role of the spammer in the criminal scheme needs to be better analysed, with a focus on their connections with criminal organisations.**

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Most importantly, these elements of the counterfeit medicines problem are rarely publicised and properly communicated to both the public and the authorities involved in fighting this illicit activity. The public is often unaware that a medication may be counterfeit and infiltrate the legitimate market: the new regulations explicitly request an effort on information, as clearly stated in the DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source (2011/62).

*Article 85d*

*Without prejudice to the competences of the Member States, the Commission shall, in cooperation with the Agency and Member State authorities, conduct or promote information campaigns aimed at the general public on the dangers of falsified medicinal products. Those campaigns shall raise consumer awareness of the risks related to medicinal products supplied*

*illegally at a distance to the public by means of information society services and of the functioning of the common logo, the Member States' websites and the Agency's website.*

The next risk communication exercises for informing the patients should properly take into account this change of the framework.

**In order to ensure patients and consumers take more precautions when purchasing medicines, it is extremely important to dedicate more effort towards informing them on the existence of counterfeit medicines, on the best ways in which safe purchases can be performed, and on the fact that every citizen can be a potential victim.**

**With the aim of enhancing the commitment of law enforcers to properly fight this crime, specific information should also be communicated to them, highlighting the consequences of the problem and organised crime involvement.**

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## **5.2 Responding to Organised Crime (Who)**

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This report clearly highlighted the managers of this deadly trade (from production to distribution) and identified those who are really profiting from this crime. The cases collected and presented have also shown that the problem of counterfeit medicines is transnational and not linked to selected countries or regions. The extreme profitability of this crime has ensured that criminals are fully exploiting the possibilities provided by the different demands existing in different markets. Furthermore, the distance between a product's place of manufacture and its final destination does not pose any problem to organised criminals who can exploit alliances, trade routes and trade methods which have already been established for other transnational trafficking.

**The international community -- together with Governments and national authorities -- needs to recognise that the counterfeiting of medicines is a transnational criminal activity managed by organised crime. It is an emerging threat allowing transnational criminal networks to obtain huge profits and is clearly connected with other activities and interests of criminal organisations.**

**Due to the international dimension of the crime, it is important to have international and intersectorial forums and task-forces involving all interested stakeholders (health authorities, police forces and customs, manufacturing and distribution companies and health professional associations) in the development of proper counteractions.**

**The IMPACT experience has shown the importance of this cooperation scheme, producing efforts to foster the dialogue among different countries and, especially, different stakeholders and supporting the adoption of commonly agreed instruments in the fight against counterfeit medicines.**

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Organised crime involvement is, in recent years, quite frequently associated to counterfeiting and piracy and also to medicines counterfeiting. However, there is still a general lack of studies which clearly present counterfeiting as an organised crime activity.

**Research needs to be conducted to clearly establish that organised crime involvement in counterfeiting is neither sporadic nor accidental. On the contrary, transnational criminal organisations are the real managers of this illicit trade.**

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Criminals are smart and follow specific strategies when performing their illicit activities and counterfeiters of medicines are no exception. The products flooding developed and less developed countries are often differentiated, following similar market research strategies performed by a licit company. Advertisement and commercialisation methods also differ between markets. Comparative research and analysis focused on cases, data, criminal organisations' transnational connections and commonly used trade methods, which is extremely important because it could support the creation of mapping exercises aimed at highlighting, among other aspects, the involvement of various criminal organisations, their alliances and trade strategies at the international level, the trade routes used, and links with other crimes. The collection of such information would greatly support the planning and implementation of responses by policy makers and law enforcers respectively.

**In depth research has to be conducted to better understand how criminal organisations work and which strategies they use for the introduction of counterfeit medicines into the relevant state territory and the commercial market. Information of this kind would greatly support the preparation of appropriate responses at both national and international levels.**

**Coordination between the various ongoing studies should also be achieved in order to rationalise the use of resources and to obtain results applicable in broader regions.**

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Once the involvement of organised crime is clearly established, the investigative phase should support proper prosecution of cases related to medicines counterfeiting and the identification of the real perpetrators of the crime. For this reason:

**The investigation phase should not be limited to simply the arrest of street sellers or raids on local markets and warehouses. Further efforts have to be produced to identify the chain of perpetrators with a final objective to dismantle the criminal organisation. In this sense, connections between medicines counterfeiting and other crimes committed by criminal organisations could be of great interest for the investigators while, on the other hand, investigating organised crime involvement may allow for the use of a broader and more effective range of investigative methods.**

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## 5.3 Improving the Situation (How)

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Several steps and numerous efforts are needed to produce a change in attitude towards the issue, encouraging both the international recognition of the problem of counterfeit medicines and improving international and national responses to the problem.

Reliable knowledge and information are the basis upon which a common response to medicines counterfeiting can be built. An interesting possibility for the collection of information would be the creation of databases which compare data deriving from enforcement actions undertaken by police and customs with data deriving from platforms controlling the licit trade of specific goods. This would allow research efforts to be based on a comparable and consistent basis, which would in turn serve as a driving force in the campaign to change international and national actions.

Since the collection and comparison of data would involve a great deal of effort -- and since the said information would derive from several different public sector actors (police forces and customs for instance) and private sector actors (platforms created by private producers to control the trade of a specific category of goods, such as medicines for examples) -- the UN may act as reference point for the said collection and analysis phases, owning the necessary independence from external pressures and guaranteeing the security and confidentiality of information when needed.

For these reasons:

**It is of paramount importance to create mechanisms to collect data and evidence on the phenomenon, on its consequences and on its diffusion in developed and less developed countries. The information obtained would support the analysis of various aspects of the problem, including: the strategies of criminal organisations managing this trade; distribution mechanisms; the ways in which consumers can be better protected and informed in less developed countries; and the role of the internet in developed countries.**

**To this aim, it would be very useful to conduct further research on methodologies and systems to compare and assess the aforementioned data, especially in consideration of the fact that the retrieval of such information can be extremely difficult due to the underground nature of the problem. It is important however, that such methodologies and systems keep in consideration the different situations existing in developed and less developed countries.**

**The UN together with existing networks and task-forces active in the field could coordinate and take a leading role in this respect by promoting, supervising and managing the creation and functioning of such data retrieval and analysis systems. They could also act as a reference point for the sharing of information and good practices put in place by different stakeholders in the fight against counterfeit medicines.**

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As counterfeiting has directly affected private companies and brand/patent owners, these entities have employed strategies to combat counterfeiting for quite some time. The presence of IPRs protection units are more and more frequent in big multinationals and their job has progressively become similar to that of law enforcers. These IPRs protection units also conduct studies, collect evidence, analyse data and often possess knowledge on the problem related to their product that is superior to that of law enforcers. For this reason, it is important to establish cooperation mechanisms with the private sector, both for obtaining more knowledge on the situation (and if possible also information and data) and for supporting the investigations.

**The private sector has the potential to play an extremely important role in the fight against counterfeiting. Therefore, appropriate cooperation mechanisms should be explored to directly involve the private sector paying attention to avoid any possible conflict of interests. Such collaboration could support investigations and prevention of counterfeit medicines, and could also greatly contribute to the expansion of research on the phenomenon.**

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After the collection of knowledge on the problem, information sharing will be vital to support a better understanding of medicines counterfeiting and of its consequences. However, the sharing and communication of information, where possible, should not be limited to specific actors, but needs to be translated into suitable materials capable of being used to support awareness raising activities targeting consumers and the public at large. A general change in attitude is needed to fight counterfeiting. Citizens must be aware of the existence of the problem, what it entails, and how to prevent themselves from being the next victim. However citizens are not the only ones in need of receiving better information on the problem. It is fundamental that law enforcers are also better informed so as to clarify their perceptions of the issue and present them the serious dangers created by the problem, which go beyond the pure economic damages. It is very important to identify proper channels for the diffusion of the information so that it reaches the targeted audience. In this respect, the usual methods used during awareness campaigns (such as posters on the streets, airports and train stations or sporadic street campaigns in tourist locations) should be flanked by new methods of reaching the potential consumer.

**Proper awareness raising campaigns should be prepared and implemented to inform the citizens on medicines counterfeiting and on the dangers created by this crime.**

**In this respect it is important to explore the possibilities that the new technologies offer to spread the information. As counterfeiters are, for example, exploiting the advantages provided by the Internet to offer their products, awareness campaigns should also offer recourse to innovative strategies in order to increase their chances of reaching the target of the campaign.**

**Furthermore, training/awareness, information exercises, and dedicated workshops should be organised for law enforcers with the aim of providing them with better information on organised crime involvement in the counterfeiting of medicines and on the importance of properly contrasting its perpetration.**

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Fighting counterfeiting in general, and particularly the counterfeiting of medicines, requires significant efforts. As highlighted in this report, many countries do not possess the financial, human and organisational resources to properly set up control and prevention mechanisms. However, as counterfeit medicines are a global concern, these countries should not be left alone in this fight and should receive proper support.

**The international community should support less developed countries in their efforts to reduce the problem of counterfeit medicines. Some aspects which constitute the priorities for intervention and support may be identified as:**

- creating/improving control mechanisms;
- creating and enforcing proper legislation;
- setting up a National Central Authority in those countries where this Institution is missing, with specific competence and powers focusing on the problem;
- continuing to support to the existing coordination task-forces (such as has been done with IMPACT);
- creating appropriate market regulations and favouring generalised access to medicines.

**These actions should be tailored to the specificities of each country or area of intervention and should follow an assessment on the existing situation. They could be developed and tested as pilot initiatives to evaluate their effectiveness and their possible replication in other areas.**

**Due to the UN series of competencies in various aspects that are of fundamental importance for the creation and implementation of a strategy against counterfeit medicines in less developed countries, the UN could possibly apply an integrated approach to the problem which would take into account the existing Conventions and regulations (in particular the MEDICRIME Convention of the Council of Europe -- once it will enter into force -- and the relevant chapters of the UNTOC for what concerns organised crime involvement), the different aspects of counterfeit medicines and the complexity of the response to this crime.**

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In recent years, efforts have been made by the UN to facilitate a multi-disciplinary dialogue aimed at creating a shared approach to fighting counterfeit medicines. One of the most important examples is the IMPACT taskforce created by the WHO. These initiatives are extremely important and represent the basis upon which a common strategy against counterfeit medicines can be built and implemented. They allow for the discussion and sharing of good practices among different stakeholders coming from several countries and

sectors of activity, facilitating the possible replication of successful initiatives. They can also facilitate discussion on the improvements that are needed in both national and international responses and can provide guidance to Member States in reforming their national legislation and/or in properly applying the instruments that are already present in their national legislative framework. These experiences should further discuss the involvement of organised crime in counterfeit medicines and how a possible application of the UNTOC to the problem could support the response to this crime.

An integrated and shared approach would also facilitate a shift in the strategies against counterfeit medicines, and would allow for the eradication of misguided perceptions that only tag a few specific regions of the world as culprits. In reality, every country in the world is potentially affected by the problem in all its stages, from production to distribution, and consequently, each country in the world must be a part of the solution. It is only by finding mechanisms through which to work together that we will be able to advance our efforts to stop criminals from profiting from this deadly trade.

**The international community should support the creation of specific platforms or forums aimed at creating a shared approach against counterfeit medicines, involving both public and private stakeholders, following the spirit with which the IMPACT task-force, for instance, was created. Such platforms and forums would symbolise the international recognition of the global nature of the problem and would greatly facilitate the creation of appropriate global responses.**

**At the same time, the international community should facilitate the creation of shared approaches, recognising that all the countries affected at different levels by counterfeit medicines are part of a global solution. By criminalising specific areas and regions of the world, we run the risk of isolating them, giving criminals the opportunity to exploit such a situation and to continue, almost undisturbed, to be involved in what is, for them, a very profitable business.**

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