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How do the Pharmaceutical Industry and Health Authorities fight together against drug counterfeiting ?

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How do the Pharmaceutical Industry and Health Authorities fight together against drug counterfeiting?

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Abbreviations

API	Active Pharmaceutical Ingredient
DSCSA	The Drug Supply Chain Security Act
CRPT	Center for Research in Perspective Technologies
EMA	European Medicines Agency
EU	European Union
FAMHP	Agency for Medicines and Health Products
FASFC	Federal Agency for the Safety of the Food Chain
FDA	Food and Drug Administration
FT-IR	Fourrier-Transformed Infrared Spectroscopy
GDP	Good Distribution Practice
GMP	Good Manufacturing Practice
GSMS	Global Surveillance and Monitoring System
GTIN	Global Trade Item Number
HIV	Human Immunodeficiency Virus
IP	Internet Protocol
IPR	Intellectual Property Right
ISPE	International Society for Pharmaceutical Engineering
NDC	National Drug Code
NIR	Near Infrared Spectroscopy
NMR	Nuclear Magnetic Resonance
OECD	Organization for Economic Cooperation and Development

OTC	Over The Counter
PSI	Pharmaceutical Security Institute
QP	Qualified Person
QR	Quick Response
R&D	Research and Development
RFID	Radio Frequency Identification Device
RP	Responsible Person
S/N	Serial Number
SNI	Standardized Numeric Identifiers
UN	United Nations
UNODC	United Nations Office on Drugs and Crime
USA	United States of America
WCO	World Customs Organization
WHO	World Health Organization
XRD	X-ray Diffraction

1. Introduction

Counterfeiting of consumer products (ie copies of luxury products, clothes, electronic components …) is usually a very well-known issue and regularly communicated in the media. It is important to stress that medicinal products are also affected and that, besides the economical element of counterfeiting, this issue has a significant impact on patient safety and public health in general.

Although the medicinal product is very particular in nature and use, it should not be forgotten that it remains a consumer product generating significant revenues and of broad use across markets. Revenues generated can be as high as from narcotics traffic with a lesser risk in case of prosecution which makes it overall attractive. As a result, drug counterfeiting and traffic of fake medicines have developed quite significantly impacting public health leading over Health Authorities and pharmaceutical companies to take actions, develop anti-counterfeiting regulations and measures.

Recent examples of police operations executed in 2021 that highlight the ongoing international fight against this issue include Operation Pangea XIV coordinated by INTERPOL across 90 countries that led to a seizure of counterfeited medicinal products and devices sold online (including COVID-19 related products) worth more than 23 millions dollars. Operation Shield II coordinated by Europol seized thousands of tablets, ampoules, doping substances, COVID-19 related medical products etc. for a total worth of 63 millions of euros.

The importance of drug counterfeiting in the pharmaceutical world and my limited knowledge of the subject led me to choose this topic, wishing to increase both my expertise in this area and raise awareness of readers. My work's objectives will, first of all, be to set the context around this issue such as for its localization, type of counterfeited drugs, contributing factors and consequences on health, economy and on the pharmaceutical industry. It will be followed by outlining measures taken by Competent Authorities as well as technical solutions such as overt and covert, developed in order to secure the authorized supply chain. Lastly, the implementation of drug serialization in major markets (Europe, United States of America (USA) and Russia) will be detailed and the work will end on a brief explanation of the pharmacist's important role in securing the authorized supply chain.

2. Definitions

2.1 Medicinal Product

As per the European Medicines Agency (EMA), it is a "*substance or combination of substances that is intended to treat, prevent or diagnose a disease, or to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action*". (*Medicinal Product*, n.d.)

2.2 Counterfeited medicine

As per the World Health Organization (WHO) definition from 1992, "*A counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.*" (Kopp, n.d.)

This definition has evolved and has been revised by WHO in 2007. Its aim was to clarify the different terms by creating a clear distinction between substandard, falsified, and unregistered/unlicensed drugs. (OECD et al., 2020). The revision was meant to mainly base definitions on impact on public health while not taking into account the intellectual property aspects of the problem. (World Health Organization, 2017b)

Definitions can be found below:

- "*Substandard: Also called "out of specification", these are authorised medical products that fail to meet either their quality standards or specifications, or both.*
- *Unregistered/unlicensed: Medical products that have not undergone evaluation and/or approval by the national or regional regulatory authority for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation.*
- *Falsified: Medical products that deliberately/fraudulently misrepresent their identity, composition or source*." (World Health Organization, 2017b)

The terms "counterfeited" and "falsified" will both be used in this work.

2.3 Supply Chain

International Society for Pharmaceutical Engineering (ISPE) is defining the supply chain as "*The sequence of processes involved in the production and distribution of a commodity. A supply chain normally encompasses the following three functions: -Supply of materials to a manufacturer; -The manufacturing process; and, -The distribution of finished goods through a network of distributors and retailers to a final customer. Companies involved in various stages of this process are linked to each other through a supply chain*".(*Supply Chain | ISPE | International Society for Pharmaceutical Engineering*, n.d.)

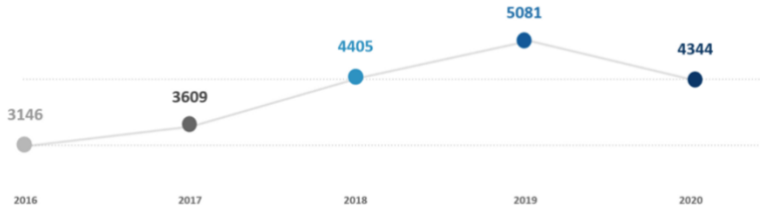
3. Current Situation and Global Repartition

3.1 Facts and Figures

According to World Customs Organization (WCO), drug counterfeiting is representing a $200-billion business annually and is now considered a more lucrative business than narcotics. It is therefore a very significant issue globally recognized by both governments and the pharmaceutical industry.(Michael White, 2021)

The graph below from the Pharmaceutical Security Institute (PSI) shows the number of pharmaceutical crime incidents used as an indicator of drug counterfeiting. Such incidents[1] kept increasing annually until 2019 with a decrease in 2020 that is attributed to the Covid 19 pandemic. (Pharmaceutical Security Institute, n.d.-b)

Figure 1: Evolution of pharmaceutical crime incidents from 2016 to 2020 (Pharmaceutical Security Institute, n.d.)



The graph indicates an increase of cases these last years, but data only reflects a fragment of the impact of counterfeited drug today. In fact, reports of incidents are not only dependent of the market's counterfeited drugs occupancy but also depend on the staff's ability to report them. As trainings and formations take place, number of reports increases consecutively. (World Health Organization, 2017a)(World Health Organization, 2017b)

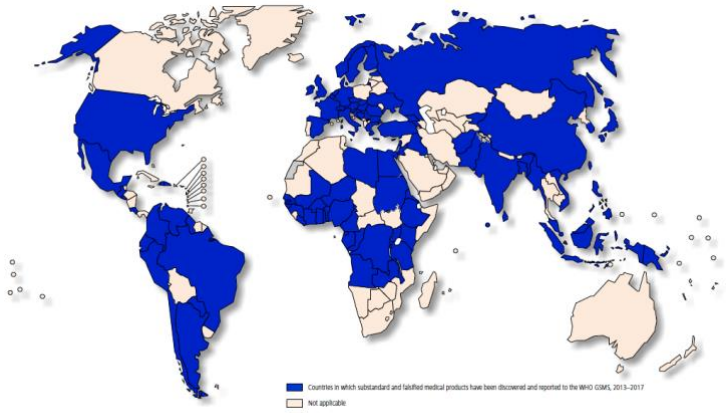
For example, since 2012, WHO has trained people to become "focal points". They are people especially trained and mandated to manage information about counterfeited and substandard drugs, but mostly, to report these incidents to local and international organizations such as WHO. As expected, this led to a rise of reports the following years. PSI has also specified that the rise in their incidents numbers both were due to more reports from their member companies and from government agencies. (OECD et al., 2020) (World Health Organization, 2017b)

[1] The word "Incident" is defined by PSI as "*a discrete event triggered by the discovery of counterfeit, illegally diverted or stolen pharmaceuticals*"(OECD et al., 2020)

3.2 Localization

3.2.1 Countries where counterfeited drugs have been reported

Figure 2: Map indicating countries where substandard and falsified medical products were discovered and reported to WHO, from 2013-2017 (World Health Organization, 2017)



As shown on the map above, most countries are impacted by substandard and falsified products. The problem is therefore global and doesn't only apply to middle and low-income countries, highlighting the urgency to respond at an international level.

In 2006, WHO evaluated that 10% of medicine around the world were counterfeited. However, this percentage doesn't reflect reality since this problem differs from one country to another, and because of the complexity of its measurement. Moreover, based on the localization of the problem, it's more accurate to say that it ranges from 1% in developed countries to more than 10% in developing countries. For instance, in developed countries such as USA, Japan, Canada, countries from the European Union (EU) etc. it is said to be less than 1% due to regulatory systems and market control. Whereas, in developing countries it can go from 10%, to more than 20% in former Soviet Republics and above 30% in areas of countries located in Africa, Asia or Latin America. (*TheNewEstimatesCounterfeit.Pdf*, n.d.)

Numbers speak for themselves when talking about the impact in low and middle-income countries. Main reasons why they are easy targets for counterfeiters are often a collection of factors such as: limited access to good quality medicine, poor governance, corruption, and poor technical capacity to assure quality in manufacturing and distribution of products. (World Health Organization, 2017a)

3.2.2 Provenance of counterfeited drugs

Falsified drugs, as well as drugs in general, can be produced in countries far from where they will be distributed. They are often manufactured at low costs in countries such as China and India, then send through criminal networks to another site where they will be assembled with their packaging, also produced in a different country.(OECD et al., 2020) (United Nations Interregional Crime and Justice Research Institute, 2012)

Based on Organisation for Economic Cooperation and Development (OECD) numbers of seized counterfeited products and drug in the EU from 2014 to 2016, the top provenance is India with a total of 47% followed by China (37%) and Hong Kong (8%). Singapore, Switzerland as well as Australia also appear in this top 10.(OECD et al., 2020)

OECD has also looked at customs seizures and legal trade intensities, this allowed them to define top 10 provenance economies of counterfeited drugs. Again, the top three economies that export counterfeited drug worldwide and to the EU are: India, China, and Hong Kong. We can also find other sources that export worldwide, some of which are: United Arab Emirates, Egypt, Philippines, Singapore, Viet Nam etc. For the EU, we will find respectively the Philippines, Russia, Singapore, Turkey and much more. (OECD et al., 2020)

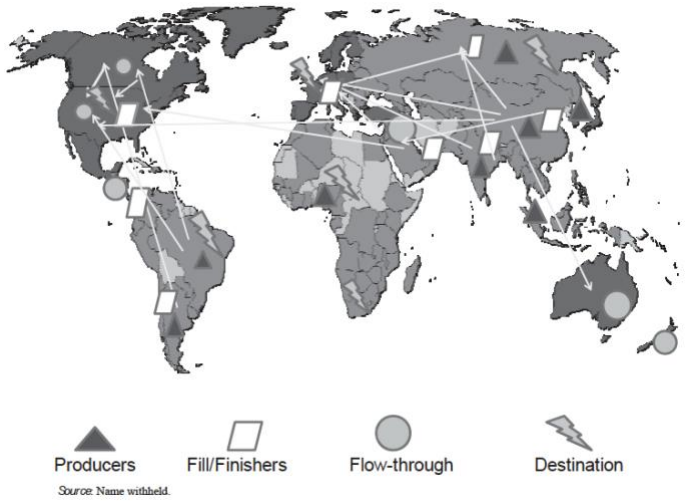
Data available on the capacity of an economy to manufacture pharmaceutical products and their degree of re-exportation can be used to identify key provenance and mostly transit points.

Key provenances and transit points worldwide		**Key provenances and transit points in the EU**	
Producing economy	Transit points	Producing economy	Transit points
India	Hong Kong	India	Hong Kong
China	United Arab Emirates	China	Singapore
Philippines	Egypt	Philippines	Turkey
Vietnam	Cameron	Thailand	Iran
Indonesia	Turkey	/	Switzerland
Pakistan	Singapore	/	USA

Table 1: Key provenances and transit points of counterfeited drug worldwide and in the EU from 2014 to 2016. (OECD et al., 2020)

Countries are listed by their importance in these markets. The table shows that India, China, and the Philippines appear both as top producing economies worldwide and in the EU. As for transit points, Hong Kong appears first for both categories whereas Turkey and Singapore take part with different importance. (OECD et al., 2020)

Figure 3: Map showing the complexity of flow from manufacturers to the final destinations (International Institute of Ressearch against Counterfeit Medicines and Eric Przyswa, 2013)



3.2.3 Transport of falsified drugs

The transit of falsified medication is done by multiple types of transports. It goes from air, sea, and road to smaller shipments by mail, courier and even travelers. Packages are distributed all around the world using these methods and making it difficult to trace their origin. Moreover, falsified drugs or medical products will often be sent separately. For example, tablets can be sent in a box and blisters in another and be covered by other counterfeited products such as mobile phones. It's a very appealing process for counterfeiters because it reduces the risk and renders complex the task of detection and tracing. (World Health Organization, 2017b)(International Institute of Ressearch against Counterfeit Medicines and Eric Przyswa, 2013)(United Nations Interregional Crime and Justice Research Institute, 2012)

In addition to this technique, the increase of the number of intermediates increases risks for counterfeited drugs to enter the authorized supply chain. In fact, documents will be modified throughout the process as for their dates, quantities and substances transported, as well as shipping companies and other people involved in the distribution.(World Health Organization, 2017b) (United Nations Interregional Crime and Justice Research Institute, 2012)

Based on OECD numbers of custom seizures of counterfeited drugs worldwide from 2011-2013 and 2014-2016, we can see that the majority comes from mail/express courier followed by air then sea in 2011-2013. However, there's a shift three years later with mail/express courier up to 96%, air decreasing to 4% and sea/road almost insignificant (0,1% and 0,2% respectively) (Fig.3). If we look at the numbers of custom seizures in the EU during the same years, we can draw almost the same conclusion with mail/post/express courier and air being by far the most used transports (Fig.4). (OECD et al., 2020)

Figure 4: numbers of custom seizures of counterfeited drugs worldwide from 2011-2013 and 2014-2016 (OECD et al., 2020)

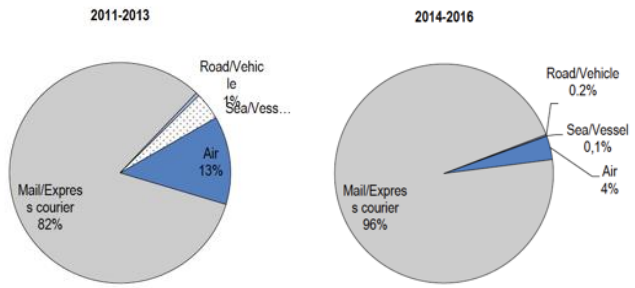
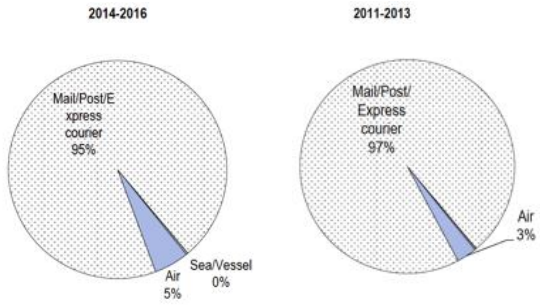


Figure 5: numbers of custom seizures of counterfeited drugs in the EU from 2011-2013 and 2014-2016 (OECD et al., 2020)

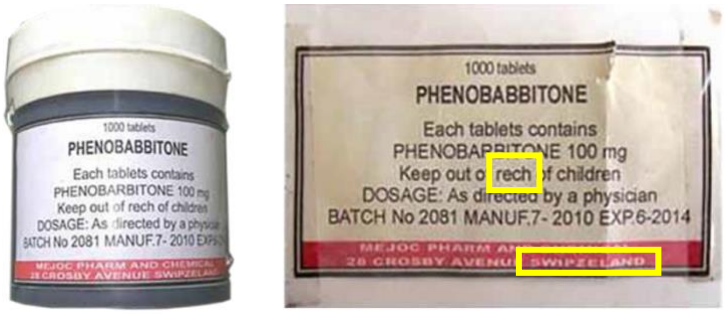


Many factors play critical roles in the shift, these past years, from sea to mail and courier. Small shipments are very attractive to counterfeiters and criminals since they represent lower risks. For instance, even if shipments transiting through cargoes are less exposed to detection, in the event of a seizure, large quantities will be lost. This represents a huge amount of money for criminals. Overall, they will be more tempted to send small shipments which in case of confiscation will cost less. Moreover, the population's habit of buying everything online has had a major impact. The number of packages exploded lately, making it difficult to detect fraudulent transactions. The task is even more complex since the sender's information is not always verified and because documents are commonly in paper form. Authorities have sounded the alarm and recommend using electronic forms which provide information before the shipment arrives at destination point. (OECD et al., 2020)

3.3 Type of counterfeited drugs

There's a vast diversity of therapeutic classes found in falsified drugs. They differ based on regions where they are found because counterfeiters adapt their products to the market's needs and demands, seizing any opportunity to increase their income. For instance, in industrialized country we will find drugs such as anti-cancers, diet related drugs, painkillers, antivirals and other lifestyle products. On the other hand, in less developed countries most classes found are life-saving products such as anti-malarial, anti-human immunodeficiency virus (HIV) and tuberculosis drugs. There's also a difference packaging wise with packaging of high quality made almost identical in developed countries, and poor-quality packaging in less developed countries. An example can be found on Fig.6. The picture shows the packaging of counterfeited phenobarbital found in Guinea-Bissau in 2013, it contains spelling mistakes in the words "reach" and "Switzerland".(United Nations Interregional Crime and Justice Research Institute, 2012)(*Counterfeit Medicines and Organised Crime*, n.d.)(International Institute of Ressearch against Counterfeit Medicines and Eric Przyswa, 2013)(World Health Organization, 2017b)

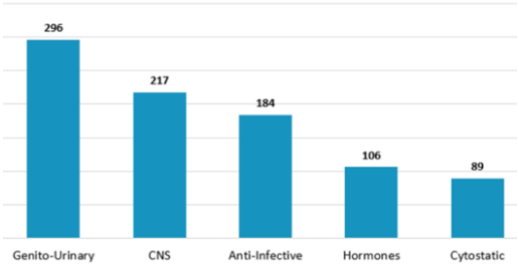
Figure 6: Counterfeited phenobarbital found in Guinea-Bissau in 2013 (World Health Organization, 2017b)



The most reported therapeutic classes of falsified medicines to GSMS (Global Surveillance and Monitoring System for substandard and falsified medical products) between 2013 and 2017, were anti-malarial medicines which represented 19,6% and antibiotics with 16,9%. They were followed by anesthetics/painkillers, and lifestyle products (erectile dysfunction, dieting, cosmetics etc.) both representing 8,5% of total reports. Cancer, heart, mental health medicines and much more were also mentioned. It's important to step back and put these numbers in context. Public health reasons push investigators to focus more on antimalarials and falsified antibiotics which create drug-resistance problems. This leads to under-representation of other therapeutic classes such as lifestyle products. In addition to this, the Global Fund to Fight AIDS, Tuberculosis and Malaria, runs routine surveys and reports them directly to WHO, increasing number of reports for these therapeutic classes.(World Health Organization, 2017b)

In 2020, PSI data of counterfeited drugs incidents from year indicate that genito-urinary, central nervous system and anti-infective drugs were the most present in the 4,344 incidents that occurred that year. A total of 2,451 different medicines were impacted, showing an increase of 23% compared to 2019.(Pharmaceutical Security Institute, n.d.-c)

Figure 7: Therapeutic categories involved in counterfeited drug incidents (4,344) in 2020 (Pharmaceutical Security Institute, n.d.-b)



Nowadays with the COVID-19 pandemic worldwide, international organizations such as WHO and INTERPOL have warned authorities of the emergence and rise of falsified products related to coronavirus. This pandemic creates a great opportunity for criminals to expend their activity and make more money. Not only do they benefit from an international market, but also from delays and disorganization in the supply chain of authorize products. This event generated the production of multiple products such as antivirals, hand sanitizers, tests, equipment such as facemasks, “traditional medicines” and vaccines. Seizures worth thousands of millions of dollars have already taken place at the beginning of the pandemic. For instance, a collective action, led by INTERPOL, took place in March 2020 with a total of 90 countries fighting against the online sale of COVID related products. This so called “Operation Pangea XIII” concluded in a seizure of falsified products worth more than 14 millions dollars. (*Asset-Tracit_examining-the-Negative-Impacts-of-Illicit-Trade-on-Sdg-16_2021.Pdf*, n.d.)(Seed, 2021)

4. Factors contributing to counterfeited drugs

4.1 Financial aspects

Counterfeiters involved in falsified medicines trafficking are aware of the colossal incomes, low risks of detection and weak penalties of this activity. Overall, this makes it very appealing for these criminals which are known to be usually involved in other crimes such as narcotics, humans, and arms trafficking. This business injects a lot of money which can also be used to finance other criminal activities such as drug trafficking. It's easy for criminal organizations to massively produce fake medicines since their production and distribution have a lot in common with drug production. In addition to these, they usually have superior technologies to create the best look-a-like packaging to mislead consumers. An example of the probability of falsified medicines compared to drugs, can be that 1kg of heroin will cost more to produce and will sell at lower prices than 1kg of Viagra ®. Even more shocking, an average of 16000$ a day could be earned working in an organization as a counterfeiter in Russia. (World Health Organization, 2017b)(United Nations Interregional Crime and Justice Research Institute, 2012)(OECD et al., 2020)(M.L.Acri, 2018)

4.2 Access and affordability of medicine

Limited access to quality medicines and their prices, are serious factors pushing patients toward buying retailed price drugs that are mostly falsified. This problem is predominant in low to middle-income countries where drugs represent a big expense for families. It's especially the case when health care systems and insurances do not, or not fully, cover the product's price. Patients will then turn to cheaper medication found in unregulated markets like local street markets or e-pharmacies.(World Health Organization, 2017b)(United Nations Interregional Crime and Justice Research Institute, 2012)(Pisani et al., 2021)

Access to medicine can be harsh in other situations such as environmental disasters or political conflicts involving war for example. These events increase the need for medical care and medicine, while also impacting the supply chain causing shortages. The distribution and storage of drugs can be disrupted causing delays and lack of products. On the other hand, problems in the supply chain can also come from theft or diversion of products that were meant to be sold at lower prices or were offered by organizations and charities. Moreover, planned orders have the disadvantage of attracting these thieves.(World Health Organization, 2017b)

Sometimes the lack of medicinal products doesn't come from criminal acts, but from a global disorganization. In some countries, data and tools which help predict demand of medication aren't made available and stock can be limited. Moreover, shortages can be exacerbated by unexpected diseases outbreaks rising the need of specific medication. This doesn't only push patient toward the bought of falsified products but they also lur health workers. They are more tempted to find manufacturers that can offer quick restock of the product while lowering their quality standards.(World Health Organization, 2017b)

Lastly, restricted access to certain medicine because of potential health threats (i.e: abortive actions) or illegal uses as narcotics, play predominant roles in maintaining this issue. Drugs used for recreative purposes or unlicensed ones (off-label) are available only with prescriptions. This causes users to find illegal sources where no legislation applies. An example is misoprostol which is used to protect the stomach from acidity and ulcers. The drug is a prostaglandin analog that also induces contraction and labor. Therefore, it was also illegally used by women to end unwanted pregnancies. Ultimately, counterfeiters used this as an opportunity to sell falsified misoprostol to this category of patients.(World Health Organization, 2017b) (Pisani et al., 2021)

4.3 Justice

Figure 8: Percentage of pharmaceutical crime arrests by region in 2020 (Pharmaceutical Security Institute,

This map shows the percentage of arrests for counterfeiting, diversion, or theft of medication in 2020, in regards of their localization. A total of 2,574 people were arrested last year which represents an increase of 1% compared to numbers from 2019. It's not to be forgotten that arrests can vary from a country to another due to difference in law enforcement and reporting. As exposed, we can see that most arrests are done in Asia where most manufacturers are found. There's an increase in arrests related to transport whereas there's a decrease of arrests in manufacturing, distribution and point of sale of products. Those numbers seem insignificant if compared side to side with narcotics manufacturing and sale. For example, in the USA in the

year of 2020, a total of 153,696 of arrests occurred for those reasons.(Foundation, 2021) (Pharmaceutical Security Institute, n.d.-a)

Major factors that attract criminals into drug counterfeiting are that both risks of prosecution and penalties are weak compared to narcotics trafficking. An example that highlights the gap sanction wise is the case of France considered as a severe country for penalties for drug counterfeiting. Someone who is involved in this crime, whether it's manufacturing, distribution, sale or even advertising of falsified medicine, will be sentenced to 5 years of jail and to pay 375,000 euros. On the other hand, a narcotic trafficker will face up to 30 years of jail and even life sentence and 7,5 millions of euros. (World Health Organization, 2017b)(Taverriti-Fortier et al., 2015)

The root of the issue is that most countries do not recognize drug counterfeiting as a crime even if it can be as life threatening as narcotics and knowing that patients will involuntary expose themselves. Even if the problem is acknowledged in other countries, it's said that 30% of them do not have regulatory authorities to appropriately fight drug counterfeiting. Furthermore, countries which do have regulatory authorities can be quite limited budget wise. In addition to this, the international aspect of the problem and the difficulty to trace the origin and prove where the activity occurred, renders the task even more difficult. Often, national police with no expertise on the subject will have to deal with it and will need the help of foreign jurisdictions. Altogether, this requires money, trained agents, time and can be limited by language barriers. (OECD et al., 2020)(M.L.Acri, 2018)

4.4 Detection

Low risks of detection are contributing to the enhancement of drug counterfeiting. As criminals know, it's hard for officers to detect a counterfeited drug. This requires specific technologies and trainings, which aren't always made available. Legislations and local requirements also impact detection as some countries lack of implementations to secure the supply chain. The task is even harder because huge criminal organizations work with sophisticated technologies to ensure that the packaging is identical to the referenced drug's one. This means that the detection of falsified drugs would need to be done by taking samples and sending them to labs where tests such as spectroscopy or chromatography would be done. Sadly, it would be both time and money consuming and most countries wouldn't afford this at a large scale. (World Health Organization, 2017b)(*Detecting Counterfeit Medicines | University of Oxford*, n.d.)(OECD et al., 2020)

4.4.1 Methods used for detection

Analytical methods are required to detect counterfeited drugs as they are visually close to original drugs. Different types of methods exist and will be used based on the type of drug or if a quantitative, qualitative or both analyses are needed. The site where analyses will be done as well as the operators, the cost and speed will also influence this choice. Methods used include spectroscopy and chromatography.(Lamalle et al., n.d.)

Usually, rapid techniques such as spectroscopy will be used as they require less or no sample preparation and can also be used on dry products through their packaging. Spectroscopic techniques include Fourier-transformed infrared (FT-IR), near infrared (NIR), Raman, colorimetry, X-rays diffraction (XRD) and nuclear magnetic resonance (NMR). Most used techniques include Raman spectroscopy as it can be used with a portable device that allows screening of products through their packaging and identifies APIs and excipients. Unfortunately, it can only be used on non-fluorescent products as it can disturb its signal. NIR is also a widely used spectrology method that is a fast and cheap and can be used through the medicine's packaging. It discriminates a counterfeit product from a genuine one. FT-IR and NMR give information about the API's structure and analogs found in counterfeited products but require sample preparation (case of NMR) or are used with other analytical techniques (chromatography). Less commonly used methods are Colorimetry and XRD. They are both effective but overall more expensive and better alternatives do exist. (*Chromatography in the Detection and Characterization of Illegal Pharmaceutical Preparations | Journal of Chromatographic Science | Oxford Academic*, n.d.)(Lamalle et al., n.d.)(Martino et al., 2010)

In terms of chromatography, they are in-labs separative techniques which are used to detect and characterize products. They give information about the product's ingredients as well as their quantity and can be combined to spectroscopic methods. Different types of chromatography are used such as: liquid, gas, high-performance, thin-layer chromatography etc.(*Chromatography in the Detection and Characterization of Illegal Pharmaceutical Preparations | Journal of Chromatographic Science | Oxford Academic*, n.d.)

4.5 Parallel trading and diversion

4.5.1 Parallel trading

Parallel trading is an authorized and common practice in the EU that allows buyers to acquire a product at a lower price in a EU country. The product needs to be repacked under specific regulations prior to be shipped to another market in the EU where it will be sold at a higher price. This means that the product will pass through various distributors and numerous transactions will be done before the product reaches its destination. This complexity in the distribution chain will complicate the task of regulators, enable their verifications and increase the risk for counterfeited products to enter the authorized supply chain. (United Nations Interregional Crime and Justice Research Institute, 2012)("What Is Parallel Trade," n.d.)

4.5.2 Diversion

Illegal diversion of pharmaceutical products happens when a drug which is approved for a certain function in a particular market, is intercepted and re-marketed in another country violating the producer's instructions. It can happen within the same country or city, or at an international level. The goal is to make profit by selling drugs at full price while they were originally dedicated to humanitarian organizations or were promotional samples for hospitals for example. Diversion often requires repackaging products and transfer them through multiple distributors, which can lead to the insertion of counterfeited drugs in the authorized supply chain.(OECD et al., 2020)(United Nations Interregional Crime and Justice Research Institute, 2012)

4.6 E-pharmacies

The number of online pharmacies has exploded these last years with the growth of technology. Buying medicine online has become very popular especially in high-income countries such as the USA where up to 26 million people buy their medicine online. According to WHO, 50% of medicine bought online on websites that hide their Internet Protocol (IP) address, are counterfeited. Overall, less than 1% of e-pharmacies are legal and licensed. (United Nations Interregional Crime and Justice Research Institute, 2012)(World Health Organization, 2017b)

Online pharmacies are very attractive to both counterfeiters and patients. Criminals find an international market which guarantees their anonymity and lowers the risks of sanctions and seizures. They also use these websites as an opportunity to gather the buyer's information and defraud them. They approach buyers with spam mails and online advertising, luring them with lower prices and all type of medication made available without prescriptions. Patients will also be attracted by discretion brought through the internet, especially for illnesses linked to psychological and sexual problems. Moreover, these sites offer rapid services with products sent directly to the buyer's home and convenient purchases which able patients to bypass discussions with health workers. Websites are also designed to offer short descriptions which falsely allow patients to self-diagnose and direct them towards multiple treatments. All types of medicine can be found online from life-style products to life-saving ones. Most purchased classes online are painkillers, weight related products, sedatives, and libido boosters. (United Nations Interregional Crime and Justice Research Institute, 2012)(OECD et al., 2020)

Different tools were developed by authorities in the aim to help patients to detect illegal e-pharmacies. For example, in the EU a common logo was created and guarantees the authenticity of the website. It represents a cross in a green background and the national flag of the EU country where the pharmacy is registered. It also links the patient to a website of a national authority which gathers all legal e-pharmacies.(European Commission, 2016)

Figure 9: EU common logo for licensed e-pharmacies (AFMPS, n.d.)

5. Consequences of drug counterfeiting on:

5.1 Individuals and Health

Counterfeited drugs can impact patient's health at different levels with the worst-case scenario being death. If we look back at WHO's definition from 1992, it is said that they can or cannot contain the correct ingredients or can contain an insufficient dose of the active pharmaceutical ingredients (API). A patient who will take a treatment which ends up being counterfeited and that contains no API, will be left untreated and can possibly die from his disease or from the counterfeited product's nature. The "Avastin® Case" from 2013 highlights the lethal aspects of the problem. This drug contains bevacizumab, which is an anti-angiogenic compound used for the treatment of different cancer type (colon, rectum, lung etc.). The Food and Drug Administration (FDA) warned health professionals as they had detected a counterfeited version of the drug in the USA. It appeared that this one didn't contain any API and even contained carcinogenic chemicals. This led to both a deterioration of the patients' health and to additional risks from the other chemical compounds. The number of patients concerned is yet unclear but they may have lost months to live.(Miller, 2020)(*Avastin - Drug Information - Chemocare*, n.d.)(OECD et al., 2020)

Additionally, patients can also suffer from adverse events related to incorrect ingredients, toxics, microbiological substances, and other chemicals found in the drug. Since these products are only made for profit, there are a lot of quality issues related to stability, expiry dates, controls in manufacturing of the product and interactions between different medicines. An important aspect that must be taken into account for these patients is that they will have additional costs related to first counterfeited and later on original treatments, care of potential adverse events and other health issues encountered. (OECD et al., 2020)(United Nations Interregional Crime and Justice Research Institute, 2012)

Another issue partly caused and maintained by these falsified medicines, is drug-resistance. Antibiotics and anti-infective medications are known to be often counterfeited and some of these drugs will be composed of insufficient doses of API. This leads to the elimination of some pathogens but gives the opportunity to survivors to mutate and become resistant to the drug. These resistant pathogens are then able to multiply and spread themselves to other patients. Overall, not only does it complicate the therapeutic care of patients that will have to receive second or third-line drugs instead of first line drugs that are cheaper and more effective, but it

creates co-resistance in diseases such as malaria and HIV. They are indeed treated with combination of drugs, resistance to one of these could impact the other one and lead to failure of treatment.(OECD, 2016)(United Nations Interregional Crime and Justice Research Institute, 2012)(World Health Organization, 2017b)

5.2 Pharmaceutical industry

Drug counterfeiting both impact the industry's revenues and reputation. For instance, interferences in the sale of medicinal products between the year of 2012 and 2016 in Europe led to a revenue loss of 9,6 billion of euros. In addition to this, companies must pay to set up safety measures to secure their supply chain. This requires the use of expensive forensic technologies on packaging, covert and overt (detailed in chapter X). They are also likely to investigate on incidents which involve their products. Consequence of this is that money spent for those activities will not be used for research and development (R&D) of other innovative products. Pharmaceutical compagnies tend to invest massively in R&D (15 to 17% of their revenues) as intellectual property on innovations are key for their prosperity. Drug counterfeiting is causing an economical threat on this sector, hindering the research of new or better treatments while also impacting employment.(Blackstone et al., 2014) (OECD et al., 2020)(OECD, 2016)(Miller, 2020)

In terms of reputation, industries will suffer from loss of trust from costumers who consumed the counterfeited version of their product, and from questioning of their product's quality and safety.(OECD et al., 2020)(OECD, 2016)

5.3 National economy

The use of falsified drugs has multiple economic implications that must be considered. First of all, it creates more costs for national healthcare systems and more specifically for health insurances. They will have to pay for additional treatments and medical resources needed to cure the patient's disease, potential adverse events and infections which occurred because of the counterfeited product. Costs associated to drug-resistance and higher prevalence of infectious diseases, must also be taken into account. (World Health Organization, 2017a)(OECD et al., 2020)

Furthermore, since the criminal production of these products isn't declared, it represents a loss for governments in terms of taxes incomes from pharmaceutical industries' profit. Taxes from household income will also be reduced as counterfeited products will have direct and indirect effects on both employment and household spent on medicine. (European Union Intellectual Property Office, 2016)

Lastly, weaknesses in the pharmaceutical sector will curb economic development by limiting potential investments. Moreover, fighting against this problem will also require regulatory actions and law enforcements. It represents major costs for governments that will also inject money in disbanding criminal networks.(OECD et al., 2020)

6. Countermeasures taken in main markets to fight against drug counterfeiting

Given the complexity of medicines supply chains, there is not one solution to prevent counterfeiting and the approach must be holistic involving multiple measures such as adapted laws and regulations with appropriate enforcement and penalties, a secure supply chain and supporting technologies.

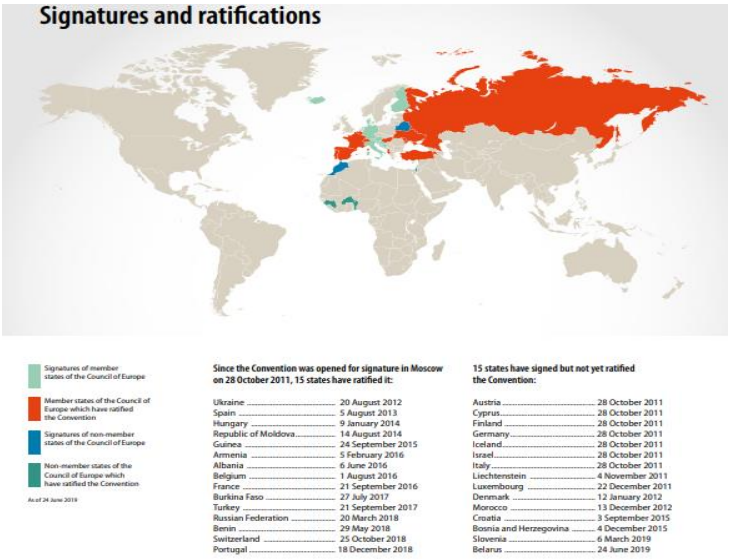
6.1 Authorities

Over the last decade in Europe, a significant number of legal initiatives have been taken to fight against drug counterfeiting including the MEDICRIME Convention and the EU's Falsified Medicines Directive.

6.1.1 MEDICRIME Convention

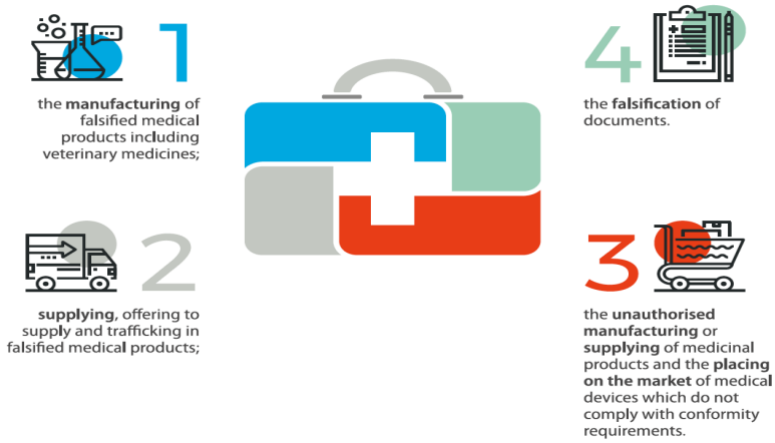
At the end of 2010, the Council of Europe adopted the "Convention on the Counterfeiting of Medical Products and Similar Crimes Threatening Public Health (CETS No. 211) ", also known as the MEDICRIME Convention. This convention entered into force in January 2016 and is the only tool, at the international level, that criminalizes the counterfeiting of medicinal products and other types of pharmaceutical crime that threaten public health. It covers both human and veterinary medicinal products. So far, the convention has been ratified by 15 countries as of 24 June 2019. (The Council of Europe et al., 2019)(Council of Europe, n.d.)

Figure 10: Map showing countries who signed or ratified the MEDICRIME Convention (The Council of Europe et al.,2019.)



This treaty calls for multilateral collaboration and creates the opportunity for co-operation between international bodies such as INTERPOL, Europol, UNODC (United Nations Office on Drugs and Crime), the WCO and WHO. It also brings a significant change to protect the victims of falsified medicines. Indeed, so far countries were prosecuting counterfeiters based upon intellectual property rights laws which didn't support prosecution based on harms for the victims of falsified medicines. This convention is now allowing victims who have been exposed to the danger of falsified drugs to take legal actions against counterfeiters. Moreover, criminalizing drug counterfeiting is also allowing countries to increase prosecutions and therefore should make such activities less attractive for criminals. Acts considered as crime by the Convention are represented on the figure below (Fig.11). (OECD et al., 2020)(The Council of Europe et al., 2019)

Figure 11: Acts considered as crimes by the MEDICRIME Convention (The Council of Europe et al.,2019.)



6.1.2 Falsified Medicine Directive (FMD)

It is a EU Directive (2011/62/EU) passed by the Council of European Union and European Parliament in 2011 and which became effective on the 2 of January 2013. It was followed by delegated regulations (operational in February 2019) that provided more details for the implementation of the directive and its requirements. The main objective of the directive was to protect patients, secure the supply chain of medicines in Europe (from manufacture to delivery) by preventing the entrance of counterfeited products. The directive includes four pillars that will be detailed below.(OECD et al., 2020)

6.1.2.1 First pillar: Safety Features.

They are required to verify the medicinal product authenticity as well as its identity. To ensure this, the directive requires the presence of a unique identifier to every individual medicinal product pack and an anti-tampering device on the outer packaging. The products will need to be scanned by wholesalers and distributors as needed, and by pharmacies and hospitals to verify their authenticity. The anti-tampering device also must be verified. It's compulsory for medicinal products subject to prescription and for products available without prescriptions if they are at risk of falsification.(Medicine and Healthcare Products Regulatory Agency, 2019)(OECD et al., 2020)

6.1.2.2 Second pillar: enhancement of Supply Chain control and Good Distribution Practices .

As per the EMA, "*Good distribution practice (GDP) describes the minimum standards that a wholesale distributor must meet to ensure that the quality and integrity of medicines is maintained throughout the supply chain*". They ensure medicinal products in the supply chain are authorized, stored and transported appropriately, no mix up with another product and reaching the right and authorized destination. They also ensure the detection and reporting of defective product and subsequent recall from the market. (European Medicines Agency, 2018)

In the context of the FMD, the aim of the revised GDP for medicinal products (Commission guideline 2013/C 343/01 on Good Distribution Practice of medicinal products for human use) is to ensure that counterfeited products do not enter the authorized supply chain. The previous version that was in place for many years has been strengthened by requiring a wholesale distribution authorization issued by the national competent authority for anyone willing to operate in wholesale distribution of medicinal products in EU. Such authorization is subject to regulatory inspection to verify compliance with GDP. (European Medicines Agency, 2018)

In addition, importers and distributors of active substances that will be used in Europe must register to the national competent authorities and comply with GDP requirements for active substances. These GDP guidelines (Commission guideline 2015/C 95/01 on principles of Good Distribution Practice for active substances for medicinal products for human use) are different from the GDP for medicinal products and aim to ensure counterfeited or substandard active substances are not entering the supply chain at the manufacturing sites level. (European Medicines Agency, 2018)

6.1.2.3 Third pillar: Active Substances and excipients

API and excipients used in manufacturing of medicines in the European Union must comply with relevant GMP (Good Manufacturing Practice) and GDP. Audits must be performed by qualified agents to assure conformity. The directive also includes tougher rules on the import within EU and the registration of manufacturers, importers as well as distributors of active substances. (Medicine and Healthcare Products Regulatory Agency, 2019)

6.1.2.4 Fourth pillar: E-pharmacies

Online pharmacies can only be run by entitled and registered individuals that sell products authorized in the concerned Member State. The directive requires a common EU-wide logo to identify legal online pharmacies and link to authority's website as explained in chapter 4.6. Member States are also required to list authorized internet pharmacies and to run awareness campaigns on the subject.(Medicine and Healthcare Products Regulatory Agency, 2019)(OECD et al., 2020)

6.2 Official Organizations

6.2.1 World Health Organization

WHO is an international organization that has been existing since the 7th of April of 1948. It gathers 194 Member States that are led by the Director General. The organization's headquarters resides in Geneva and multiple affiliates are based in six regional and 150 country offices around the world. It collaborates with the United Nations (UN), governments, ambassadors, health and scientifical experts, as well as private organizations to promote health coverage, face health emergencies and ensure the well-being of the world's population. In fact, WHO also plays a key role in the fight against drug counterfeiting by coordinating programs and providing guidance to its members. (*Who We Are*, n.d.)(*What We Do*, n.d.)(*WHO Organizational Structure*, n.d.)(*About WHO*, n.d.-a)(*About WHO*, n.d.-b)(*History*, n.d.)

In July 2013, WHO launched a program called GSMS which stands for "Global Surveillance and Monitoring System" with the aim of reducing the risks caused by substandard and falsified medicines. It covers multiple activities and systems that ensure the share of information and coordination of member states and national authorities. The first objective, already mentioned in chapter 3.1, is the training of focal points. They are instructed by the Geneva-based Substandard and Falsified Medical Products Group to become contact points between national authorities and global bodies. They will alert both of these in case of suspicion of substandard or falsified products and share important information with national authorities. Workshops have already been held to train these focal points by giving them necessary skills to detect, respond adequately and report these incidents to GSMS. The second objective concerns the development of tools in order to report incidents which is associated to the third objective being the development of a global database. Reports will be compiled into a database by qualified staff and will give tips in detection and response to incidents by national authorities. It leads us to the fourth objective, which is the analysis of this database in order to provide evidence-based recommendations for corrective actions. In case of an emergency (adverse reaction in patients), the system will search for similar reports and WHO will have 24h to contact the reporter. It will give assistance to handle the incident and find its source , and create a medical alert if needed. (*WHO Global Surveillance and Monitoring System*, n.d.)(World Health Organization, 2017b)

WHO also provides guidance that sets directions to member states to define their local measures and strategies to fight drug counterfeiting. It includes guidance on prevention, training,

detection, and response to the problem. It also aims to work on factors contributing to this problem.(World Health Organization, 2017b)

6.2.2 INTERPOL

INTERPOL stands for the "International Criminal Police Organization" and gathers 195 countries. It allows countries to contact them at any time to get access to their criminal data base and coordinates operations to counter terrorism, organized crime, and cybercrime. INTERPOL is actively fighting the sale of counterfeited medicines and medical devices online by launching operations such as the Pangea Operation. It also aims to raise awareness on the use of these products. (*What Is INTERPOL?*, n.d.)(*Pharmaceutical Crime Operations*, n.d.)

Operation Pangea has been initiated in 2008 and gathered an increasing number of countries ranging from 8 to 153 in 2021. During Pangea XI carried out in 2018, police, customs, and health regulatory authorities from 116 countries seized 500 tons of illicit products for a value of USD 14 million. Most seizures include broad types of drugs such as anti-inflammatory medication, anti-depressants, painkillers, hypnotics, erectile dysfunction, anabolic steroids to treat diabetes and cancer etc. They can be hidden by other products such as DVD packages or clothing and are send in smaller parcels through multiple shipping routes to avoid detection. From the operation I to XI, more than 105 million of units and 1,1 million of packages have been seized. Eighty-two thousand of illegal pharmacies were shut down and a total of more than 3000 arrests occurred highlighting the importance of such operations. The most recent Pangea Operation XIV seized 23 million USD worth of products linked to COVID-19 pandemics such as face masks and testing kits. (*Operation Pangea – Shining a Light on Pharmaceutical Crime*, n.d.)(OECD et al., 2020)(*Thousands of Fake Online Pharmacies Shut down in INTERPOL Operation*, n.d.)

Figure 12: Impacts of Pangea Operations from 2008 to 2018 (OECD et al., 2020)

Year (Pangea number)	Number of countries	Seizures		Number of arrests	Number of websites closed
		Quantity	Value (millions of USD)		
2008 (I)	10	NA	NA	NA	NA
2009 (II)	24	167 000 items	NA	221	72
2010 (III)	45	1 million	2.6	NA	290
2011 (IV)	81	2.4 million items	6.3	551	13 500
2012 (V)	100	3.75 million items	10.5	80	18 000
2013 (VI)	100	9.8 million items	41	58	9 000
2014 (VII)	111	9.4 million items	31	237	10 600
2015 (VIII)	115	20.7 million items	81	156	2 414
2016 (IX)	103	12.2 million items	53	393	4 932
2017 (X)	123	25 million items	51	400	3 584
2018 (XI)	116	500 tonnes	14	859	3 671

Notes: [1]Arrested or under investigation. NA: Not available.
Source: INTERPOL news releases at www.interpol.int/News-and-Events

An equivalent organization at European level is Europol which gathers the 27 Members States of the EU and leads operation against terrorism, cybercrime, and organized crime such as drug trafficking. They work hand in hand with national authorities, international organizations (INTERPOL), industries and governments with the aim to identify and seize counterfeited drugs. They have coordinated different operations with the most recent one being Operation Shield II. (About Europol, n.d.)(Drug Trafficking | Europol, n.d.)

In 2021, Belgian authorities participated to Operation Shield II and seized 87.241 tablets, 99.549 ampoules, 24 syringes et 46 kg hormones in action against counterfeit and anti-doping drugs. The operation was led by the French Gendarmerie, customs organization, the Federal Agency for Medicines and Health Products (FAMHP), Federal Agency for the Safety of the Food Chain (FASFC) and coordinated by Europol. This operation took place from 1 April to 15 October 2021 and involved multiple EU countries targeting trafficking of doping substances and medicinal products including anti-cancer drugs, erectile dysfunction medicines, pseudoephedrine, painkillers, antiestrogens, antivirals, hypnotics, antihistamines and anxiolytics. The operation seized a total of 63 millions of euros worth of medicines, doping substances and COVID-19 related medical devices. It also led to the arrest of 544 suspects, the investigation of criminal organizations and a total of 283 websites were shut down.(*Opération Shield II : Les Autorités Belges Saisissent 87 241 Tablettes et 99 549 Ampoules Dans Le Cadre d'une Action Visant Les Médicaments Contrefaits et Contre Le Dopage | AFMPS*, n.d.)(*544 Arrests and €63 Million of Fake Pharmaceuticals and Illegal Doping Substances Seized*, n.d.)

6.2.3 World Customs Organization

WCO is contributing to fighting against counterfeit medicines through managing an Intellectual property right (IPR), Health and Safety Program. By that mean, WCO is providing coordination of the anti-counterfeit traffic efforts of its members and other international organizations through border controls. They are also working in partnership with the private sector allowing access to the commercial data and information to facilitate the detection of counterfeited drugs. WCO and its members are also working closely with pharmaceutical trade associations to avoid duplication of work and ensure collective efforts in fighting illicit traffic of medicines. (*World Customs Organization*, n.d.)(OECD et al., 2020)

6.3 Technical solutions

There a few available technologies supporting the authentication of medicines and securing the legitimate supply chain. They include overt, covert technologies and track-and-trace technologies.

6.3.1 Overt anti-counterfeiting technologies

They are security features visible by the human naked-eye and used to protect and authenticate products. It means that healthcare professionals and users must be familiar with them to effectively recognize them since their verification requires a careful inspection of the security features. Examples of overt technologies includes color shifting inks, watermarks, security thread, holograms and tamper-evident labels that can be verified to ensure authentication and integrity of the product. They are expensive and complex to reproduce but can be copied, and it is difficult for a non-trained healthcare professional to detect if they are.(Shah et al., 2010)(Kumar & Baldi, 2015)

Figure 13: Hologram sticker on medical products (*Hologram Stickers And Strip For Pharma Sector*, n.d.)

Figure 14: Example of tamper-evident label (*Tamper-Evident Solutions for Pharmaceutical Packaging*, n.d.)

6.3.2 Covert anti-counterfeiting technologies

It refers to features that can only be verified using specific equipment and having the end-user informed of the nature and location of secret hidden features. A few examples include “invisible” ink for the human naked-eye but visible with a UV lamp, digital watermarks or infrared fluorescent pigments. Such features are more secure and difficult to copy but also more complicated to use. Covert technologies also include chemical markers that require laboratory testing to verify the authenticity of the product and therefore are significantly more difficult to

use for routine checks. (International Federation of Pharmaceutical Manufacturers & Associations, n.d.)

Figure 15: Example of authentication by invisible ink (Product Protection through Invisible Ink with REINER® Marking Systems : REINER®, n.d.)

6.3.3 Traceability technologies

Traceability technologies involve serialization and require the assignment of a unique identification number to every individual medicinal product pack. Such identification number is uploaded by the manufacturer and stored in a central database that can be accessed to verify the product authenticity in the supply chain and at the point of dispensing to the patient.(International Federation of Pharmaceutical Manufacturers & Associations, n.d.)

Technologies used are mostly barcodes (2D), Quick Response code also known as QR code (3D) and others such as the Radio Frequency Identification Device (RFID) which consists in a microchip and an antenna. It allows to verify batch information transmitted through electromagnetic waves to a reader. It's a very effective technology but the cost (10 to 20 times the cost of a barcode) may limit its use. (Shah et al., 2010)(Daoud et al., 2020)

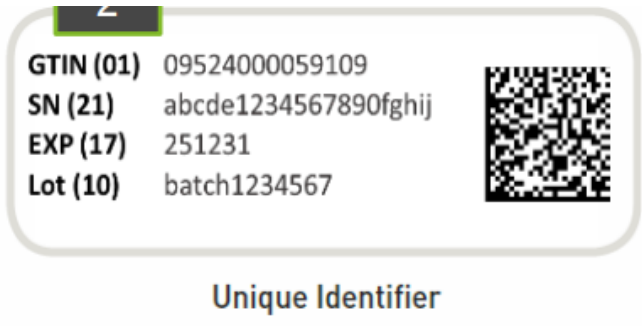
Serialization, traceability legislation and associated requirements can differ significantly from one country to another as well as the implementation strategies and timelines as shown on the figure below (Fig.16).

Figure 16: Map on the Serialization Legislation Landscape("Global Serialization Landscape," n.d.)

6.3.3.1 Implementation in Europe

In Europe, effective since February 2019 according to the FMD delegated regulations to support the traceability requirements (first pillar) , every individual medicinal product pack is now be identified using a Global Trade Item Number (GTIN) and a Serial Number (S/N). GTIN is a number that identifies a product (company, product name, dosage, and packaging format). The most common standard GTIN used in the pharmaceutical industry is GTIN-14 (composed by 14 numbers) where the S/N identifies specifically every associated pack.(*European Pack Coding Guideline V4_0.Pdf*, n.d.)

Figure 17: Example of Unique Identifier (Tom, n.d.)



The products having a unique identification number will need to be scanned by pharmacies and hospitals at the time of dispensing in order to verify their authenticity and that the unique code is available in the database. Should the product not be identified as matching a genuine pack registered in the database, an alert will be launched, and the product will be blocked nor dispensed as considered suspicious.(HRABOVSZKI, 2019)

6.3.3.2 Implementation in USA

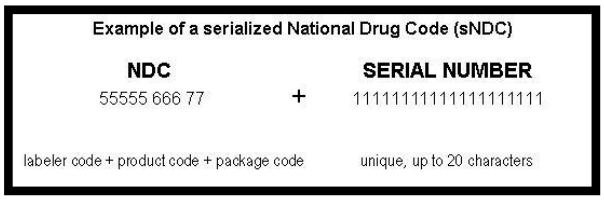
The Drug Supply Chain Security Act (DSCSA) setting requirements for drug traceability in the USA has been approved by the Congress in November 2013. They are applicable to certain prescription drugs. The implementation approach is more flexible as compared to the FMD and has been defined in multiple steps in a 10-year period outlined in the schematic below.(Center for Drug Evaluation and Research, 2021)(*DSCSA Guide*, 2021)

Figure 18: DSCSA implementation timeline (DSCSA Guide, 2021)

By November 2017, manufacturers must have serialized products and the same requirement applies for repackagers in November 2018. By November 2019, distributors must verify Standardized Numeric Identifiers (SNI) for all packages and shipments and the same principle is mandatory for dispensers by November 2020. Next deadline is set in November 2023 and concerns all the people cited above as a system must be in place to exchange information between members.(*DSCSA Guide*, 2021)

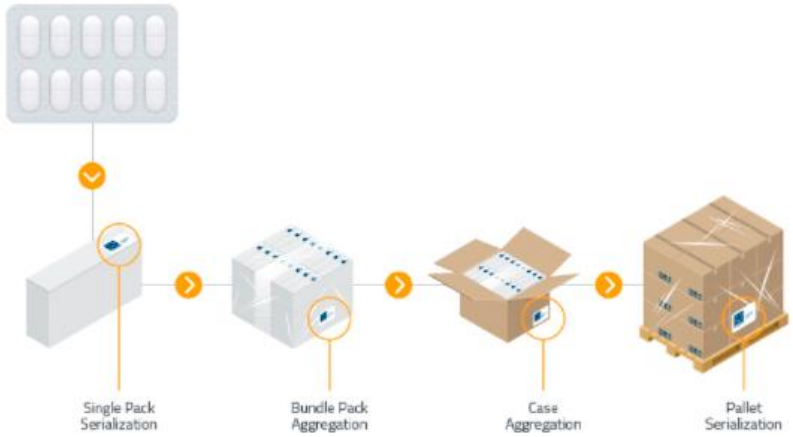
These SNIs are made of the 20-character NDC (National Drug Code) and a serial number. In addition to the SNIs, other information including batch/lot number, Global Trade Item Number (GTIN) and expiration date are also required. Also, the smallest packaging unit needs to be packaged with a 2D Barcode Matrix including human-readable text. (Office of the Commissioner, Food and Drug Administration, 2019)

Figure 19: Example of a sNDC (*Office of the Commissioner, Food and Drug Administration, 2019)*



The DSCSA also includes the requirement for aggregation which is not mandated by the FMD as it only requires product verification at the point of dispensing. Aggregation is allowing to build a hierarchical serialization structure associating drugs and transport units (bundle, cases and pallets) as shown in the scheme below. Practically, it means the transport unit label can only be scanned to verify authenticity and not every single pack it contains as shown below. (Fig.20).(*Solutions Finder- Aggregaje tion*, n.d.)

Figure 20: Serialization and aggregation process (Solutions Finder- Aggregation, n.d.)



6.3.3.3 Implementation in Russia

Serialization regulations Russia Federal Law No. 425-FZ went into effect in July 2020 although the original deadline was January 2020. They cover all prescription and also over-the-counter (OTC) drugs to be sold on the Russian market. Including OTC drugs in the scope of serialization requirements is more demanding than the FMD and DSCSA. (*Top Four Questions About Russia's Serialization Laws, Answered*, 2020)

The new regulations require the inclusion of a crypto code to be included on all 2D barcodes in addition to the GTIN, serial number, batch number, and expiration date, also required by the FMD or the DSCSA. Such crypto codes cannot be generated by manufacturers but must be obtained from the Center for Research in Perspective Technologies (CRPT) in charge of the Russian track and trace digital system (aka Chestny ZNAK). The expected benefit of the crypto codes is to enhance security as it is impossible to duplicate or create.(*Top Four Questions About Russia's Serialization Laws, Answered*, 2020)(*Russian Serialization & Aggregation Regulations – Anti-Counterfeiting, Identification, and Brand Protection Solutions*, 2019)

7. Pharmacist's role

Pharmacists play a major role in health care and must be aware of dangers surrounding the use of counterfeited drugs. All sectors are impacted whether we talk about hospitals, dispensary pharmacies or the pharmaceutical industry.

As a dispensary and hospital pharmacist, it's crucial to protect patients by raising awareness and explaining the health risks of ingesting fake drugs. It's also important to share information about buying drugs online since most of e-pharmacies are illegal and sell counterfeited drugs. The pharmacist must educate itself through regular trainings, but programs should also be implemented during university courses to share knowledge on the subject. The other aspects that must be taken into account, are that pharmacists should purchase medicines from wholesalers and choose distributors that are reliable. They must comply to laws and regulations from health authorities to ensure the quality and safety of products. Lastly, medicines should be verified during dispensation and any suspicion on a product must alert the pharmacist that will report to health authorities.(Louisiana, 2014)(Rajapandian, G., Narayanan, N., Maheswaran, A., & Chanchal, P., 2013)(Besançon, 2008)

Pharmacists from the pharmaceutical industry have also an essential role as they must secure the supply chain. It's done by working on technical solutions and by investigating on incidents in order to prevent them. They work with authorities that implement regulations and laws to protect the health system and most importantly patients.

It's important to stress out the specific role of the Responsible Person (RP) in the distribution and the Qualified Person (QP) in the manufacturing and importation of medical products. Both must be competent, qualified, experienced, have knowledge and trainings in GDP and GMP. They must comply with the Member State's legislation and are designated by the wholesale distributor and manufacturing authorization holder. The RP, who usually is a pharmacist in Belgium, must ensure that the distributor complies to GDP and other relevant obligations. The QP, who must be an industrial pharmacist in Belgium, is ensuring that manufacturing and importation of medicinal products are done in compliance with GMP.(*LOI - WET*, n.d.)(European Parliament and Council, 2001)(*Guidelines of 5 November 2013 on Good Distribution Practice of Medicinal Products for Human UseText with EEA Relevance*, n.d.)

8. Conclusion

The medicinal product is subject to very high regulatory and quality standards during its development and entire lifecycle. In order to meet such requirements, the pharmaceutical industry is investing and spending huge amount of money to ensure anytime patient safety and a positive risk benefit balance. Health Authorities are also contributing to patient protection though the approval, monitoring of drugs and securing authorized supply chains.

Unfortunately, as for any consumer products, medicinal products are affected by counterfeiting and counterfeiters are avoiding most or all of these requirements creating a significant negative impact on patient safety and public health.

Such trafficking activities are generating very high revenues and are considered a more lucrative business than narcotics with a lesser risk in case of prosecution which makes it overall very attractive. The increased popularity of e-commerce, which is the favorite way of shipping counterfeited drugs, is also an important contributing factor.

It is therefore a very significant issue globally recognized by both governments and the pharmaceutical industry, which led over the last years to multiple actions to fight against drug counterfeiting. The main recent regulatory actions is including the Council of Europe who adopted the MEDICRIME convention to criminalize the counterfeiting of medical products, the Interpol cooperation between police forces around the world in making illicit international activities and the WCO organizing flash searches of containers in various parts of the world.

In addition, more stringent regulatory control of medicines and enforcement by Health Authorities of regulations which aim to prevent counterfeited medicines getting into the hands of patients, such as the FMD and the DSCSA in the USA.

Pharmaceutical companies have equally developed procedures, techniques, and tools to protect their product from counterfeiting. Those are including, amongst others safety features (tamper evidence packaging, holograms), serialization and track and trace increasing end-to-end supply chain security from manufacturing sites to pharmacies. avoid fake drugs to enter the authorized supply channels and overall implementing new rules and regulations in collaboration with Health Authorities.

Although this issue is now globally recognized and measures have and are still to be implemented, drug counterfeiters are also adapting (ie copies of safety features) and operating

in organized global criminal structures. This makes the fight more complex and requires permanent adjustments of regulations and technical solutions, global information sharing, police coordinated actions and training of all involved personnel.

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Methodological approach

In order to complete this work, many databases have been consulted to gain quality and up-to-date information. Bibliographic research was done using specialized websites such as PubMed, ScienceDirect, ResearchGate, Cochrane Library etc. with the word “counterfeited”, “falsified” and “fake” drugs as “MESHs”.

Only few articles gave a holistic view on the subject and it was then found more appropriate to look for publications from Health Authorities and Organizations (ie OECD, WHO, EMA, FDA), pharmaceutical associations (ie PSI, EFPA) and websites on technical solutions as well as implementation progress.

To complete this information, pertinent articles found on specialized websites cited above were identified and selected. The selection was based on dates of publications, giving priority to most recent articles, as well as their relevance. All sources were cited with the American Psychological Association style then gathered with a reference management tool into a bibliography.

Drug counterfeiting is a worldwide issue threatening patient's health, causing economic losses, and impacting pharmaceutical industries' reputation. Criminals attracted to massive profit and weak penalties are adapting to local markets and new consumption patterns such as online purchase of medication. It's therefore crucial for healthcare professionals to secure the authorized supply chain by implementing technical solutions along with regulations and raise awareness on dangers related to consumption of these products.
This bibliographic end of master's thesis named "How do the Pharmaceutical Industry and Health Authorities fight together against drug counterfeiting?" will gather and sum up pertinent information around this issue and set the actual context of drug counterfeiting.
All countries are affected but the African continent is mostly targeted with up to 30% counterfeited medicines. Broad type of drugs is counterfeited and often manufactured in China and India then sent by air, sea or mail in small parcels to avoid greater loss in case of seizure. Factors such as limited access, affordability, parallel trading, e-pharmacies, diversion, justice and detection are contributing to the development of this problem. Multiple countermeasures have been put in place by Authorities and the pharmaceutical industry to mitigate drug counterfeiting risks. They involve publication of regulations such as the MEDICRIME Convention, Falsified Medicine Directive in Europe and the Drug Supply Chain Security Act in USA. In addition, to comply with such regulations, technical solutions have been developed and implemented by the industry across multiple markets. Adaptation of criminals to theses measures require to make the fight more complex throughout permanent adjustments of regulations and technical solutions, global information sharing, police coordinated actions and training of all involved personnel.

La contrefaçon de médicaments est un problème mondial menaçant la santé des patients, causant des pertes économiques et affectant la réputation des industries pharmaceutiques. Les criminels, attirés par les profits importants et les faibles sanctions, s'adaptent aux marchés locaux et aux nouveaux modes de consommation tels que l'achat de médicaments en ligne. Il est donc crucial pour les professionnels de santé de sécuriser la chaîne d'approvisionnement légale des médicaments en mettant en place des solutions techniques et réglementaires et de sensibiliser aux dangers liés à la consommation de ces produits.

Ce mémoire bibliographique de fin de Master intitulé « Comment l'Industrie Pharmaceutique et les Autorités de Santé luttent ensemble contre la contrefaçon des médicaments ? » rassemblera et résumera les informations pertinentes relatives à cette question et donnera le contexte actuel de la contrefaçon de médicaments.

Tous les pays sont touchés mais le continent africain est principalement visé avec jusqu'à 30% de médicaments contrefaits. De nombreuses classes de médicaments sont contrefaits et souvent fabriqués en Chine et en Inde puis envoyés par voie aérienne, maritime ou postale en petits colis pour éviter une plus grande perte en cas de saisie. Des facteurs tels que l'accès limité, les moyens financiers, le commerce parallèle, les pharmacies en ligne, le détournement, la justice et la détection contribuent au développement de ce problème. De multiples contre-mesures ont été mises en place par les autorités et l'industrie pharmaceutique pour atténuer les risques de contrefaçon des médicaments. Ils comportent la publication de réglementations telles que la Convention MEDICRIME, la directive sur les médicaments falsifiés en Europe et le « Drug Supply Chain Security Act » aux États-Unis. En outre, pour se conformer à ces réglementations, des solutions techniques ont été développées et mises en œuvre par l'industrie dans de nombreux marchés. L'adaptation des criminels à ces mesures nécessite de rendre la contrefaçon encore plus complexe à travers des ajustements permanents des réglementations et des solutions techniques, un partage global de l'information, des actions policières coordonnées et la formation de tous les personnels concernés.

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