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ORGANIZED CRIME STRATEGIES IN THE PRODUCTION AND TRADE OF COUNTERFEIT MEDICINES INDICATIONS REGARDING ORGANIZED CRIME MOTIVATIONS, MODUS OPERANDI AND STRATEGIES

1. INTRODUCTION

- 1.1 Definition of counterfeit medicine**
- 1.2 Measuring the magnitude of the problem**
- 1.3 Complexities of the legitimate production and distribution processes as facilitating factors for counterfeiting of medicines**

2. THE INVOLVEMENT OF ORGANIZED CRIME

- 2.1 Organized crime and market choices**
- 2.2 The implication of organized crime in counterfeiting of medicines**
- 2.3 The motivations at the basis of organized crime involvement**
- 2.4 Modus operandi**
- 2.5 Entering the legitimate supply chain**

3. INDICATIONS

4. CASES SUPPORTING THE INDICATIONS

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1. INTRODUCTION

This research has been elaborated within the framework of the SAVEmed project, financed by the European Commission and aimed at developing an innovating anti-counterfeiting technology capable of substantially increasing the security of the medicines' market and the safety of patients. The purpose of this research is to provide the "technological partners" with a series of information, data, and suggestions concerning the strategies used by organized crime for the management of the production and distribution of counterfeit medicines, indicating them what they should take into account during the project in order to create a technology that can directly respond to the identified criminal strategies. This element is one of the innovative components of the SAVEmed project since this is the first time that a criminological research directly influences the creation of an anticounterfeiting technology, contributing to make this project a breakthrough in the fight against counterfeit medicines and the criminal organizations that are behind this trade. Part of the information presented in this paper has been collected through interviews with 15 different National Drug Regulatory Authorities of EU Member States that UNICRI conducted during the project. Thanks to these interviews some "border line" topics that are included in this paper were brought to our attention, as the need to start investigating the problem of fake food supplements which are often only a cover for a counterfeit medicine.

Since the focus of the research is the need to provide concrete indications to the technology partners, the structure of this paper will be organized accordingly. The indications will be presented after a brief introduction to the problem and a more extended analysis of how organized crime is managing the production and trade of counterfeit medicines. Case studies confirming the relevance of the indications will be presented separately at the end of the research.

1.1 Definition of counterfeit medicine

According to the definition elaborated by the World Health Organization (WHO) in 2006, a counterfeit medicine is a pharmaceutical product whose origin and/or identity specifications have been deliberately and fraudulently modified, regardless whether it is a pharmaceutical product protected by a patent or whether it concerns a generic drug. This commonly accep-

ted meaning falls within the broader definition of *substandard medicines*. The meaning associated with “counterfeit medicines” incorporates various cases that are ascribable to the adulteration/replication of a product and/or tampering of the relevant packaging:

- Products containing the same active ingredients and the same excipients of the original pharmaceutical agent, correctly packaged and labeled, but illegally imported into a country.
- Products containing the same ingredients of the genuine medicine, with genuine packaging, but containing 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 original products with genuine packaging, but containing harmful substances instead of the same 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.
- Products with counterfeit packaging that do not contain active ingredients.

Nonetheless, the WHO has now proposed a more comprehensive definition, which includes substandard/spurious/ /falsely-labelled/falsified/counterfeit (SSFFC) medical products. The SSFFC medicines are medicines that are deliberately and fraudulently mislabelled with respect to identity and/or source. As the WHO indicates:

- Use of SSFFC medicines can result in treatment failure or even death.
- Public confidence in health systems may be eroded following use and/or detection of SSFFC medicines.
- Both branded and generic products are subject to counterfeiting.
- All kinds of medicines have been counterfeited, from medicines for the treatment of life-threatening conditions to inexpensive generic versions of painkillers and anti-histamines.
- SSFFC medicines may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient or too much active ingredient, or with fake packaging.

The counterfeiting of medicines may also involve products being initially genuine but whose packaging has been modified declaring a higher level of active ingredients than the actual amount of the product, thereby allowing for an increase in sales' price. Expired drugs may also be placed within packages that report a later expiration date.

In its 2007 report on counterfeiting and piracy, the Organization for Economic Cooperation and Development (OECD) provided a list of 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; hormones and vitamins; and treatments for hair and weight loss.¹ Literally all kinds of medicines have been or can be counterfeited.

"Counterfeit medicines" are not the only problem. According to several EU regulatory authorities, the issue is broader and includes also illegal medicines. The focus of the attention needs to be expanded since the counterfeiters and, more in general, the criminals involved in these illicit activities are more and more interested in trafficking other profitable products such as food supplements, herbal products or steroids.

1.2 Measuring the magnitude of the problem

As for many criminal activities, reliable estimates on counterfeit medicines are extremely hard to come by. Reliability of the existing estimations is hindered by the obscure underground markets and by the challenges that authorities and experts often encounter in distinguishing a counterfeit medicine from an original one. Statistics are based on official data collected by regulatory authorities and law enforcement agencies in different countries. They depend on the capacity of the stakeholders to collect the information, on the fluctuations of law enforcers' performance and on data comparability.² Notwithstanding such caveats and

¹ OECD (2007), "The Economic Impact of Counterfeiting and Piracy", Directorate for Science, Technology and Industry, Committee on Industry, Innovation and Entrepreneurship, June 4th, p.10

² The accuracy in estimating the problem may be also linked to the definition itself of counterfeiting, which may change according to the country.

lack of exact estimations, available estimates can serve as useful indices to confirm the existence of the phenomenon and understand its trends.

According to the WHO estimates, counterfeit medicines represent approximately 10 per cent of the entire amount of medicines worldwide. Furthermore, countries such as the US, Australia, Canada, Japan, New Zealand and those within the EU have a very low proportion of counterfeit medicines, and their share accounts for no more than 1 per cent of the total market value.³

However, the considerable amount of counterfeit drugs cases declared on an annual basis by industrialized countries prove that this problem affects, to a greater or a lesser extent, both developed and developing countries. Mainly in Africa and partially in Asia and in Latin America, counterfeit medicines' sales would range 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 value⁴.

The size of the problem is also confirmed by the statistics gathered and elaborated by the national health and safety regulatory authorities. Some of these statistics and data are listed below to show how widespread the diffusion of counterfeit medicines is and how it virtually affects every region in the world:

- Just after a case of fake heparin in 2008, the *United States Food and Drugs Administration* (FDA) issued statistics reporting an 800 per cent increase in the incidence of fake drugs within the period of 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 operation achieved tremendous results, with more than 34 million illegal pills seized within two months, ranging from antibiotics, anti-cancer, anti-malaria and anti-cholesterol medicines to painkillers, and Viagra.

³ IMPACT (2006), "Counterfeit Medicines: An Update on Estimates", November 15th, available online: <http://www.who.int/medicines/services/counterfeit/impact/TheNewEstimatesCounterfeit.pdf>

⁴ Ibid.

- 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 former 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.
- The *General Directorate of Medicines, Supplies and Drugs* (DIGEMID) of the Department of Health (MINSA) in Peru seized around 460,000 adulterated and expired medicines in 2005 alone.
- 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. It was also found that some of the medicines sampled had expired over 10 years before.
- 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.
- In 2004, the *Ebonyi 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.
- According to the *Associated Chambers of Commerce and Industry of India* (ASSOCHAM) 20 per cent of the medicines sold in India are counterfeit. Among them 60 per cent lack active ingredients, 19 per cent contain incorrect ingredients and 16 per cent have either harmful or inappropriate ingredients, such as talcum powder. Other estimates show that 38 per cent of the medicines used in government hospitals are fake.⁵
- According to two official surveys conducted by the Cambodian Ministry of Health with the support of the WHO, the number of purchased counterfeit drugs was far from being di-

⁵ “Counterfeits, Spurious & Contraband Goods: Preventive & Remedial Issues” by ASSOCHAM

minished along the years. In the year 2000, national drug-testing laboratories in Phnom Penh and Bangkok proved that 3.5 per cent of the tested antibiotics and painkillers samples turned out to be counterfeit, and contained less than 60 per cent of the labelled quantity of active ingredients. In 2003, when the survey was repeated, the percentage had risen to 11 per cent.⁶ In 2010 the *Inter-Ministerial Committee to Fight Counterfeit and Substandard Medicines* (IMC) led an operation which forced almost 65 per cent illegal pharmacies to shut down and five manufacturers to stop from selling their products in the whole country.⁷

- According to a study conducted by a team from the Oxford University's Center for Tropical Medicine in Vientiane, Laos, the percentage of counterfeit over-the-counter antimalarial artemisinin tablets increased from 38 per cent to 53 per cent between 1999 and 2004.⁸

The phenomenon is similarly widespread with reference to the kind of drugs that are fraudulently produced and traded. Experience has shown that almost every existing medicine can be counterfeited, regardless of its kind, composition, form and purpose.

1.3 Complexities of the legitimate production and distribution processes as facilitating factors for counterfeiting of medicines

A clear distinction shall be made between the legal and the illegal supply chain. In the legal supply chain there are some vulnerabilities that might facilitate the introduction of counterfeit medicines. Occasionally counterfeit products may be introduced through unscrupulous wholesalers or through unscrupulous re-packagers involved in the legal parallel trade system in Europe⁹. However, in developed countries, the majority of the problems are

⁶ "Counterfeit pharmaceuticals: Murder by medicine", Nature 434, 132-136, 10 March 2005; Published online 9 March 2005 – article available here: <http://www.nature.com/nature/journal/v434/n7030/full/434132a.html>

⁷ "Cambodia Takes Action in Fight against Substandard and Counterfeit Medicines as Unprecedented Number of Illegal Pharmacies are Forced to Shut Down", The Standard, News and Information about the United States Pharmacopeial Convention, Vol. 7, issue 4, summer 2010 - article available here: <http://www.usp.org/pdf/EN/aboutUSP/theStandard2010Summer.pdf>

⁸ "Fake Pharmaceuticals: Increase In Counterfeit Anti-Malarial Drugs Prompts Call For Crackdown And Better Detection", Science daily, 20 June 2006 – article available here: <http://www.sciencedaily.com/releases/2006/06/060619005440.htm> and "Media Reports on Medicine Quality: Focusing on USAID-assisted Countries", by the Promoting the Quality of Medicines program, updated 3 August 2010 – available here: <http://www.usp.org/pdf/EN/dqi/ghcDrugQualityMatrix.pdf>

⁹ D. Sword, "Finding a Cure for Counterfeit Drugs: Technologies that Combat Vulnerabilities in the Pharmaceutical Supply Chain", in PharmPro, 27 May 2010, available online: <http://www.pharmpro.com/articles/2010/05/lab-instrumentation-Finding-a-Cure-for-Counterfeit-Drugs/>

related to the illegal supply chain, such as the “black market”, the street vendors, the online sales or the distribution of particular products in gyms or beauty centers. The situation is different in developing countries. In these regions, there are many weak points also in the legal supply chain, rendering the system and patients more vulnerable.

The following considerations on the legitimate production and distribution processes of medicines is a useful starting point for our analysis focused on how counterfeiters can market their products exploiting the market’s vulnerability.

The production/manufacturing process of legitimate medicines is quite complex. However, it might be divided into two main phases: the primary production phase and the secondary production phase. The first essentially refers to the production of active ingredients which allow the desired therapeutic effects to be attained. The secondary production phase 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 starts.

The distribution phase can also be divided into two phases which we will refer to as the ‘primary’ and ‘secondary’ distribution. The primary can develop in two distinct modalities. In most cases, it is entrusted by the producer to large wholesale area distributors who distribute it to the retailers or directly to the pharmacies. In fewer cases, producers themselves directly sell their products to the retailers, and in this case, the product is intended for exclusive sale to the patient and cannot be re-introduced into the distribution chain. The secondary distribution may appear more complex and does not directly involve manufacturers. It utilizes intermediary parties operating between the wholesale distributors and the retailers, often referred to as “brokers”. These intermediary parties vary in size and usually do not distribute the entire range of products of a pharmaceutical company. They operate by acquiring products from wholesale distributors or other sources and then re-sell them to other wholesale distributors or retailers. The excessive complexity of the distribution chain may create difficulties in controlling that all the parties are respecting good distribution practices and established agreements, adding an element of vulnerability and opening the door for possible insertions of counterfeit medicines into the distribution chain.

In theory, these operations could potentially benefit the final consumer since they may lead to lower retail prices. For instance, the intermediary producers acquire drugs at reduced prices, derived from surpluses in production or storage on the part of producers or large distributors and pharmacies; 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 (for example 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. Finally, the existence of significant differences in the sale prices of drugs across different geographical areas creates opportunities for other operators, the parallel importers, who exploit these differences and generate profits by acquiring the product in countries where the sale price is lower and then re-selling it in countries where it is higher. However, this complexity of the distribution chain presents vulnerabilities that may facilitate the entry of unauthorized or counterfeit products into the legal market. The monitoring of drug movements during their journey from the producer to the patient becomes very difficult. The higher is the number of brokers within the distribution chain, the more strenuous it becomes to monitor the origin of the product and identify its commercial route.

Both intermediary and parallel distributors are entities that operate at the secondary distribution level. Parallel distributors need to have a license in order to operate legitimately but do not need to have any form of agreement with the producer. The same applies to intermediary distributors, who also do not need to stipulate an agreement with the producer.

The existence of commercial operators that are not subject to specific commercial agreements with the manufacturer may add an element of uncertainty to the system. This element is worsened by various factors. One factor is that intermediary distributors – operating in the secondary market – do not receive the goods directly from the producer but simply re-distribute the products amongst various market players. It is thus not possible to identify the supply sources and this may pose a significant element of risk. Given that these parties are directly involved in the distribution of significant amounts of products, an imprudent purchase 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 process and the numerous transfers of products render it virtually impossible to identify the real origin of the medicines in question.

Counterfeit medicines may be inserted into the distribution chain in multiple ways and at almost all levels. The complexity of the distribution process, the scarce and rarely implemented controls in the distribution and re-packaging phases, and the existence of transportation documents that can easily be modified are some of the factors which weaken the system.

Moreover, commercial practices adopted by some brokering companies and intermediaries illustrate how their behaviour may facilitate the trade in counterfeit medicines. During the transport phase, the distribution brokers often conceal the names of the previous suppliers on the shipping documents to prevent customers from bypassing them in future purchases. This so-called “neutralization” is applied by many intermediaries to protect their commercial interests and exclude as many competitors as possible from the distribution chain and the business. Through this practice, the origin of the medicine is also concealed, as any hint referring back to its provenance disappears, making it literally impossible to trace the provenance of the drug or the medical substance. This can lead to unfortunate results, as ignoring the origin of the product also means ignoring its quality.

Despite security measures undertaken to protect the distribution chain, counterfeit drugs can still find their way into the legitimate supply chain. Brokers acting as middlemen between manufacturers and distributors may play a role in this, as they may either intentionally conceal or simply ignore the real origin of the products they trade. In this regard, the scandal of the counterfeit home diabetes test “OneTouch” provides a good example. Investigations revealed that copies of Diabetes testing strips were produced in China, without respecting the production quality standards, and were channeled through Canada into the United States. Counterfeit 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 had supplied American pharmacies with the bogus stripes – claimed that they had only distributed the products because they wanted to achieve more competitive prices and that they believed that the counterfeit strips were only lower-priced gray market products, diverted from normal distribution channels.

In addition to the above mentioned vulnerabilities, counterfeiters can also take advantage of gaps in the regulation of specific commercial practices (mainly parallel trade and diversion) and of the use of the Internet as a distribution channel. These gaps will be now better explained.

- Parallel trading

It is worth mentioning that within Europe the framework of the parallel trade is closely monitored, and the regulations in place will be further strengthened following the implementation of Directive 2011/62/EU of the European Parliament (amending the Directive 2001/83/EU relating to medicinal products for human use), which concerns the prevention of the entry into the legal supply chain of falsified medicinal products. Although European regulation has come a long way in ensuring the adequate monitoring of parallel trade, the overall system is still subject to a variety of risks that warrant a general overview.

Parallel traders, even those operating in relatively regulated markets like the European one, are not legally required to verify the origin of the products they buy, as they are only required to check that the person or company they buy from has an appropriate license. This leaves room for possible infiltration of counterfeit medicines in the legal supply chain.

In the case of parallel trading, a drug that is sold in a given country through the various stages of the ordinary distribution chain is again acquired by the major distributors to be inserted into the parallel distribution chain. The product is thus transferred to a new and more lucrative market by means of parallel intermediaries/distributors, taking advantage of the price differential that exist in different countries¹⁰. The times a pharmaceutical product is being 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 still does not exist an efficient mechanism for verifying the licenses of parallel importers; similarly, there is no obligation for the parties involved in the parallel distribution process to record product batch identification numbers.

¹⁰ These price differential are due to marketing strategies employed by manufacturers, government policies or by the local market forces.

A change in the country of sale of the drug necessarily implies that the package and prescription instructions will be modified or replaced. This phase is not free from risks and creates possibilities for counterfeiters to infiltrate the legitimate supply chain.

The following case shows the vulnerabilities linked to the parallel trade in medicines. An amount of 40.000 packs of tablets were seized in the U.K. by the Medicines and Healthcare products Regulatory Agency (MHRA) in 2007. The seizure involved fake medicines for the treatment of cancer, blood-clot and psychotic disorders. They were packaged in France, made in China and shipped to Singapore, subsequently a wholesaler in Luxembourg had bought them and, in turn, sold them both to a Belgian wholesaler and to another one based in Liverpool, who had sold them to other U.K. parallel importers. Among these latters, one noticed certain anomalies on the packaging and reported the case to the pharmaceutical company which in turn contacted the MHRA, leading to the seizure.¹¹ Although the case highlights the inherent vulnerabilities of the distribution of pharmaceuticals, it is also an example of good communication practice between the parallel distributor and the authorities. Their collaboration actually enabled the seizure of the counterfeit medicines avoiding possible dangers for consumers.

- Repackaging

Further difficulties for the identification of counterfeit drugs arise when original pharmaceutical products transit in various countries, and numerous importers, retailers and distributors are involved. In this context, an extremely delicate phase is that of repackaging. The repackaging process takes place throughout the distribution and shipment procedure and is a necessary step in ensuring that the package and instructions related to a particular drug are understandable by the patients. This process may be implemented by the importers themselves – when granted a special license – or by specialized parties authorized 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, fulfills a descriptive function and guarantees the originality of the drug through anti-counterfeiting features within the packages or labelling.

¹¹ "Parallel trade in drugs puts EU patients at risk", by Oliver Morgan, The Observer, 29 June 2008 – article available here: <http://www.guardian.co.uk/business/2008/jun/29/pharmaceuticals>

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, leaving room for mistakes in the reprinting phase. Thus, this procedure presents several loopholes through which counterfeit medicines may enter the legal supply chains.

Given its multifaceted nature, and the vast number of entities it involves, the repackaging phase may be exploited to disguise the provenance of counterfeit medicines, making tracing almost impossible and leaving the question of who makes the counterfeit drugs difficult to answer.

There are additional complications linked to repackaging. For example, despite the fact that each package replaced ought to be destroyed, counterfeiters have been known to re-use them to dispense their non-legitimate products

Rewrapping may also create opportunities for the adulteration of boxes. Two very common practices of falsification of packages are linked with: 1) the quantity of the Active Pharmaceutical Ingredient (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 potential use of rejected hospital material should also be underlined here as a possible risk. This process is facilitated in cases where the drug package does not include anti-counterfeiting features. 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. However, this is unlikely to happen in smaller countries where there are few companies in charge of destroying the hospital waste. They use to destroy both the content and the package of the hospital material, so that it is almost impossible that these products re-enter into the legitimate supply chain.

Repackaging is a necessity for parallel distributors in Europe, as they are obliged to label the product which they are placing on the market in the approved language specimens of the market of destination, and insert the patient leaflet in the appropriate language as approved for the particular product by the drug regulatory authority of the destination market. In order to exchange the 'old' leaflet with the correct one, parallel distributors must open the original package and thereby break possible anti-counterfeiting features. They are not free to replace such features with a feature of their choice, because the form of repackaging (re-labeling of existing package; or re-boxing, i.e. producing a new outer carton) is determined by trademark rules, not by patient safety rules, and the parallel distributor must not harm the reputation of the trademark's owner. This means for example that it is not possible to re-seal an opened package with an anti-counterfeiting sticker indicating that "this package has been opened and repackaged under GMP conditions by company X" because such an addendum to the labeling may be considered as a violation of the trademark law.

The maintenance of information relating to the characteristics of a medicinal product, in particular its batch number and expire date, are mandatory conditions for the repackaging process, and must be shown on the outer carton of repackaged products. When medicines are re-boxed, the original packaging material must be destroyed in a GMP controlled process.

Although the risks that we have outlined above are a reality that is to be confronted, the positive aspects that arise from parallel trading as monitored by the European Union's regulatory framework also warrant some attention. On one side, parallel trading is a legal commercial practice in Europe. On the other side, repackaging of medicines in the region is highly regulated, both at the level of companies that repackage as well as at the level of each product undergoing a repackaging. Products for parallel distribution are exclusively sourced in a country of the European Economic Area (EEA). Companies that engage in parallel distribution must be holders of a manufacturing authorization and they are subject to regular controls and inspections by the respective national authorities. They must operate along good manufacturing procedures, and the final batch released by a parallel distributor is - equal to the situation of any manufacturer - the responsibility of a Qualified Person (QP) who will normally also be responsible for Quality Assurance. These provisions are there to ensure that repackaging observes equally high standards of packaging as at any pharmaceutical manufacturer.

The recently adopted EU directive on Falsified Medicines is going to further strengthen the modalities for repackaging; it obliges a repackager to replace safety features which had been fully or partially removed during the repackaging process. The European trade association for parallel distribution (EAEP) has advocated for parallel distributors being obliged to produce new outer cartons when repackaging, thereby replicating not only the necessary trademark and other relevant labeling information, but also safety features that will have equivalent effect to those put on the package by the original manufacturer.

- 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. 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 both cases, through diversion the products will not reach their intended destination but will be marketed at full price.

The motivation underlying these operations is the difference in purchasing 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.

With regards to international diversion, the 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 re-packaging also make the authentication phase very difficult for retailers.

- The Internet

One of the main challenges in the fight against counterfeit drugs is represented by the Internet, which is increasingly becoming one of the main distribution channels for this type of products, also according to the main regulatory agencies at European level.

People suffering from several kinds of diseases, especially those that are seen merely as taboos (for example sexual or psychological problems), may turn to the Internet for medical advice and treatments. However, and according to WHO estimates, half of the drugs sold on rogue Internet sites are fakes.¹²

In an attempt to encourage patients to buy from legitimate producers over the Internet, Pfizer - the pharmaceutical company which produces the well known Viagra – recently decided to sell their blue pills online. Pfizer also conducted a survey on 935 men over 35 years of age. Among its findings it resulted that 50 per cent of the surveyed people purchased online medicines without a prescription and 67 per cent of them bought erectile dysfunction drugs. 60 per cent of the interviewed men also stated that the possibility that the drugs were counterfeit would have influenced their decision to purchase prescription-only medicines through the Internet.¹³

Moreover, the Internet is used as a tool for self-diagnosis and self-treatment for patients willing to bypass classic medical control. By consulting general information on illnesses, their prime or possible symptoms and suggested cures, an increasing number of patients think that the solution to their health problem can be found 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 clear example of how the cyber environment may contribute to the spread of counterfeit medicines is represented by an operation conducted by the FDA. 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 (emails sent in bulk for advertisement and promotion reasons) were sent from an address licensed to someone in the Russian Federation, the website server used by the counterfeitors 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 in the USA.

¹² See WHO website, <http://www.who.int/mediacentre/news/releases/2006/pr69/en/>

¹³ “Counterfeit medicines”, The Parliamentary Office of Science and Technology, January 2010 Number 352 – article available here:
<http://www.parliament.uk/business/publications/research/post/publications-by-year/pubs2010/>

The use of the Internet 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 unauthorized online source could become an entry portal for counterfeit medicines which, due to the single market, could then reach any destination within the Union.

In this regard we may point out that counterfeiters exploit the Internet as an important channel of offer for products at both the retail and wholesale level.

In the first case, the consumer is often deceived through attractive and convenient prices and a constant stream of unsolicited commercial messages (a.k.a. spam) in her/his inbox which will link them to a legitimate looking Internet site where they can make their purchases.

Although there is currently no legislative framework that governs spam at the international level, several countries and organizations are already taking action to improve international cooperation in anti-spam action both on a technical and a regulatory level. This cooperation is mostly driven by the exchange of information and best practices. In Europe, after the implementation of the [European Directive on Privacy and Electronic Communications \(2002/58/EC\)](#), which entered into force in 2003, unsolicited communications via e-mail or phone have become more rigidly regulated across all the EU Member States.

In addition to the ready availability of spam advertising, the chance to show up in search engine results and to place advertisements on legitimate websites is additionally alluring for counterfeiters. In 2010 a fake drug scam involving U.K. higher education institutions was uncovered. Counterfeiters exploited software flaws in a widely used technology named PHP, utilized to make websites more interactive. Spammers injected a code associated with terms such as Viagra, Cialis and other drugs and each time a person would look for online drugs, universities and colleges' web addresses would pop up. Once online visitors clicked on the link, they would immediately be re-directed to an online fake pharmacy. Because of this scheme, several institutions that made use of the ".ac.co.uk" domain unwittingly showed

customers to websites that were offering counterfeit pills. According to the researchers thousands of organisations fell victims of such drug spammers.¹⁴

In the case in which criminals exploit the Internet trying to insert counterfeit medicines into the distribution chain at the wholesale level, counterfeiters penetrate the distribution chain exploiting the fact that various distributors are constantly searching for low-cost products to maximize profits. Once the products are acquired by the distributors, they can be marketed as any other drug deriving from an authorized source and tracing their origin will almost be impossible.

Furthermore, given the impersonal nature of online commercial exchanges, the Internet provides an element of anonymity that is especially alluring for counterfeiters. Through this medium, the perpetrators may disguise their identity and conduct business on a global scale, operating across various judicial jurisdictions. Consequently, 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 on various Internet sites involved in 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 unauthorized distribution network for medicines was discovered originating in India and extended throughout North America. A similar case occurred within the EU when, in 2001, a criminal group established a network of online 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.

- The role of facilitators

¹⁴ "Fake drug scam hijack UK college websites", BBC News, published online 5 March 2010 – article available here: <http://news.bbc.co.uk/2/hi/technology/8550219.stm>

Credit card issuers, money transferer services, Internet providers as well as private mail services can be considered as indirectly partly responsible for the distribution of counterfeit medicines. These services may facilitate these kinds of crime since (even if involuntarily or because of negligence) they allow transfers of money, they host illegal websites or transport of prohibited items from one country to another. To date there is no regulation placing liability on these services for the role they play in aiding the criminal network. Due to their involuntary involvement in this process, they should be encouraged to cooperate through specific tools such as the adoption of voluntary codes of conduct and awareness raising campaigns in the fight against trafficking of counterfeit medicines, following the example of what has been done for the prevention of child pornography online.

- Further elements on the vulnerability of the system

Some factors across the EU involuntarily play a role in facilitating the activities of counterfeiters, especially when these elements contribute to hinder the response put in place by law enforcers. The problem of jurisdiction, for instance, can greatly limit the powers of investigators. For this reason, cooperation between law enforcement agencies and regulatory agencies at national and international level and with the private sector¹⁵ are more and more important in the fight against counterfeit medicines. The issue of jurisdiction over the Internet is even more controversial and should be regulated since it is easy for organized criminals to create their own heaven in the cyber space.

Further difficulties are faced by national authorities at the detection and prevention level. One of the main difficulties is to prove the involvement of organized crime; this is primarily due to a lack of resources and poor information sharing between the authorities, both at national level and in the EU. Furthermore, if on the one side the problem is to understand, follow and prevent the strategies of counterfeiters – once a strategy has been identified, counterfeiters rapidly change their modalities of action – on the other side there might be technical difficulties related to the instruments needed to analyse the products.¹⁶ Moreover, it is impossible to check every truck or container at the border of the EU, thus it is extremely important to implement a system of risk assessment based on intelligence and profiling. In

¹⁵ The corporate security of private companies, in charge of intelligence, is not limited by jurisdiction.

¹⁶ These instruments are very expensive and, usually, the national authorities do not have enough resources to provide themselves with these kinds of tools.

this regard, there are already several good practices in Italy, Portugal, Ireland and other EU countries. There are many different criteria to assess the risks related to particular products. For example, in Finland a big case of counterfeit medicines was discovered because of the repetition of the same addressee, based in a remote region of the country, that caught the attention of the customs officers in charge of the controls.

Several national regulatory agencies also underline how important is the cooperation with the manufacturers, in view of detecting illegal products and for the analysis of the medicines. There are good practices of cooperation within the public sector: in Spain, the Spanish Agency of Medicines and Health Products (AEMPS) established a pilot experience in cooperation with the Postal Customs and with the intervention of the Tax Agency (Agencia Tributaria), the Postal system (Correos) and the colleagues of the Pharmaceutical Inspection. The aim of this pilot experience was to demonstrate that the authorities have a clear vision of what is going on in the field of trafficking of illicit medicines and to establish evaluation criteria of risk assessment modalities.

Similar experiences exist at the European level, even if they are not always provided by law but rather based on good relations established among the people involved. In this perspective, the political will of the governments and their consequent support – both in terms of resources and the development of a solid legal background – is a crucial aspect in view of preventing and tackling the phenomenon of counterfeit medicines.

2. THE INVOLVEMENT OF ORGANIZED CRIME

2.1 Organized Crime and market choices

Robust evidence shows that organised crime is increasingly involved in counterfeiting.¹⁷ Counterfeit medicines are by no means an exception. Once recognized that counterfeiting is part of the strategies of organized crime, it is interesting to consider more in detail the specific role it plays within these strategies as well as how organized crime contributed to transform counterfeiting into a mass-production industry.

With regards to counterfeit medicines, it is possible to identify clear market choices operated by counterfeiters, especially with reference to the distribution of different categories of drugs in developed and developing countries. Counterfeitors exploit the demand for specific pharmaceutical products existing in a given socio-economic context, often operating with a high level of organization and demonstrating a veritable planning capacity which is owned by the managers of this trade. A significant difference remains in terms of the type of counterfeit medicines which reach these two markets. In Europe, the United States and Canada, for instance, the trafficking of fake medicines primarily involves pharmaceutical products that are lifestyle-related. These so-called lifestyle drugs include pharmaceutical agents against male sexual dysfunction, substances for weight loss, fake steroids, or products to slow down the aging process.

Counterfeiting of medicines in developing countries, on the other hand, usually targets drugs used to treat serious diseases such as malaria, vaccines of all types, antibiotics and antiretrovirals for HIV. The differences in counterfeit products between these two market "types" reflect the specific marketing strategy adopted by counterfeiters. Drugs with the highest market share and/or profitability are marketed. Furthermore, counterfeiters can count on an almost rigid demand curve in developing countries, due to the need to combat epidemics or serious diseases, the elevated cost of drugs designed for these functions and the low supply of such products combined with the constant need for medical supplies and low levels of wealth.

Intelligence obtained through investigations and police raids in Europe, the United States of America and Canada, demonstrates that production, consumption and distribution of counterfeit medicines is a global phenomenon that is not limited to emerging economies.

¹⁷ See, UNICRI (2011), *Counterfeiting: A Global Spread, A Global Threat. An Update*, p.78 and followings.

This global market of counterfeit medicines is similar to the legitimate one 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 from the place of its final marketing. It exploits the possibility of producing at reduced costs, and relies on well established organized criminal networks. The attention of the counterfeiters is always directed towards those products that are more profitable. As widely reported by the drug regulatory agencies at European level, the market of food supplements, steroids and herbal products (containing active ingredients) has been increasing during the last years. As a consequence, also the counterfeiting of these products, which can illegally contain active ingredients, is augmented. The following case is an example.

In 2005, the Spanish police raided six laboratories in the northeastern region of Catalonia. The operation resulted in the seizure of 30 million doses of counterfeit anabolic steroids, hormone-boosting substances and cancer drugs, which weighted a total of 10 tons. The substances came in various forms including vials, capsules, tablets and doses for injection. 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 were carried out 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 "healthy food" stores. Even though the production of the fake substances was taking place in Spain, the authorities concluded that the ingredients used for their production originated from Mexico, Brazil, and Thailand.

This case serves to depict the 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 authorized 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 the countries involved, demonstrate the complexity of the production processes and the interconnection of supply markets all around the world, which are interesting factors that will be shortly discussed.

2.2 The implication of organized crime in counterfeiting of medicines

Some of the key issues to be addressed are the profile, motivation and *modus operandi* of those individuals hidden behind the counterfeiting production and distribution chain. However, factors contributing to the spread of counterfeit medicines are based on various levels that have to be examined as a whole as they are inherently connected and influence each other.

The numerous cases of seizures, alerts and recalls of counterfeit medicines in almost every region of the world, corroborate the transnational scope of the phenomenon. This huge market and the level of organization of the counterfeiting network supports the conclusion that counterfeiting is based on complex and sophisticated structures often set and maintained by organized 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. There is serious evidence establishing links between counterfeiting and other forms of organized criminal activities such as narcotic drugs production and trafficking, trafficking in persons, arms trafficking and money laundering. The knot of this link is obviously the economic benefit.

The reasons behind the close interconnection between counterfeiting and other forms of organized crime can be briefly summarized in the following assumptions. There is a wide range of means and aims used by medicine counterfeiters which are compatible with other types of criminal activities. For example, medicine counterfeiters can use their installations and equipment to produce narcotic drugs and *vice versa*. This is best represented in the Jupiter Operation¹⁸. Analysts were investigating fake antimalarial drugs in Southeast Asia and found traces of safrole, a carcinogenic precursor to MDMA, better known as Ecstasy. Such discovery suggested that the same criminals who produced party drugs were also producing fake antimalarials.¹⁹ What is more, counterfeiting can finance and be financed by

¹⁸ Operation Jupiter is led by INTERPOL in partnership with the World Customs Organization (WCO). Launched in 2004, Operation Jupiter expands in scope every year. Each phase of the operation targets an increasingly wide range of counterfeit and illicit goods, in more distribution channels and in more countries. Operation Jupiter V (2010) resulted in the seizure of nearly 8 million counterfeit products worth more than USD 200 million and led to nearly 1,000 arrests.

¹⁹ “The fatal consequences of counterfeit drugs”, by A. Marshall published on Smithsonian magazine, October 2009 – available on-line: <http://www.smithsonianmag.com/people-places/Prescription-for-Murder.html?c=y&page=3>

other forms of organized crime. 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.

Before further elaborating on the organized crime involvement in counterfeit medicines, it is important to define the concept of organized crime. We will do this by referring to the definition provided for in the United Nations Convention against Transnational Organized Crime (UNTOC) (2000) – the most important international regulatory instrument on this subject – which identifies an organized criminal group 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 offences...in order to obtain, directly or indirectly, an economic or other material benefit*”.²⁰

2.3 The motivations at the basis of organized crime involvement

The involvement of organized crime in the production and trade of counterfeit medicines is often bypassed by key stakeholders, at times even by governments and law enforcers. One of the most common questions raised on this issue concerns the reasons at the basis of organized crime interest in counterfeiting. The reply to this question is linked with the general expansion of the interests of criminal organizations, which have become more and more prone to exploit every opportunity for profit. However, an in-depth analysis of the relation between counterfeiting and organized crime allows for more interesting elements to come to the surface.

The assumption that organized crime is essentially dedicated to offering illegal goods and services that are in demand within a given territory may be taken as a starting point. Organized crime supplies a range of services to potential customers and, from this point of view, does not significantly differ from any legal entrepreneurial venture. The criminal activity is essentially linked to the existence of demand for illegal goods and/or services. The evolution of this demand – or rather, the changes in the object of this demand – is among the factors that in the ‘70s caused a change in the criminal structures.

²⁰ Refer to: United Nations, *United Nations Convention against Transnational Organized Crime*, Art. 2 (a), available online: <http://www.unodc.org/documents/treaties/UNTOC/Publications/TOC%20Convention/TOCebook-e.pdf> [last accessed on 22 March 2011].

The modus operandi with which the production and distribution of counterfeit medicines are organized is based on a set of alliances and trafficking schemes that reflect those established with the narcotic drugs trade. Generally speaking, offering illicit goods and services often means that a production and distribution structure/network has to be put in place, with different forms and dimensions, and various organizational levels. In some cases, the goods or services will be produced and sold within the same territory, while in others an actual trading scheme will have to be created – as in the case of narcotics – leading to the establishment of alliances involving various criminal organizations. For example, criminal groups involved in the trafficking of counterfeit medicines use the same intimidation, corruption or extortion practices established in their other trades. These practices can extend to concealment methods, trade routes or document forgery which explains why counterfeit medicines are often found alongside cargoes of other illicit goods. These practices may take place at both national and international level.

Counterfeeters profit by exploiting primarily two forms of demand, firstly they attract consumers seeking the counterfeited version of the product and secondly the demand generated by those who find the legal market unattainable because of shame or financial reasons. Alongside these types of demand, organized criminals are also profiting by exploiting the legal market. This generally happens when they present themselves as legitimate suppliers to other actors of the distribution chain, who fail to accurately evaluate the source of the product.

This combination of demands and penetration into the legal market is a fundamental element in the creation of a real “business case” for criminal organizations which see in counterfeiting an opportunity for immense profit.

- Profits vs. risks

The trade in counterfeit medicines is a high profit/low risk criminal activity, and as such it is extremely attractive to organized criminal groups. This is exemplified by the proven involvement in this activity of criminal groups such as the Russian mafia, the Chinese triads, the Colombian cocaine traffickers, and the Mexican mafia. 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 risks (especially where regulations and enforcement are weak and sanctions are clement).²¹

The high profit margins that derive from the production of counterfeit products in general are clearly visible through an analysis of available cases provided by law enforcement agencies. These cases involve criminal organizations that were obtaining huge profits from counterfeiting activities and that were subsequently dismantled by law enforcement actions leading to the confiscation of relevant proceeds of crime. Digital piracy is an interesting example. In the U.S., for instance, the Federal Authorities estimated that the revenues of a dismantled criminal organization dedicated to this trade could reach 1.2 million USD per year, while in another case, also in the U.S., it has been established that a criminal organization remitted to manufacturers of counterfeit goods in Asia 9.8 million USD.

For what concerns the specific case of counterfeit medicines, according to the *Centre for Medicine in the Public Interest*, counterfeit drug sales generated 75 billion USD globally in 2010, with an increase of 92 per cent with respect to 2005. The *Peru's Association of Pharmaceutical Laboratories* (ALAFAARPE) affirms that the value of sales of counterfeit drugs in Peru has risen from an estimated 40 million USD in 2002 to a 66 million USD in 2006. Finally, 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.

The level of profitability of counterfeiting has been estimated similar, or even higher, to that of the trade of narcotics. The table below has been kindly provided by Europol. It clearly shows the profitability of Sildenafil in comparison to different types of narcotic drugs and presents why criminal organizations are so interested in the trafficking of counterfeit and falsified medicines.

²¹ R. Bate (2008), Making a killing. The deadly implications of the counterfeit drug trade, The AEI Press, p. 35, available online at: <http://counterfeiting.uncri.it/docs/Making%20a%20Killing.the%20Deadly%20Implications%20of%20the%20Counterfeiting%20Drug%20Trade.%20Roger%20Bate.pdf>

Active ingredient	Purchase prices €/Kg in 2007	Retail prices (street prices) €/Kg in 2007	%
Opium*	190	52 000	27 400
Cocaine*	1470	67 000	4 600
Heroin*	7190	47 700	660
Sildenafil API Viagra®	60	100 000	166 700

*UNODC World Drug Report 2009

Source: Europol, undistributed materials

Another interesting study was conducted by the Institute for International Research on Criminal Policy²² which analyzed the vulnerability of the European Pharmaceutical sector to the penetration of organized crime, by taking into account particular 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. The purpose of the study was to interpret, through the analysis of the combination of elements that characterize the European pharmaceutical market, the motivations of organized criminal groups in infiltrating

²² T. Vander Beken (ed.), The European pharmaceutical sector and crime vulnerabilities, 2007

the market as well as the “assets” that the sector offers for the expansion of illegal activities. According to the study, this vulnerability is 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, 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.

For criminals, the risk involved in counterfeiting is significantly low, given that law enforcers often tend not to consider counterfeiting as a top priority for action. Penalties in the majority of countries are also less severe if compared with those applicable to other “serious crimes”. The relatively low level of apprehension generated by this illegal activity is due to the initial perception that counterfeiting was associated only to luxury or textile goods, and it did not generate sufficient concern to warrant incisive action by law enforcement officials. The involvement of organized criminal groups in these activities has, however, multiplied the number of goods subject to unauthorized replication, thereby leading to the “evolution” of counterfeiting and its transformation into a large scale trade.

Additionally, the significant potential for intimidation and corruption by organized crime has facilitated the expansion of trafficking in replicated products as well as the opportunity to offer them within normal sales channels, thereby also reaching unaware consumers. Increasing evidence of the presence in the market of counterfeit goods potentially harmful to the health and safety of consumers should disown the idea of counterfeiting being a “victimless crime”.

To give an idea of the evidence, we cite a few dramatic figures.

- ◆ Counterfeit tuberculosis and malaria drugs alone kill 700,000 people a year, which is the equivalent of four fully laden jumbo jets crashing every day.
- ◆ According to WHO, 200,000 lives per annum could be saved if malaria was treated without using fake drugs.

- ▲ In 1995 in Niger almost 50,000 people suffering from meningitis were treated with vaccines received as a gift by a country considered safe and 2,500 of them eventually faced death.²³
- ▲ In 2001 192,000 deaths occurred in China, officially caused by treatments which used counterfeit medicines.²⁴

One of the primary appeals in counterfeit medicines for organized criminal groups is that the production and distribution processes can easily build upon their other illicit trades. This logistical simplicity extends to technologies that determine the external appearance of the product and to trade routes previously created by various groups to manage other types of illegal trade. The combination of these characteristics ensures that counterfeiting is an opportunity that modern organized crime will not fail to exploit. In addition to these elements, several investigations conducted by law enforcement agencies around the world demonstrated that counterfeiting is also an important instrumental tool for criminal groups to easily launder proceeds from other crimes²⁵. Considering that counterfeiting is a huge source of money with a relatively low risk and a tool to launder proceeds of crime, the profit vs. risks ratio is extremely favorable for counterfeiters and constitutes one of the most important motivations at the basis of organized crime involvement in this illicit activity.

2.4 Modus operandi

We will now analyze the various ways in which organized crime manages the production and distribution of counterfeit medicines with the aim of identifying important elements to be taken into account during the planning of a strategy against this crime and, in particular, during the design of an anti-counterfeiting technology.

The production phase, the infrastructure and logistics needed for the production of fake medicines are very similar to those used for the production of narcotic drugs under the form of pills, allowing the criminal organization to easily diversify the types of illicit products it

²³ World Health Organization, Fact sheet n°275, November 2003 – article available here: <http://www.who.int/mediacentre/factsheets/2003/fs275/en/>

²⁴ “Le marché mondial du faux”, P.Delval, CNRS editions, 2010, p.119

²⁵ For more information on ways in which organized crime uses counterfeiting as a money laundering tool refer to: “Counterfeiting: a global spread, a global threat, 2011 edition”, UNICRI, p. 101

offers. For example, in Canada 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, contained hundreds of thousands of ecstasy and methamphetamine pills as well as 35 kilograms of bulk powder which could be used to manufacture another 160,000 ecstasy pills. Also on the site were 25,000 Viagra tablets and 31,000 Cialis tablets that were seized during the raid.

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 suggests that counterfeit medicines are being mass produced by those involved in the relevant criminal networks.

Mass production and mass distribution of fake medicines, together with the level of resemblance these copies have with the original drugs, demonstrate, that this illegal activity is not undertaken just by individual offenders but has instead become a business of well organized criminal groups. Production and transportation techniques, distribution networks and 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 organized 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. For the counterfeit market to flourish, great emphasis is placed on the exterior elements of the product, such as its appearance and packaging. At a glance the counterfeit products are generally easily mistaken for the original ones, as their external elements are often identical. The quality of the packaging boxes, blister packs, bottles, tubes, etc. that contain the drugs is the primary convincing factor for the consumer and this is why criminals try to create a perfect copy of these external elements. 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 fake drugs were produced revealed that they are often equipped with highly accurate

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

The case of a counterfeited cancer medicine “Avastin” found in Denmark exemplifies how the counterfeiting of packages can seriously jeopardize the integrity of distribution within the licit drug market. In the “Avastin case”, the Denmark-based broker company never conducted checks on the product itself since as the distributor they were not entitled to open the packages. They only monitored the batch numbers of the vials and ensured that they corresponded to the batch number of the packages. The product was sold from a transit warehouse in Switzerland to a transit warehouse in Great Britain, while the final destination was California. The counterfeiting of the packaging rather than that of the drug proved instrumental in allowing the penetration into the legal market.

Unscrupulous practices are applied not only in the production phase but also during the transportation phase. The example presented above is very useful to present one of the strategies used by counterfeiters for trading counterfeit medicines: covering the real provenance of the products by multiplying the steps of the distribution chain in order to hide its real origin. In this case, the criminal organizations 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 they render it extremely difficult to trace the shipped product, establish the dates of shipment and predict the final destination. Through the multiple stopovers the fake medicines pass through various intermediaries and their accompanying documents may be subjected to various modifications with respect to dates of transportation, transported quantities, kinds of substances being shipped, names of shipping companies and persons involved.

To complicate matters further for law enforcers, transportation of counterfeit medicines can involve complete products or only its components, which are to be assembled elsewhere. Parts of the product can, for instance, originate from one country and other components 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. For example, the packages of counterfeit medicines can be shipped separately from the counterfeit drug in order to avoid the identification of either product. The intricate production/distribution practices designed by

the criminal groups engaged in counterfeit medicines, greatly hinder any efforts to trace, detect and identify the products at border controls.

The trafficking routes that are used for the trade in counterfeit medicines connect the markets of developing countries with those of Europe and North America in a variety of ways. The raw materials and counterfeit drugs often originate from Asia, Latin America and Eastern Europe and reach the most profitable markets through various trade routes depending on the type of product. The European continent is also a site hosting production centers for counterfeit medicines. The presence of such centers in Europe, as well as the complexity of the utilized trade routes, is clearly illustrated by a case involving the marketing of counterfeit Zantac – a drug used to treat gastritis – in which the raw materials were derived from Turkey while the manufacturing process was implemented in Greece. The final product was then marketed through a Dutch importer by means of a Swiss “broker”.

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

Several interviews conducted with National Drug Regulatory Authorities highlighted cases in which medicines were coming from China and Hong Kong and were passing through big commercial hubs in the EU. Malta, Bulgaria and Belgium are some of the most important entry points; but also worth mentioning are Hamburg in Germany or Naples and Taranto in Italy. In Belgium, in particular, there is a lot of trafficking of counterfeit medicines from India which are re-exported to Africa via the Brussels' Airport. A recent report by the Dutch authorities identified the most important countries of origin for counterfeit medicines in Singapore, Hong Kong, India, China and Russia. If the products are shipped by sea, they usually arrive in Rotterdam while if they come by air, they arrive in Amsterdam Schipol. The authorities of Northern, Central and Eastern Europe also identify Russia and Ukraine as the main countries of origin and production. Finland, for instance, is considered as a transit country both because it borders with Russia and because it is expanding its flight connections with the main Asian countries.

In general, regarding the issue of the main trafficking routes, the information collected through the National Drug Regulatory Authorities often confirm that following complex routes in order to divert the investigations and cover the real provenance of the illicit products is one of the main strategies of organized crime.

2.5 Entering the legitimate supply chain

The sales of fake pharmaceuticals seem to follow the existing market practices both in the national and international markets. Depending on the market structures and the marketing strategies, counterfeit medicines can appear in local dispensaries or on-line pharmacies. While it seems that at the European level the legal supply chain is very closely controlled, as mentioned above, there are still issues linked to the existence of online pharmacies and the use of the Internet, as well as to the illegal supply chain that penetrates non-medical environments (ie streets, gyms and beauty centers).

To enter the legal supply chain counterfeiters may rely on existing connections with distributors and traders. Intelligence shows that counterfeiters use intimidation and blackmail practices to generate fear amongst retailers and prevent them from reacting and taking legal action. However, in the case of counterfeit medicines criminal groups also attempt to penetrate the legal distribution system at a higher level, by operating as an actual distributor. There are 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 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 bear a degree of responsibility. When they do not act responsibly and do not verify the sources from where they purchase, they may involuntarily grant organized criminal groups the power and the capacity to penetrate the legitimate supply chain, mixing counterfeit and genuine medicines up.

Aside from instances of traditional counterfeit medicines, criminals also enter the licit market by hijacking authentic medicines – through the smuggling, repackaging and altering of their expiration dates. The final purpose is to make these products re-sellable and to re-introduce them into the market. Instead of being destroyed, the expired (and thus useless and

ineffective) drugs find their way 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. 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, these elements make these type of medicines an appealing and very promising market for organized 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.

Several cases concerning illegal manufacturers and unlicensed intermediaries have also shown that criminals who operate in a more coordinated way and develop large amounts of an ample range of counterfeit pharmaceuticals often try to deceive authorities by masking themselves as transparent legitimate businesses. 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 licenses 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. These deceiving practices together with corruption, intimidation, blackmail and violence against public officials render the legitimate supply chain more vulnerable to criminal groups.

3. INDICATIONS

Counterfeiting of medicines should be tackled by law enforcement and medicines agencies as an organized crime activity. Investigative tools employed for organized crime should be utilized nationally and internationally to investigate and prosecute this crime.

Being mostly a transnational activity, Member States and law enforcement agencies could make reference to the United Nations Convention against Transnational Organized Crime (UNTOC) to support their investigations and cooperation across borders. At the European level, some important legal instruments are the MediCrime Convention and the Directive 2011/62 on Falsified Medicines.

The following are the indications that UNICRI identified for the technology partners and summarize those elements that should be taken into account during the creation of the anti-counterfeiting technology.

- Increase the cost of replication for counterfeiters

The profitability of the trade is one of the most important motivations for criminals, pushing them into the business of counterfeit medicines. The technology under development should take this aspect into consideration, allowing legitimate producers to use it without excessive financial implications but creating an important financial burden for counterfeiters in the case in which they want to replicate it. In this case the technology will directly impact the counterfeiters' "business case".

- Verification tool inside/incorporated by the medicines

Since reproducing the exterior features of a medicine is quite simple for counterfeiters,²⁶ the technology under development should allow for a verification method applied also on the

²⁶ According to David Shore, associate director of global security for Europe at Pfizer, any new security features for packaging last only about 18 months before counterfeiters can produce fake copies.

external appearance of the product. In this case, counterfeiters would find it more difficult to create externally identical copies of original products while this solution would also allow for an easier “first sight” distinction between the original and the fake product.

- Allow easy checks at all stages of the supply chain, especially by poorer countries

The technology under development should allow for an easier and immediate verification by Customs and Law Enforcement Authorities regarding the genuinity of the products. This is to say the creation of a feature that is immediately visible, difficult replicated, linked-attached-comprised by the product itself, and easily verifiable with the means available to developing countries

- Possibly link the medicine to its intended commercial route

The code or identification method in the medicine should also be linked to a total traceability technology in order to control the different stages that the product passed during the supply chain. This would allow for the verification of the respect of the trade route that was intended for the specific product and for the identification of incorrect behaviours in the case in which the trade route has not been respected. A next step could be a type of verification process “step by step” during the supply phase and an alarm system in case a product is passing through a distribution step that was not intended for it.

In general, several regulatory agencies would welcome the possibility of making controls on safety issues at every stage of the distribution process. However the lack of resources is a serious burden over the implementation of a monitoring system that would enable law enforcement agencies to check every step of the distribution, even if it would help to strengthen controls.

- Involve and take the facilitators

As in the case of other serious crimes as drug and arms trafficking or pedopornography, “facilitators” should also be involved in the fight against counterfeiting of medicines. Credit card issuers, money transfers, Internet providers as well as private mail services should be involved through tools such as the adoption of voluntary codes of conduct and awareness

raising campaigns. Possible penal liability could be also explored in case the crime is committed thanks to the services provided for by such entities and with reason to believe that a certain degree of knowledge existed.

- Tablets machines

Machineries used by counterfeiters to perfectly replicate the external appearance of specific drugs are very often quite sophisticated in terms of technology they use. There is no control or restriction over the movement of such machineries, and no information regarding, for example, where they end up when they are dismissed by a legitimate pharmaceutical company or who purchases them “second hand” from the producers. If such machineries would be put under a regulatory system whereby producers are requested to keep and share information on who purchases them, this may provide addition important information to help track down counterfeiters.

Create a link with the packaging

We have seen how the various phases of the supply chain, especially those including repackaging, may facilitate the introduction of counterfeit medicines into the legitimate supply chain. The possibility of double verifying that the package and the content are what they were intended by the manufacturer would allow for an immediate verification of the genuinity of both elements (package and content). In this case each package should be linked to its content in a unique way (or types of packages for types of content) but a sort of unique verification element linking the package to its content would be extremely important.

Give consumers the possibility to recognize the genuine product

The previous element would also allow consumers to perform a check regarding the product they bought. Since a large amount of counterfeit medicines are purchased through the Internet, allowing buyers to check the shipment they receive could be an improvement as well as a way of empowering individuals in their choices. Nonetheless, this element should not entail any verification “burden” on the consumer. These responsibilities need to be on the relevant authorities, manufacturers, distributors and pharmacies. Moreover, even if this element might be useful on the consumers’ side, it does not prevent the profits to arrive to

criminals and thus could not be used against organized crime. It would be, in fact, only a post-purchase verification²⁷.

Inter-agencies cooperation and political willingness of states

During the interviews we conducted, several national regulatory agencies underlined how important is the cooperation with the manufacturers, in view of detecting illegal products and for the analysis of the medicines. A prompt inter-agencies communication can be an important way to rapidly detect possible dangerous products as well.

Good practices of inter-agencies communication exist at European level, even if they are not always regulated by existing laws but rather based on good relations established among the people involved. In this perspective, the political willingness of the governments and the consequent support – both in terms of resources and the development of a solid legal background – is a crucial aspect in view of preventing and tackling the phenomenon of counterfeit medicines. An attempt in this sense can be the use of the “EU risk information form” in relation with counterfeit medicines.²⁸

The political willingness is a fundamental aspect also with regard to the implementation of new technologies to track and trace the medicines: they are a very important instrument, but they need to be supported by effective policies and legal instruments, as well as by continuous training to keep the police and customs officers up to date with the evolving challenges posed by the criminal networks operating in this field.

²⁷ The impossibility to use consumers' verification as a tool against criminals was highlighted by some participants to the first roundtable meeting of the SAVEmed project during the discussion on “OC Strategies”.

²⁸ The purpose of the RIF is to exchange risk information dealing with routine control concerns. A RIF should raise the awareness of the offices concerned with regard to a potential irregularity. It can be prepared following a finding of an irregularity (for example a misdeclaration or finding of counterfeit or undeclared CITES goods) and could give information on the technique used to find the irregularity, for example the result of a physical examination or a classification decision. The RIF is aimed at being a simple and easy to use form which can be exchanged rapidly directly between customs offices. It can be used to support targeting and risk analysis in a simple and effective manner at the external frontier. Several pilot actions have been carried out in partnership between the Commission and the EU Member States on the distribution of the RIF. An example is the dissemination by the Commission to all Member States and Candidate Countries risk analysis centres, information regarding the protection measures relating to avian influenza in Thailand. EU customs have been given detailed information to include in their risk assessment strategies to support their controls in the fight against the possible illegal importation of prohibited poultry products from Thailand.

4. CASES SUPPORTING THE INDICATIONS

APIs used to produce medicines killed hundreds of people across the world

The case herewith presented concerns fake heparine, which was shipped halfway around the world, and may highlight with immediate evidence some of the main points discussed above:

- Between 2007 and 2008 eleven countries including Germany, France, Denmark, Italy, the Netherlands, the United States, Canada, Australia, New Zealand, Japan and China reported cases of contaminated heparin within their markets. From November 2007, an unexplained spike in adverse events related to Heparin worried the medical community, so much so that in January 2008 a number of incidents forced a recall of Heparin products. It was determined that all adverse events reported up to that point had come from Heparin manufactured and distributed by a well known American pharmaceutical corporation company. Since then, investigations found that the Chinese factory which supplied raw materials for the American corporation was substituting oversulfated chondroitin sulphate for raw heparin. Oversulfated chondroitin sulphate mimics the function of heparin, but is not approved for use in medications. In July 2008, the FDA formally acknowledged the connection between the contaminants found in the Heparin manufactured by the American pharmaceutical corporation, and the serious, even deadly, side effects experienced by patients who used it.

Chinese officials have denied that any contamination took place and blocked FDA investigations aimed at determining exactly where and how the contaminants entered into the production process. The FDA's working hypothesis was that this was intentional contamination. Testing has shown that in some batches of recalled heparin, up to 1/3 of the material was a contaminant. As the contaminant was approximately 99% cheaper than raw heparin, it is possible that production costs played a part in the substitution.²⁹

²⁹ U.S. Food and Drugs Administration, Drugs, Informations on Heparin: 2008 Heparin Contamination, <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM112597>

This case shows a very interesting element regarding organized crime strategies. Criminals have acquired enough knowledge to fool authenticity tests on products, especially on APIs. This element supports the need to ensure that also APIs can be verified at different stages of the supply chain and that these controls are rendered easy to perform.

- Another case presenting similarities with the previous one is the case of toxic syrup containing counterfeit dyethylene. In April 2006 the Panamanian Government Health Agency manufactured cough and antihistamine syrup, mixed with 99.5 per cent pure glycerin syrup shipped from Barcelona, Spain. In September, patients exhibiting unusual symptoms started to come to Panama City public hospital. Victims were counted all over the country and raised alert. Investigators from the United States Centers for Disease Control and Prevention tested suspect bottles of syrup and found traces of a toxic substance used as industrial solvent and primary ingredient for antifreeze: diethylene glycol. Medical authorities stated that a precise account of the victims was impossible, as many of them were buried even before the cause of their death was discovered.

In the same year, an investigation of The New York Times found out that loads of diethylene glycol manufactured near the Yagtze Delta in China reached the port of Colon in Panama, passing through a Spanish trading company in Barcelona, which served as a stopover as well as second distribution point. Diethylene glycol was used for the preparation of various types of medicines – cough syrups, fever medications, injectable drugs – and sold as 99.5 per cent pure glycerin.

The label of the counterfeit glycerin falsely attesting the purity of the shipment was repeatedly altered by the traders who erased the name of the manufacturer and of the previous owner. This practice is called “neutralization” and is often applied by brokers and companies to protect their own interests. In this case counterfeiters clearly took advantage of this commonly utilized practice to allow the fake ingredient to reach its final destination without raising any suspect.

This particular case clearly shows how traders bought the toxic ingredient without testing it and without knowing where it came from or who manufactured it, which further underlines how easy it was for counterfeiters to spread their fake product. The New York Times discovered that the Chinese manufacturer was not certified to make pharmaceutical

ingredients, information that traders might have acquired as well just by carrying out more accurate inquiries.

The problem of diethilene glycol is unfortunately not isolated to this case.

- Back in 2005 many deaths occurred in China due to the administration of diethylene glycol syrup. Advertisements of the toxic syrup also appeared on an Internet website, posted by the manufacturer. In this case the Internet proved as a veritable easy source of counterfeit drugs for online customers. The government was unable to stop the poisoning which spread all over the country causing one of the biggest domestic scandals of the year.

In the past two decades diethylene glycol was responsible for at least eight mass poisonings around the world. Beyond China and Panama it has caused mass poisoning in Haiti, Bangladesdh, Argentina, Nigeria and twice in India. According to researchers' estimates, thousands of people have died, proving how easy it is for counterfeit drugs to contaminate the worldwide market and make this crime way far from being victimless.

These cases show a series of very interesting elements linked to our indications. First of all it is extremely clear that the problem of counterfeiting does not refer only to "finished" medicines, as it can involve APIs and other ingredients. The toxic substance was in fact traded as glycerin, demonstrating that every ingredient of which a medicine is composed should be subject to control and identification procedures. The supply chain needs to consent easy checks at all stages in order to avoid such misfeasances and allow for the APIs detection and neutralization of the counterfeiters' intervention. The implementation of more rapid checks by customs officials at the borders proves once again to be necessary. Furthermore this case also shows the importance of linking the medicines or their ingredients to their intended commercial route with the use of innovative technology. In the cases described above, new monitoring technology could have empowered traders to conduct independent checks on the product which would have blocked the distribution phase at an early stage and prevented the spread of the toxic product.

Fake drugs into the legitimate supply chain

In some areas of the world, it may be tremendously easy for counterfeiters to introduce fake drugs into the legitimate supply chain and the examples below will provide evidence of this situation. Some of the cases presented in this research already showed that counterfeit medicines have been found in legal and authorized pharmacies in several countries around the world. In addition other cases are presented in this section.

- In 1992 more than 200 unwanted pregnancies resulted out of the use of counterfeit birth control pills in Brazil. Although the drugs did not contain any active ingredient, they were sold in authentic packages.³⁰ In 2005 when counterfeits were found in the U.K. legal supply chain with a valid batch number, Pfizer recalled 120,000 packs of Lipitor, its cholesterol lowering drug, from 240 pharmacies. Sixty per cent of the retrieved stock turned out to be fake³¹.

These cases clearly show the importance of some of the proposed indications. The examples have been chosen because they represent a very similar situation that happened in two different and distant countries with almost 15 years of time span between them. This clearly shows that after 15 years counterfeiters were still able to use the same strategy to market counterfeit medicines and that every country is a potential target of these organized crime activities.

These cases have two important elements in common: the use of original packagings for the trade of counterfeit medicines and their insertion into the legal supply chain. This means that criminals have been able to obtain original packagings, fill them with counterfeit medicines and infiltrate the supply chain so deeply that they were sold at regular pharmacies. This highlights the extreme potential vulnerability of the medicines' supply chain and the possible ineffectiveness of those security features that are applied only to the packaging. This gives more and more importance to the need to create a unique link between a security feature on the packaging and one on the medicines, creating a sort of unique self-verification tool. If this system was used, the counterfeiters would have had great difficulties in introducing their products into the supply chain because they would have not known how to replicate the unique symbiosis existing between the original packaging and the original medicine. Even in

³⁰ "I farmaci contraffatti", D. Di Giorgio, Edqm, 2009 pp 33-34

³¹ www.mhra.gov.uk/index.htm

the case in which they would acquire such knowledge, the costs of replication would be very high³², reducing the “business case” for criminals.

The same cases also show the importance of allowing easy checks by the Regulatory or Law Enforcement Authorities at all stages of the distribution, using also a way to link the medicine to its intended market route. This would have prevented the possibility for the counterfeit medicines to reach the pharmacies because it is highly improbable that the counterfeiters would have known or respected the intended commercial route of the original packagings they acquired. A technology proposing this feature, in addition to the constant checks to be done during the distribution chain, would have created an additional difficulty for counterfeiters because during one of the various checks the fact that the intended distribution route was not respected would have come to light.

Finally, these two cases also show how important it is to give consumers the possibility to check the authenticity of the products they buy, especially allowing them to use a self verification tool that will “validate” the content with the packaging. It is in fact evident that validating only the packaging is not a guarantee for consumers.

- In 2007 the Medicines and Healthcare products Regulatory Agency (MHRA) recalled from U.K. pharmacies a parallel distributed stock of Clopidogrel tablets branded as Plavix, after the discovery of counterfeit tablets in the legal supply chain. The counterfeit drugs were supplied in French livery via parallel distributors into the U.K supply chain. Parallel traders used a very simple strategy: they applied an overlabel on livery cartons or remanufactured packages and wrote them in English.

Once again, often the authenticity of the packaging turns out to be misleading in relation to the actual content of the drugs. Therefore it is clear the absolute necessity to create a link between the medicines and their packaging. In particular, when repackaging activities are involved, assuring a permanent connection with the packaging is a fundamental step in order to guarantee the maximum level of safety regarding the genuineness of the medicine inside.

³² The system that is proposed by the SAVEmed project to legitimate manufacturers will result cheap in view of the production volumes of their products.

- As we have seen in the 1992 and 2005 cases, and as also reported by the Canadian Criminal Intelligence Service, counterfeit drugs are not unlikely to be sold within licensed pharmacies. In Canada, in particular, despite in-depth safeguards across the country, criminals succeeded to identify vulnerabilities in more than an occasion. This is exemplified in the case of the seized grey-market Norvasc pills used in the treatment of hypertension and angina. Here, the eleven patients of the pharmacy who were prescribed Norvasc died and the Ontario Coroner's Office conducted an investigation to determine if the counterfeit medication was a contributing factor to those deaths. In January 2006 it was determined that in four of the eleven deaths the medical cause of death included "possible unauthorized medication substitution".

In such a circumstance, if those consumers could have been able to perform a check on the medicine they bought, their lives could possibly have been spared. As it is proved, counterfeit drugs can be found in regularly licenced pharmacy stores and thus be immediately used by unaware consumers. That is why the possibility to empower consumers giving them the chance to check the originality of a medicine is important. Allowing individuals to perform easy checks is also a step ahead in order to spread awareness on the counterfeit pharmaceuticals plague.

This case also confirms the importance of performing controls during all the steps of the distribution chain. All players involved should be allowed and asked to perform checks on their own as well. This could enable them to both make sure that the legal chain has been respected at each stage and to concretely try to recognize the difference between an original medicine and its copies.

EU as transit zone: the effective response of the law enforcement agencies

Several cases demonstrated the role of Europe, and especially Eastern and Central Europe, as transit zone for counterfeit products coming from the Far-East and directed to the EU or even across the Atlantic. Due to the huge number of containers and shipments crossing Europe, it is impossible to check all of them and thus the effective response of the law enforcers is extremely important when the risk is detected.

- In 2008 in Czech Republic, customs officials of Kralupy and Vlatvou (north Prague) destroyed one tonne of fake medicines in an industrial furnace. Approximately one million pills were discovered by way of x-rays that examined incoming packages in the regular post. Officials, using x-rays to monitor incoming packages uncovered what was estimated as a million pills and tablets, most often sent from China, India or Hong Kong. Then the drugs were being distributed throughout Europe. Police busted a counterfeit drug ring producing steroids and other hormone-based drugs. In addition to those, police seized "hundreds of thousands" of tablets for illnesses like kidney and liver disease and erectile dysfunction.³³

Of course, not all the countries in the world have the same human and financial resources to dedicate to the problem. In addition, counterfeit medicines have shown-up in the legal distribution chain of both developed and developing countries, demonstrating that the issue of more effective controls and easier checks during the distribution chain is extremely important. When developing an innovative anti-counterfeiting technology it is important to remember that counterfeit medicines are a global problem and that it is extremely important to grant also poorer countries the possibility to protect their citizens against this plague. The effective response of the LEAs, also through the use of technology, is crucial both at the prevention and detection level.

The role of brokers and the high risks connected to the repackaging process

- The scandal of the counterfeit home diabetes test "OneTouch" strips imported into the US 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 only distributed the products because they wanted to achieve more competitive prices.

³³ Velinger, J. Customs officers destroy tonne of fake-brand medicines. Radio Prague. Jul 2, 2008, www.radio.cz/en/article/105717;

Johnstone, C. Czech police pounce on hormone drugs ring. Czech Position. Jul 26, 2011, www.ceskapozice.cz

This particular case clearly shows how allowing easier checks at the various stages of the supply chain could contribute to reduce the dangerous effects of brokers' reckless behaviours. In such a case the chance that the counterfeit products could reach up to 35 countries could have been lowered simply by setting up easier and more immediate controls. Moreover if a link between medicines and their commercial route was established, it would have made it much more difficult for brokers to mindlessly spread their hazardous products all over the world.

- At the beginning of 2005 counterfeit Tadalafil tablets aiming to treat erectile dysfunction and shipped to the Czech Republic from the Philippines were found by Customs Administration officers. Their batch number was not consistent with that of the authentic product but there was no proof that the counterfeit drugs had been introduced in the legal distribution channels. Nevertheless in 2004 counterfeit tadalafil tablets of the same batch number had been found in the legal distribution channel in the United Kingdom, allowing creating a link with the products found in the Czech Republic.
- Another interesting example is that of counterfeit clenbuterol tablets traded from the Czech Republic to the United States, bearing a batch number that had previously already been placed on the Czech market. Out of 53,760 packages on the market, that same batch had already gone through the distribution process and the seizure consisted of only 14 packages, that is to say the small stock actually detained by the wholesaler. Such a case presents similarites with the previous one and, even though no proof was found that the product had entered the legal distribution channel (no pharmacy or distributor was identified as sender), what happened in the United Kingdom may allow us to think that the same might have occurred also in this case. The product was detected as counterfeit by the Czech authorities and it was withdrawn from the market, althought there were no indications the legal supply chain had been infiltrated.
- It is clear that intervening in the repackaging process is a very easy operation for counterfeiters, as it occurred in the case of the re-packaged paracetamol tablets sold in Kenya as anti malarial pills presumably produced in backyard operations in or around Nairobi. Whereas the authentic packs presented slight differences due to paper shifts in the manufacturing process, counterfeit ones looked all identical on both sides, as it was a

simple operation for counterfeiters to copy the layout of one single pack then multiply it to make fake copies.

All these cases show how the authenticity of the packaging, their exterior quality or the authenticity of batch numbers constitutes no guarantee on the authenticity of the medicine. As demonstrated throughout the various examples, repackaging activities contributed to easily allow the worldwide diffusion of fake drugs. The phenomenon triggers the necessity to easily check products during the various phases of the supply chain, as well as linking them to their commercial route. A link between the medicine and its packaging as well as arranging more controls along the supply chain could have stopped the counterfeit tablets.

For all these cases it is also valid an element that was previously presented: the need to increase the cost of production/replication for counterfeiters. A verification tool inside the medicines as well as a self-verification system with the packaging, if implemented, would contribute to add an element of difficulty for the replication of the drugs operated by counterfeiters. As previously discussed, such tools could also enable both individual consumers and all those responsible for controls to perform a check on the medicines at various stages. Obviously higher costs and more controls along the supply chain operated by different subjects would contribute to deter counterfeiters' activity.