

**NATURE, EXTENT, AWARENESS, AND ATTITUDES TOWARDS
COUNTERFEIT MEDICINE
IN LEBANON**

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ABSTRACT

Counterfeit Medicine (CFM) is defined as a product that is deliberately and fraudulently mislabelled with respect to identity and/or source. According to the World Health Organization, the extent of the CFM problem is not really known, however, the incidences of medicines on sale range from 1% in developed countries to 10-30% in some developing countries. The international concern is the risk CFM poses for public health. There are no reported studies on the nature, and extent of CFM, nor public and pharmacist awareness and attitude towards CFM, in Lebanon.

The study's objectives were to determine the nature and extent of counterfeit medicines and to assess public and pharmacist awareness, and attitudes towards CFM in Lebanon.

The nature of CFM was determined using five identified CFM samples. The study used both physical examination, and chemical analysis using four instruments. The physical examination classified all five CFM samples as counterfeits. Three of the analytical methods used identified three of the CFM as counterfeits, and one identified four CFM as counterfeits. The nature of the counterfeits were; medicines with incorrect quantities of active ingredients in 3 cases, medicines with correct quantities of active ingredients with counterfeit packaging in 1 case, and medicines with high levels of impurities / contaminants in 1 case.

The extent of CFM was explored by visiting 150 households in various regions in Lebanon. The medicine was determined to be counterfeit using the medication use evaluation; by comparing photos of medicines evaluated with their originals at a later stage, at a university accredited pharmacy. Counterfeit medicines were found in 49 (32.7%) of the visited houses. The extent ranged from 3% in Mount Lebanon to 12.1% in the Bekaa.

To assess public and pharmacist awareness, and attitudes towards CFM, 3 questionnaires were used. Of the 464 participants included in the public awareness study, 93.4% reported being aware of the term CFM, and 83.4% reported the best way to avoid CFM would be to use a trustworthy pharmacist. The public attitude study included 385 participants, and the majority (83.1%) disagreed that CFM were as good as the originals, and 46% agreed that the original medicines were highly priced, and CFM were of better value. The pharmacist study included 223 participants and all respondents provided a definition of CFM, however there were disparities in their definition. The majority reported identifying CFM by the medicine's effect (67.7%). Almost 43% reported knowing of pharmacists who dispensed CFM.

The public and pharmacist focus groups, explored the public and pharmacist views about CFM. The 4 focus groups included 24 participants for the public, and 13 for the pharmacists'. There were 5 themes that emerged from the public's discussions; awareness, locus of control, trust, corruption, and overcoming CFM. There were also 5 themes for the pharmacists' awareness, reasons for availability of CFM, trust, corruption, and overcoming CFM.

This study demonstrated that CFM are present in Lebanon and can be found in a substantial number of homes. The awareness, experiences and views of both the public and pharmacists indicates the perceived risk these CFM pose to both the individual and the public health. The suggestion is for development of educational programs for pharmacists and the public about CFM.

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Part of this thesis (Chapter Four - public awareness towards counterfeit medicine in Lebanon) was included in a poster presentation at the 49th American Society of Health-System Pharmacists Clinical Midyear Meeting. Anaheim, California. December 7-11, 2014. (**Appendix A. Publication**)

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List of Acronyms

1.	Counterfeit Medicines	(CFM)
2.	World Health Organization	(WHO)
3.	Counterfeit Products	(CFP)
4.	Intellectual Property	(IP)
5.	Spurious/falsey-labelled/falsified/counterfeit	(SFFC)
6.	International Medical Products Anti-Counterfeiting Taskforce	(IMPACT)
7.	United States of America	(USA)
8.	European Union	(EU)
9.	United Arab Emirates	(UAE)
10.	Southeast Asia	(SE)
11.	Tuberculosis	(TB)
12.	Lebanese Order of Pharmacists (Ordre des Pharmaciens du Liban)	(OPL)
13.	Saint-Joseph University	(USJ)
14.	Ministry of Public Health	(MoPH)
15.	Lebanese Pharmaceutical Importers Association	(LPIA)
16.	Healthcare professionals	(HCP)
17.	Lebanese Order of Physicians (Ordre des Medecins du Liban)	(OML)
18.	Infrared	(IR)
19.	Near-infrared spectroscopy	(NIR)
20.	Nuclear magnetic resonance	(NMR)
21.	Fourier transform infrared spectroscopy	(FTIR)
22.	Ultraviolet-visible spectroscopy	(UV-vis)
23.	Active Pharmaceutical Ingredient	(API)
24.	Lebanese American University	(LAU)
25.	Accreditation Council for Pharmacy Education	(ACPE)
26.	Good Manufacturing Practice	(GMP)
27.	Medication use evaluation	(MUE)
28.	Data Collection Form	(DCF)
29.	Mount Lebanon	(ML)
30.	Committee on Human Subjects in Research	(CHSR)
31.	Over the counter	(OTC)
32.	Statistical Package for Social Sciences	(SPSS)
33.	SmithKline Beecham	(SB)
34.	GlaxoSmithKline	(gsk)

Continue List of Acronyms

- | | | |
|------------|--|----------|
| 35. | Central Administration for Statistics | (CAS) |
| 36. | Central intelligence agency | (CIA) |
| 37. | Medicines and Healthcare Products Regulatory Agency | (MHRA) |
| 38. | United Kingdom | (UK) |
| 39. | National Consumer League | (NCL) |
| 40. | Kruskal-Wallis | (KW) |
| 41. | United Nations Educational, Scientific and Cultural Organization | (UNESCO) |
| 42. | The Theory of Planned Behaviour | (TPB) |
| 43. | Theory of Reasoned Action | (TRA) |
| 44. | International Pharmaceutical Federation | (FIP) |
| 45. | Food and Drug Administration | (FDA) |
| 46. | Lao People's Democratic Republic | (PDR) |
| 47. | Focus group | (FG) |
| 48. | Lebanese Liras | (L.L) |
| 49. | Lebanon Anti-Bribery Network | (LABN) |

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Author's Declaration

I declare that the research contained in this thesis, unless otherwise formally indicated within the text, is the original work of the author. The thesis has not been previously submitted to this or any other university for a degree, and does not incorporate any material already submitted for a degree.

A handwritten signature in red ink, consisting of several overlapping, fluid strokes that form an abstract, cursive shape.

Signed

Chapter One

Introduction

1.1. Introduction

Counterfeiting is a substantial problem that is growing worldwide, and affects both developed and less developed countries (De Matos et al, 2007). Counterfeit products are illegal, low priced and often of lower qualities than their originals (Lai and Zaichkowsky, 1999). Recently the trade in counterfeiting has developed into an extensive threat to public health and pharmaceutical industry (Bird, 2007). The World Health Organization (WHO) estimated that the global trade in counterfeit medicines (CFM) is experiencing continuous growth (World Health Organization, 2012a), where about 1% of prescribed medicines in the developed world and about 10-30% in parts of the developing world are estimated to be counterfeits (Cozzella et al, 2012; U.S Food and Drug Administration, 2015), yet the base of the estimate is unclear. The European Commission estimated that counterfeiting in general represents around 5–7% of world trade and around 15% of the global medicines supply chain could be counterfeit (World Health Organization, 2015).

Counterfeit medicine can have serious adverse effects on users and provides substantial income to counterfeiters or organizations (General Council of Official Colleges of Pharmacists, 2010). According to Interpol, the available evidence shows that counterfeiting is linked to organized crime and terrorist organizations (Gibson, 2004). Counterfeiting is not limited to a certain product category, it is so diverse to include pharmaceuticals, medical equipment, computer software, automotive and aircraft parts, to name a few. Any well-known and popular brand product is prone to be counterfeited (Balfour et al, 2005; Berman, 2008). Counterfeit medicine is more dangerous than the copying of other products, since it poses a risk for public health, which can cause a large number of deaths, as well as financial losses for the manufacturers of the brand names (General Council of Official Colleges of Pharmacists, 2010).

This chapter provides background information about CFM in the world and in Lebanon. Starting with a general description and classification of the different counterfeit products (CFP), followed by the definition of CFM. The historical background, prevalence of CFM, reasons behind their availability and related consequences are also addressed. Finally, background information on Lebanon with a brief description of the pharmacy practice, leading to the rationale behind this study.

1.2. Counterfeit classification

Counterfeits, according to Berman (Berman, 2008), can be classified into four categories to help understand the intention of counterfeit producers and the harm associated with each category as follows:

1.2.1. Category one: look alike, sound alike products

The producers of these products in this category do not intend to deceive the public, so the public is aware that the products they are buying are not the authentic/original products. The products in this category are cheap and sometimes very cheap, in comparison to the price of the original products. Examples of companies for which counterfeit versions are available include Gucci, Prada, Chanel, Louis Vuitton products and Rolex, Chanel and Cartier watches to name a few (Berman, 2008). These products can be found in different locations depending on the country. In New York for example, such CFP can be located in well-known streets, whereas in other countries they are found in accessories shops, depending on the country's regulation related to CFP (Marcketti and Shelley, 2009). In this case, people knowingly choose to buy such products. Even though customers are aware of what they have purchased, there is harm done from a societal and business perspective, for the loss in sales to the original product owner is indirect in sales of look alike (Berman, 2008). The reason is few buyers of the original products will buy such products. However, there is no doubt the original image will be affected due to the abundant supply of look-alike products (Berman, 2008).

1.2.2. Category two: “genuine products”

The use of stolen or copied blueprints or masters, or the breakdown of products to analyse how they were made, would describe such products as “original products” (Berman, 2008). Here the copyrights of the products are being bypassed and the intention of the producers is to deceive the public into believing it is the original product from the original source. Common examples are software, CDs and DVDs. Here there is harm to the original manufacturer from the loss in sales and it is considered direct since the products are sold as the original ones. The original manufacturer can suffer loss through its quality image when consumers start to complain about a product's quality, since they do not know that the item they bought is counterfeit. Examples of counterfeit products for which counterfeit versions are available include Windows XP software, Kiwi shoe polish, and Callaway golf clubs

(Balfour et al, 2005).

1.2.3. Category three: products from current or former outsourced suppliers

Current or former outsourced suppliers can continue to produce certain products, by using an extra shift, for illegal manufacture of goods after authorized production has ceased. An example of this form of counterfeiting was an outsourcer's continued production of New Balance shoes after its contract had been terminated (Parloff, 2006). The situation here is different, since these CFP are produced on the same machinery as the original goods. As a result, these types of counterfeit goods may be difficult to distinguish from the original product. The products are the same as the original, however; the material may not be the same. Here, there is deception and it is directly affecting the Intellectual Property (IP) of the manufacturer.

1.2.4. Category four: products from outsource suppliers that do not meet manufacturer's standards

Products produced by outsource suppliers that do not meet a manufacturer's standards but are not properly labelled as seconds or destroyed. These products are reclaimed and resold as first-quality products. Kyocera, for example, filed a lawsuit against Hecmma, an outsourcer it had hired to produce cell phone batteries. Kyocera claimed that Hecmma sold batteries prone to over- heating bearing Kyocera's brand name after the company terminated its order (Spring, 2006). This type of counterfeit is the most difficult to distinguish at purchase from original products (Berman, 2008).

1.3. Definition of counterfeit medicine

A CFM can be described as a medicine that is presented in a way to look like the original medicine, although it is not. In legal terms, this is called trademark infringement; the unauthorized use of IP and is the result of deliberate criminal activity (Majid, 2008). According to Black's law dictionary, the term "counterfeit drug" maybe used to describe a medicine (drug) made by someone other than the original manufacturer, by copying or imitating an original product without authority or right, with the intention to deceive or defraud, and then marketing the copied or forged medicine as the original (World Health Organization, 2012a). According to the above classifications, CFM can be any of the last three categories mentioned above.

The expansion of CFM in 1990, led international health care experts to reflect on their prevention and to publish definitions of CFM. The definition of CFM was not differentiated from counterfeit clothes, bags or other counterfeit products until 1992, when the WHO published their first definition (Delepierre et al, 2012). Currently, there are many definitions being used globally, nonetheless, the WHO, has taken into consideration most of the terms commonly used when referring to CFM. At present, the WHO refers to CFM as “Spurious/falsely-labelled/falsified/counterfeit (SFFC) medicine” and is defined as “one which is deliberately and fraudulently mislabelled 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” (Newton et al, 2009; General Council of Official Colleges of Pharmacists, 2010; World Health Organization, 2012b). This study will use the current WHO definition (Newton et al, 2009) that is referred to in most references.

1.4. Historical Background

Counterfeit medicines have been a persistent and continual problem in society, marked with the history of crises in the supply of antimicrobials, such as counterfeit cinchona bark in the 1600s and counterfeit quinine in the 1800s (Newton et al, 2010). The bark of the cinchona tree, from South America, and extracts of the wormwood plant in China, were among the first effective antimicrobial agents to be used in Europe in the 17th century. Quinine became widely used upon its isolation from the bark in 1820 (Rosenthal, 1998). However, widespread adulteration of medicine, especially quinine initiated the first regulation of the trade in medicines, codes of practice of pharmacists and guides on the detection of counterfeit medicines in the United Kingdom, and United States of America in the mid-19th century (Bahjat, 2008).

Counterfeit medicine was first addressed at the international level in 1985 at the Conference of Experts on the Rational Use of Drugs in Nairobi. Then, the World Health Assembly adopted a resolution against counterfeit and substandard pharmaceuticals in 1988, which requested the Director-General of the WHO to initiate programs for the prevention and detection of the export, import and smuggling of falsely labelled, counterfeited or substandard pharmaceutical preparations (World Health Organization, 2012b). The WHO published its first definition of CFM in February 1992 (Delepierre et al, 2012) and since then the counterfeit market has rapidly expanded, for economical reasons

(high medicine prices, corruption), legal gaps (weak regulatory systems and weak enforcement of the law), globalisation (global nature of drug manufacturing, parallel trade, no taxes (free trade zones), repackaging) and largely the widespread use of the Internet to market counterfeit medicines and products (Siva, 2010; Traynor, 2007).

In February 2006, the WHO created the first global initiative, known as the International Medical Products Anti-Counterfeiting Taskforce (IMPACT). A total of 193 WHO Member States were included on a voluntary basis, in addition to international organizations, enforcement agencies, national medicine regulatory authorities, customs and police organizations, non-governmental organizations, associations representing pharmaceutical manufacturers and wholesalers, health professionals and patients' groups. The groups joined together to improve and bring collaboration between countries in order to work together to stop counterfeiters from producing, and trading of CFM (World Health Organization, 2008).

According to the WHO, the extent of CFM is not really known, since it relies on each country's reporting incidences of CFM, which is not always done (World Health Organization, 2012a). Therefore, it would be difficult to estimate the true extent of the problem. What is also known is that CFM are available worldwide in both developed and developing countries alike (World Health Organization, 2012a).

1.5. Prevalence

An extensive literature review was conducted to determine the prevalence of CFM in the United States of America (USA), Europe, Africa and Asia with a focus on the developing countries in the Middle East, especially Lebanon. The research showed CFM are available all over the world and are most prevalent in developing countries (World Health Organization, 2011) due to weak medicine regulation, control and enforcement. In Western Asia, in areas with limited regulatory control and free trade zones to encourage trade (Cozzella et al, 2012), weakened the safety of supply chains and encouraged illegal activity (Cozzella et al, 2012). Yet, developed countries are as vulnerable, an example; the European Union (EU) customs figures of the 2006 report showed an increase of 384% in seizures of CFM, that represented up to 2,711,410 units of CFM (European Commission, 2006). In 2008, the EU customs officials reported that a third of the CFM they confiscated along its borders originated from the United Arab Emirates (UAE), which had several free

trade zones (UNODC, 2015). Several cases have also been discovered in the legal pharmaceutical distribution chain in both North America and Europe (Besancon, 2008). In developing countries, the basic medicines are mostly unaffordable and are limited or irregularly supplied (Criminal Intelligence Service Canada, 2009). The economy of most developing countries is poor where their low income per capita and poverty have been directly linked to the problem of CFM (Erhun et al, 2001; Mehta, 2006). In addition, many countries may not have adequate health services, reliable pharmaceutical supplies, and health insurance or social security systems. As a result, patients resort to buying their medicines themselves and hence seek cheaper medicines (World Health Organization, 2008).

The incidence of CFM varies based on each country's regulatory and enforcement system. Developed countries are considered to be well regulated, with a well-controlled system, have lower rates of CFM, compared to poor and developing countries that have weaker regulatory and enforcement systems, therefore, higher percentage of CFM (World Health Organization, 2012b).

Consequently, all medicines can be counterfeited from essential medicines, that treat serious or life threatening diseases, to lifestyle medicines, that are non-essential, yet widely used, therefore, leading to serious harm and death to patients (Chika et al, 2011). Counterfeits of most commonly used essential medicines have been described in 206 cases of counterfeit anti-infective medicines from 38 countries (Clark, 2003; Newton, et al., 2006a). The counterfeited medicines were mainly antibiotics, hormones, analgesics, steroids, and antihistamines, and these medicines accounted for almost 60% of the products reported (Wondemagegnehu, 2003; World Health Organization, 2012a). Although the extent of CFM is not known, the prevalence is increasing, with a shift in focus from counterfeit life style medicines to more lifesaving medicines as is seen in most developing countries (Gaudiano et al, 2007; Cordina, 2010) and this could be due to their high prices, or the high demand and urgency associated with their use.

According to the WHO (World Health Organization, 2012a), there are six categories of CFM:

- a) Products without active ingredients, found in 32.1% of CFM
- b) Products with wrong ingredients (could be a substance with totally different activity, or similar activity, but cheaper, and when tested, less potent), found in 21.4% of CFM

- c) Products with incorrect quantities of active ingredients (lower than indicated on label/bottle), found in 20.2% of CFM
- d) Products with correct quantities of active ingredients, with fake packaging (such as altered expiry date on expired medicines), found in 15.6% of CFM
- e) Products with high levels of impurities and contaminants (such as talc powder, chalk, floor wax), found in 8.5% of CFM
- f) Copies of an original product, found in 1% of CFM (World Health Organization, 2012a).

Although, there have been many incidences of CFM in different regions of the world; yet, few studies reported the prevalence of CFM. Below are two studies that described the prevalence of CFM in their area.

A study in Saudi Arabia showed that the majority of CFM found were manufactured in India, Iran, Indonesia, Nigeria and Pakistan, where the regulations of CFM and enforcement of the laws are weak (Alsultan, 2010). The study indicated that the most common CFM were antibiotics, analgesics and vitamins. Their results showed that in 2005, 34.4% of medicines were CFM, however, in 2006 there was an increase to 49.3% of medicines that were CFM.

A study (Dondorp, et al, 2004) was conducted to assess the prevalence of counterfeit antimalarial medicines in Southeast Asia (SE), found that of the 188 tablets of artesunate, 53% were counterfeit, and did not contain any of the active ingredient, and of the 44 mefloquine tablets, 9% contained less than 10% of the active ingredient (Dondorp, et al, 2004).

The above studies gave an insight into the CFM problem in specific areas at a designated time, in a specific area/location. The studies described the situations based on the samples collected, and data analysis by investigators. The studies did not represent the whole country or all available CFM. In addition to these studies, each country reports to the WHO what is being reported in that country. In that sense, the statistics are not a true presentation of the actual situation, but an estimation of the availability of CFM. **Appendices 1.I, 1.II and 1.III**, show the reported incidences of CFM. **Appendix 1.I**, for the industrialized countries (such as the United States, Australia, Japan, Canada, New Zealand, and those in the EU). **Appendix 1.II**, for the Arab countries and Israel, and **Appendix 1.III**, for other developing countries around the world.

1.6. Causes of counterfeit medicine

The most common factors that encourage counterfeiters to produce CFM vary from one country to another, however, according to the literature the most common are: 1) lack of legislation prohibiting counterfeiting of medicines, 2) weak or minimum enforcement of laws and disciplinary actions, 3) premium paid for brand name medicine, when highly priced, allow counterfeiters to use the high cost as an incentive that provides financial benefits, 4) improved manufacturing capabilities, to produce medicines difficult to differentiate from their original, 5) shortage of medicine supplies, allow counterfeiters to infiltrate their products into the market or supply chain, and 6) globalised economy; trade involving several intermediaries and free trade zones, and increased outsourcing of manufacturing, allow counterfeiters to operate in countries that have weaknesses in the supply chain and minimal penalties for producing CFM (World Health Organization, 1999; Gordon, 2002; Wondemagegnehu, 2003; U.S. Food and Drug Administration, 2004; World Health Organization, 2006a; World Health Organization, 2015).

1.7. Consequences of counterfeit medicine

The primary problem with CFM is the significant health threat they pose and it is not confined to the individual patient, but extends to the whole society, endangering public health and safety (Luu, 2005). The consequences of using CFM may range from treatment failure, prolonged illness, unusual side effects, anti-microbial/antibiotic resistance leading to mortality from the disease or the toxic components of the CFM (Basco, 2004; Dondorp, et al, 2004; Deisingh, 2005; Luu, 2005; Newton et al., 2006a; Newton et al, 2006b). People with desperate needs, who cannot afford the full price, tend to be the most vulnerable victims (O'Mathúna and McAuley, 2005).

The following are documented outcomes of CFM:

In Russia, in 2005, more than 1,000 admissions to hospitals were the result of counterfeit insulin (Feldschreiber, 2009). In Singapore, in 2008, 150 diabetic patients took counterfeit sexual enhancement medicine (tadalafil) that contained 13 to 100mg of glyburide (hypoglycaemic medicine) (Kao et al, 2009). As a result, patients were hospitalized due to the development of severe hypoglycaemia, seven patients were comatose and four died (Kao et al, 2009). In Nigeria, in 2008, 34 children aged four months to three years died, and more than 50 were hospitalized with severe kidney damage after taking a teething

mixture that contained paracetamol (analgesic) and as a solvent, diethylene glycol (toxic substance) instead of propylene glycol (Akiny, 2013). In China, in 2009, counterfeit glibenclamide (for diabetes), was found to contain six times the normal dose that led to the death of two and hospitalization of nine people (World Health Organization, 2015).

Generally speaking, healthcare professionals do not automatically suspect CFM when confronted with patients who show signs of lack of efficacy or adverse events. As a result, there may be fatalities not attributed to CFM, due to the difficulty in proving that the patient was using a counterfeit. Consequently, there is a high possibility of under-reporting CFM cases that maybe occurring (Feldschreiber, 2009) (**Appendix 1.I–1.III**).

The WHO estimated that the emergence of drug resistance when treating tuberculosis (TB), malaria, cholera and many other diseases may be a result of substandard and CFM (World Health Organization, 2015). CFM such as antibiotics, may contain no active ingredient, a low quantity or sub-therapeutic amount of the active ingredient, that is not enough to eradicate the bacteria, causing serious consequences (Dondorp, et al, 2004; Deisingh, 2005; Newton et al., 2006a; Newton et al, 2006b), which is considered a growing international problem that is affecting both current and future generations (Cars and Nordberg, 2005; Kelesidis et al, 2007).

As a result, ignorance of the risks and attributes of CFM on the part of patients and health professionals not only increases vulnerability of CFM use, but also lowers detection and reporting rates for counterfeits. The burden due to CFM can be estimated by costs of hospitalizations or ambulatory settings for treating the consequences of CFM use (Newton et al, 2006b; Seiter, 2009; Akiny, 2013).

Furthermore, counterfeiting can play a major role in destroying the public's trust in the health care team, the physicians for prescribing CFM, the pharmacists for dispensing and the nurses for administering them (Newton et al, 2006b; Seiter, 2009; Akiny, 2013).

Likewise, counterfeiting can destroy public trust in the role of government and regulatory authorities in controlling the availability of CFM and the penalty related to such crime (Akiny, 2013). There may be a conflict of interest where governments may be reluctant to report their findings of CFM, possibly because some countries do not want to declare the extent of the problem, weakness of the system, or lack of success in dealing with CFM (Gibson, 2004).

Additionally, CFM can also have a significant impact on the pharmaceutical industry's business, not only due to the violation of patents and as a result the loss of income, but it also leads to a loss of reputation, since counterfeiting can destroy public trust in the safety and efficacy of pharmaceutical products (Cockburn et al, 2005). In addition, the public may also lose trust in the medicine itself.

Over the past decade, the pharmaceutical industry has shifted a large part of its manufacturing operations and supply sourcing overseas. The supply chain, starting with raw material to finished product, has become more complex involving a variety of locations for repackaging and distributors. Similar to any chain, the supply chain for medicine is only as strong as its weakest link. The increase in the number of handlers, suppliers and middlemen, created multi-entry points through which contaminated, adulterated and CFM infiltrated the medicine supply chain (Newton et al, 2002). These gaps provide the perfect opportunities for counterfeiters to infiltrate their CFM through the supply chain, where the medicines end up in legitimate outlets, such as wholesalers and pharmacies.

Moreover, many pharmaceutical manufacturers invest in research and development and on the production and marketing of their pharmaceutical products. Consequently, they may be reluctant to publicize the CFM problem to the healthcare team and the public. Their motivation is the belief that the publicity will harm the sales of brand-name products in a fiercely competitive business in addition to political reasons (Mehta, 2006).

The presence of laws and regulations in any country will protect against CFM, if applied and enforced, but if these laws and regulations are weak, corruption can be an expected outcome. Lack of enforcement amplifies the risk that CFM can infiltrate the market, for counterfeiters can operate with little fear of anyone being caught or punished (Morris and Stevens, 2006; Aldhous, 2005; Akiny, 2013).

Now, in the 21st century, the problem of CFM continues, the same crisis of supply shortages are still present, however, currently, the economical, political, governmental or regulatory situation of each country, add to the reasons why CFM are readily available in some countries more than others (Newton et al, 2002).

1.8. Lebanon and counterfeit medicine

Lebanon is a small country with a total area of 10,452 square kilometres located in the Middle East on the eastern shore of the Mediterranean Sea between Israel and Syria (**Appendix 1.IV**), with a population of 5,882,562 (July 2014 estimate). Around 90% of the population is literate; 93.4% of males, and 86% of females (2007 estimate) (Karam, 2004; Central intelligence agency, 2014; NationMaster, 2014). According to the Global Competitiveness report 2011/12, Lebanon ranked 49th for the quality of its higher education and training, and 35th for health and primary education out of 142 countries worldwide (Schwab and Sala-i-Martin, 2011).

1.8.1. Pharmacy practice

Pharmacy practice in Lebanon is said to date back to the 1920s, when treatments were based on herbal products. The advancement of pharmacy practice was largely related to the establishment of the Lebanese Order of Pharmacists (OPL) in 1950, an association of professionals that set firm standards for pharmacy practice in Lebanon (Khoury, 2008; Lebanese Order of Pharmacists, 2014a), however these standard are mostly related to laws and regulations of pharmacy practice (Lebanese Order of Pharmacists, 2014a). The Order is known to be formed with the intention of promoting the common interest of pharmacists in Lebanon. However, the OPL does not have a document that sets out the standards of conduct; ethics and performance that registered pharmacists must follow (General Pharmaceutical Council, 2015). The standards that would set out the behaviours, attitudes and values that registered pharmacists are expected to comply to (General Pharmaceutical Council, 2015). Although, according to practicing pharmacists; upon registration with the OPL, pharmacists are required to sign on a document that is similar to the Oath of a pharmacist (American Pharmacists Association, 2015; International Pharmaceutical Federation, 2015b), making them aware of their duties and responsibilities towards their patients and society.

As for education, Saint-Joseph University (USJ), one of the prominent universities in Lebanon, founded the first school of pharmacy program in 1889 (Université Saint-Joseph-School of Pharmacy, 2014). Currently, five universities offer pharmacy programs in Lebanon (Khachan et al, 2010; Lebanese Order of Pharmacists, 2014b). Many factors are attributed to the success of pharmacy education in Lebanon, such as the diverse academic curricula, sociocultural perceptions of people towards higher education such as; status and

knowledge, and organisational jurisprudence and licensure (Khachan et al, 2010).

Additionally, the pharmaceutical industry in Lebanon dates back to around 30 years ago, and these industries produce generic oral, topical and intravenous preparations. The exported products reached by the end of 2012 an approximate value of USD 31.45 million (Investment Development Authority of Lebanon, 2013). In 2012, Lebanon's pharmaceutical imports were estimated at USD 970 million, an increase of 12.9% over 2010 (Investment Development Authority of Lebanon, 2013). The majority of medicines imported to Lebanon account for 90% of the pharmaceutical market, while the nine local generic manufacturers produce 10% of medicines of the pharmaceutical market (Karam, 2004; Investment Development Authority of Lebanon, 2013).

Community pharmacies are considered a primary healthcare facility in Lebanon, and can only be owned by a registered pharmacist (Lebanese Order of Pharmacists, 2014a). Registration and licensing of pharmacists is the responsibility of the Directorate of Pharmacy at the MoPH. The practice of pharmacy in Lebanon is controlled, and the legislation determines who can practice pharmacy, the condition under which the pharmacy may operate, and the laws for prescribing and dispensing of medicine (Lebanese Order of Pharmacists, 2014a). A pharmacist in Lebanon is permitted to own one pharmacy, and chain pharmacies such as Boots, Walgreens, CVS, and Duane Read are prohibited in Lebanon (Lowe and Montagu, 2009; Lebanese Order of Pharmacists, 2014a). Not all medicines in Lebanon require a prescription; only restricted medicines such as psychotropics and narcotics would require one (Lowe and Montagu, 2009; Lebanese Order of Pharmacists, 2014a). The delivery of healthcare in Lebanon is provided by the government and private sectors (Hanson and Berman, 1998; Smith et al, 2001; Lowe and Montagu, 2009).

1.8.2. Background of counterfeit medicine

During the civil war in Lebanon in 1982, Hoechst Pharmaceuticals warned pharmacists and customers that their medicine Daonil® (Glibenclamide, a medicine for diabetes) was available as counterfeit. In addition, factories around Beirut were reported to be counterfeiting about 57 Western medicines. During that time counterfeiting medicine or piracy were not stopped and as a result thrived in Lebanon, since the government failed to address the counterfeiting problem (Cockburn et al, 2005; Akunyili, 2005).

By the end of year 2002, and with the increased data and knowledge of CFM, Lebanon decided to implement the hologram as a unique sign, to indicate the authentic origin of a given medicine. Accordingly, a slogan for the hologram “from the producer to the citizen/consumer” was used to stress the fact that only medicines registered and approved for importation by the MoPH, were imported with the knowledge and approval of the “Mother company”, as per the requirements of the Lebanese regulations (Ministry of Public Health, 2012). In 2004, the Lebanese Pharmaceutical Importers Association (LPIA) introduced a 3D hologram with the slogan, and now many medicines on the Lebanese market use their hologram.

1.8.3. Awareness

In 2008, in an effort to combat CFM, the OPL and the MoPH, launched a campaign on CFM to raise awareness, using billboards covering all Lebanese territories, media (TV, Radio), posters (in pharmacies, universities and hospitals), flyers for patients, in addition to interviews and press conferences (International Pharmaceutical Federation, 2012). Before the 2008 campaign, CFM were available in different places such as; pharmacies, hospitals, dispensaries, boutiques, supermarkets, and houses, until the law was enforced to limit the availability of medicines to pharmacies, hospitals, dispensaries, and other authorized settings (Nassour, 2012).

In January 2010, the Lebanese Minister of Public Health announced that nine pharmacies and four medical warehouses were closed for trading in counterfeit Plavix[®] (Clopidogrel). Plavix[®], used to prevent thrombus formation, was manufactured in China and smuggled into Lebanon and other countries in the region. Following laboratory analysis in France and Lebanon, the counterfeits were found to have only 40% of the therapeutic value of the original Plavix[®] (Lebanon Pharmaceuticals and Healthcare, 2010). The closed institutions, however, were reopened (Lebanese Broad Casting International, 2013), and the unofficial reason given was that pharmacists were not aware that the Plavix[®] was counterfeit.

To ensure that CFM were not sold within the national and private healthcare system, the OPL suggested that pharmacists be positioned at customs and within hospitals. In addition, activating the national laboratory, to test and control all the medicines available in the Lebanese market, and to analyse suspected CFM, as well as testing for bioequivalence, to ensure product safety (Lebanon Pharmaceuticals and Healthcare, 2010). To date, there is nothing to show that these recommendations were implemented.

As for awareness of CFM, a study in Poland revealed that healthcare professionals (HCP) (physicians and nurses) were less aware than laypersons about the danger of purchasing illegal medicine outside pharmacies, and had lower levels of awareness than the laypersons, about the scale of and the threats of CFM to health, and majority of HCP did not know how to report a suspected CFM (Binkowska-Bury et al, 2013).

Another study in California, USA (Law and Youmans, 2011), revealed that most pharmacists had little or no experience with CFM, and 15.9% of pharmacists did not know if they ever came across CFM (Law and Youmans, 2011).

A recent study in Jordan used a questionnaire, to identify pharmacists' awareness and the contributing factors of CFM in Amman, Jordan. The study used a small sample (62 pharmacists), and reported that the majority (76%) were aware of the CFM problem and the current laws and regulation in Jordan. However, half of respondents did not think counterfeiting was a serious problem, and reported to believe that it would be difficult for CFM to invade the Jordanian market. The study suggested that the fight against CFM is a shared responsibility among all parties involved, however, this would be best achieved through awareness campaigns (Taleb, 2013). There were no similar studies addressing public or pharmacist awareness or attitude towards CFM in Lebanon.

Consumers in counterfeiting are considered the actual force behind the counterfeiting business (Chan et al, 1998). A study that took place in London (Furnham, and Valgeirsson, 2007), studied the effect of life values and materialism on buying counterfeit products. When considering the variability in what products people were prepared to buy, medicine was a highly skewed variable, as people were less willing to buy CFM, indicating a negative attitude towards CFM (Furnham, and Valgeirsson, 2007).

Consequently, counterfeit medicine continues to be a public health and patient safety risk (Mackey and Liang, 2011; Shrivastava et al, 2013). The little that is known of the nature and extent of CFM in Lebanon, and the limited studies on public and pharmacist awareness and attitude towards CFM, steered to the purpose of this study.

1.9. Aim of the Study

The rapid propagation and negative impacts of CFM on health raised a concern related to how aware are the public and pharmacists about CFM. The available data on CFM in Lebanon were either part of the WHO reports, or cases that appeared in the mass media or newspapers. There are no studies reported in scientific journals to describe the nature or extent of CFM in Lebanon. In addition, there are no data or statistics available, by the government, OPL and Lebanese Order of Physicians (Ordre des Medecins du Liban-OML) on CFM. To date, public and pharmacists' views and attitude towards CFM have not been investigated in Lebanon. Determining their awareness and attitude towards CFM would help better understand the gravity of the problem, and determine if there would be a need to develop a recommendation plan towards controlling the availability and use of CFM in Lebanon. Pharmacists in particular, are considered the final link in the supply chain of CFM. Therefore, pharmacists' awareness and attitude would describe their ability to play the key role in preventing CFM from reaching patients, and making sure patients received safe and effective medicines.

The study's objectives are 1) to determine the nature of the CFM samples identified by the MoPH on the Lebanese market, 2) to investigate the extent of CFM availability in households in various areas in Lebanon, and 3) to assess the public and pharmacists awareness and 4) their attitudes towards CFM.

In order to determine the nature of the CFM samples identified by the MoPH on the Lebanese market, and their categories according to the WHO's six categories, two methods were used; the physical examination and chemical analysis. The hypothesis is:

a. The CFM samples are different from their originals

Exploring the availability of CFM in various households would provide a better understanding of the extent of CFM in Lebanon, and the risks related to their availability.

Therefore, the hypotheses are:

a. There are CFM available in households in Lebanon

b. The household members are knowledgeable about their medicines

Determining public awareness and attitude towards CFM, would help describe the vulnerability of the public to using CFM and how best to address future educational campaigns, with the aim to decrease the demand and use of CFM. The hypothesis is:

a. The public are aware of CFM

Therefore, the study will assess the following:

- a. Participants' experience of CFM**
- b. Participants' views of awareness campaigns**
- c. Participants know how to report CFM**
- d. Participants' believe to know who is responsible for availability of CFM**
- e. Participants' attitude towards CFM**
- f. Participants' attitude towards pharmacists who deal with CFM**
- g. Participants' attitudes towards CFP**

Assessing pharmacist awareness of CFM and CFP, and attitude towards pharmacists', who deal with CFM, will help evaluate the obstacles that may hinder the combat against CFM from reaching patients. Therefore, the hypothesis is:

a. Pharmacists are aware of CFM

Hence, the study will assess the following:

- a. Participants' experience and views towards CFM**
- b. Participants' know of other pharmacists that dispense or deal with CFM**
- c. Participants' attitude towards CFP**

The focus groups for the public and pharmacists would allow exploration of participants' perceptions to CFM to discuss in depth their thoughts and beliefs towards each of the below statements:

- a. Participants' experience and views regarding CFM**
- b. Participants' experience and views on who they believe to be responsible for the availability of CFM.**

Chapter Two

Physical Examination and Chemical Analysis of Counterfeit Medicine

2.1. Introduction

The availability of CFM makes assessing the quality of medicine a necessity, especially at places such as wholesalers, hospitals and pharmacies (Martino et al, 2010). Once a product is suspected to be counterfeit, it should be sent for analysis to confirm if counterfeit, to assess the harm it might have caused patients (Dubois et al, 2007). According to the WHO, there are six categories of CFM:

- a) Products without active ingredients, found in 32.1% of CFM
- b) Products with wrong ingredients (could be a substance with totally different activity, or similar activity, but cheaper, and when tested, less potent), found in 21.4% of CFM
- c) Products with incorrect quantities of active ingredients (lower than indicated on label/bottle), found in 20.2% of FM
- d) Products with correct quantities of active ingredients, with fake packaging (such as altered expiry date on expired medicines), found in 15.6% of CFM
- e) Products with high levels of impurities and contaminants (such as talc powder, chalk, floor wax), found in 8.5% of CFM
- f) Copies of an original product, found in 1% of CFM (World Health Organization, 2012a).

Analytical tests or procedures were developed to test a defined characteristic of the medicinal substance or product against established acceptance criteria for that characteristic (USFDA, 2014). Several studies have used different analytical techniques to identify and differentiate between suspected CFM and original products (Blok-Tip et al, 2004; Zou et al, 2006; Inoue et al 2008; Singh et al, 2009; Deconincka et al, 2012).

The first step that is most commonly used to detect and identify a CFM is the physical examination (Deisingh, 2005; Kaur et al, 2010; Martino et al, 2010; Shah et al, 2010; Savaliya et al, 2010), through comparing the physical appearances, such as the package, tablet/capsule, colour, print, font, size, shape etc... Most pharmaceutical companies include on their packaging anti-counterfeiting technologies ranging from the very simple but effective to the highly sophisticated and more secure. Anti-counterfeiting features allow authentication of the products by government, investigators or the public, they also act as a deterrent to counterfeiters (Power, 2009). Overt and covert technologies help preserve the integrity of medicines, for authentication, and confirmation that a product is genuine. Authentication can prevent patients from using a CFM that can lead to treatment

failure or death (Power, 2009; Kaur et al, 2010; International Chamber of commerce, 2013). Overt features are visible features that can help patients identify and differentiate a CFM from the original. These features are meant to be complex and difficult to reproduce, including optical variable coatings with changing colours, thermo-chromic inks, Inkjet watermarks, barcodes, and holograms. However, even the high-quality barcodes or holograms are becoming easy to replicate or counterfeit by counterfeiters (Benbasat, 1999; Deisingh, 2005; Newton et al, 2006a; Newton et al, 2006b; Lancaster, 2009).

The advantages of the overt features are; instant verification, user verifiable, add decorative appeal, no device is needed for authentication and were meant to be a deterrent to counterfeiters. However, the disadvantages are; require user education, add to a cost, and can be counterfeited (Dondorp et al, 2004; Dhar, 2009; Power, 2009; Shah et al, 2010). The covert feature is hidden, and it is there to help the brand owner to recognise/identify their product from a CFM. The public will not know it is on the package and will not have the resources to confirm it (Martino et al, 2010; Shah et al, 2010). Covert features include microscopic particles of specific colours and labels printed with colour combinations (Jotcham, 2003). The advantages of the covert features are; can be simple and low cost to implement, do not need regulatory approval and can be easily added or modified. The disadvantages include the need for strict secrecy, maybe easy to copy, and more secure options can add to complexity and cost (Power, 2009; Shah et al, 2010).

The sophisticated work of some counterfeiters has made the physical examination alone unreliable or insufficient as a single method to identify a CFM. As a result, adding the chemical analysis or analytical techniques for detecting CFM would give the results more reliability (Martino et al, 2010). The analytical techniques can determine quantitatively, the chemical composition of the medicine, as well as its impurities. Different methods are used when detecting or identifying CFM, and such methods include: the gold standard analytical method, high-performance liquid chromatography (HPLC) (Savaliya et al, 2010), or simple methods that can be considered in-field assays, such as colorimetric or simple thin layer chromatography (TLC) (Deisingh, 2005; Vredenbregt et al, 2006; de Peinder, 2008). The more advanced laboratory techniques are; vibrational spectroscopies Raman (Roggo et al, 2010), infrared (IR) or near-infrared spectroscopy (NIR), liquid chromatography-mass spectrometric (LC-MS) approaches, (Deisingh, 2005; de Peinder, 2008), and nuclear magnetic resonance (NMR) spectroscopy (Martino et al, 2010). Spectroscopy is an analytical technique that helps determine the structure of compounds or medicines. For the

specific detection of CFM, spectroscopic techniques are preferred because they are fast and need only a little or no sample preparation (Deisingh, 2005).

Vibrational spectroscopic methods have proven to be very efficient since they allow characterizing of samples by directly measuring substances in the solid state; and also rely on straightforward operational steps that provide reliable and fast results (Ortiz et al, 2013). The hand-held IR, Raman and NIR devices are becoming available and though not as sophisticated as the laboratory-based instruments, may be useful for rapid checks at inspection points (Deisingh, 2005; de Peinder, 2008; Roggo et al, 2010; Ortiz et al, 2013).

Numerous studies addressed different analytical techniques used to examine suspected CFM. One study (de Veij et al, 2008) stated that Raman spectroscopy was a fast and reliable method for detecting counterfeit Viagra[®] (Sildenafil) tablets requiring no sample preparation. Another study (Vredenburg et al, 2006) also described the non-destructive NIR spectroscopy method for fast screening of suspected Viagra[®] samples. A further study (Ortiz et al, 2013) used attenuated total reflection Fourier transform infrared (ATR-FTIR) spectroscopy to differentiate between counterfeit and authentic Cialis[®] (Tadalafil) and Viagra[®], and showed that the spectra provided relatively simple and fast screening tools. The latter study also compared the ability of Raman spectroscopy, NIR spectroscopy and Fourier transform infrared spectroscopy (FTIR) to discriminate between counterfeit and genuine samples of Cialis[®] and Viagra[®] (Ortiz et al, 2013). The variability in spectral data between the genuine samples was very low (Sacré et al, 2010; Ortiz et al, 2013).

The combination of Raman, NIR, and FTIR can provide complementary information on each medicine. These imaging techniques can identify and quantify excipients, assess the particle sizes and measure the homogeneity of the mix. Further information on hardness, compression, dissolution and moisture content can also be obtained using these techniques (Deisingh, 2005). Below is a brief description of these spectroscopies, and Ultraviolet-visible spectroscopy (UV-vis) (Ricci et al, 2007; Sacré et al, 2010).

Raman spectroscopy is an analytical technique for material characterization. It involves measurement of light frequencies scattered by molecules irradiated by a monochromatic source. The frequencies emitted may be affected by vibrational transitions of the molecules and are characteristic of particular compounds. It works by illuminating the sample with a high-powered diode laser beam that provides the required intensity needed to obtain good spectra. It is a non-destructive, specific, contact-free, and high-speed technique that needs

no sample preparation. The fluorescence in the Raman spectral region can overwhelm the relatively weaker Raman signal (Martino et al, 2010; Roggo et al, 2010; Ortiz et al, 2013). Many pharmaceutical preparations contain highly fluorescent excipients, thus affecting the quality of the spectrum (Ricci et al, 2008). Raman has been used for the screening of pharmaceutical formulation quality and CFM through packaging (coating, capsules, or blister packs) of transparent nature presenting no or few fluorescence and spectral Raman features (Hall et al, 2006; de Veij et al, 2007; Ricci et al, 2008).

NIR spectroscopy is a technique in which the near infrared region of the electromagnetic spectrum is used as an evaluation tool (Dowell et al, 2008). NIR is based on the absorption ranging from 700–2500 nm (Martino et al, 2010; Yoon et al, 2004). NIR is non-destructive, requires no sample preparation and has a high speed of analysis (Dowell et al, 2008). The spectrum can often be obtained through blisters or ampoules without opening them; acceptable materials are glass and plastics, but metal foil is unacceptable (Martino et al, 2010; The American pharmaceutical group and Wellcome Trust, 2009). NIR is a method used for distinguishing genuine, generic, and CFM (Burns and Ciurczak, 2007).

FTIR spectroscopy measures the infra-red frequencies absorbed by molecules undergoing vibrational transitions, and identifies the functional groups of chemical constituents with absorption frequencies typically expressed as a range of wavenumbers (from 4,000-400 cm^{-1}) (Martino et al, 2010). FTIR spectroscopy is non-destructive and requires no sample preparation. It is a rapid and very sensitive method for verification of pharmaceutical products. Similar to the concept of fingerprints, no two unique molecular structures will produce the same infrared spectrum. As a result, infrared spectroscopy can result in a positive qualitative analysis identification of different kinds of material (Roggo et al, 2007).

Dissolution testing is a tool in medicine development and quality control, (Siewert et al, 2003) and is frequently associated with the assessment of the *in vivo* performance of medicine (Dressman et al, 1998). Dissolution testing “.... measures the amount of medicine dissolved in a known volume of liquid medium at a predetermined time, using a specified apparatus designed to carefully control the parameters of dissolution testing” (Yu, 2012). The dissolution test can help detect bioequivalence problems and provides basic criteria for medicine release from the product (Yu, 2012). The *in vitro* dissolution testing helps predict the *in vivo* bioavailability and bioequivalence of tablets and capsules (Kaur et al, 2010; Johansson et al, 2002). The presence of incorrect excipients, poor

manufacturing processes, Active Pharmaceutical Ingredient (API) quantity, and poor storage conditions all can result in decomposition, and may contribute to poor dissolution, resulting in lower bioavailability (Newton et al, 2008).

Ultraviolet-visible spectroscopy (UV-vis) is based on the absorption of light with frequencies in the ultraviolet-to-visible range ($\lambda \sim 150 - 700$ nm), absorption generally corresponds to electronic transitions and the absorption spectrum is dependent on the chemical structure (Spectroscopic Techniques, 2001). UV-visible spectroscopy can be used to determine information as to the identity of a particular compound (Owen, 1996). The spectra are not able to provide absolute identification of an unknown, but are frequently used to confirm the identity of a substance through comparison of the measured spectrum with a reference spectrum (Owen, 1996). Unlike Raman and IR, where there are very many peaks observed and differentiation of compounds is simple, there are few peaks in UV-vis spectra and they are less good for absolute identification. However the technique is very good for quantitation of medicines (Owen, 1996).

The PricewaterhouseCoopers report on counterfeit and smuggling of fast moving consumer goods in Lebanon, reported that identifying counterfeit products depended on the quality of the counterfeit and the intention of counterfeiters to defraud consumers (PricewaterhouseCoopers, 2003). Therefore, not all products could be identified by visual inspection, as some products required laboratory testing to be identified as counterfeit (PricewaterhouseCoopers, 2003).

After the January 2010 incident in Lebanon, the closure of nine pharmacies and four warehouses for having counterfeit Plavix® (Clopidogrel) (Lebanon Pharmaceuticals and Healthcare, 2008), it was apparent that CFM were present in the Lebanese community.

Quantification of the CFM problem in Lebanon is difficult, because there are no studies measuring the direct cause and effect of CFM, such as, estimates of the cost in terms of death; increased resistance to effective treatments, and inability to work. Reported studies however; suggested that the risks and consequences of CFM are huge (Wertheimer and Norris, 2009) (Refer to Chapter One for examples). Therefore, the objective of this chapter was, to determine the nature of the CFM samples identified by the MoPH, and their classification according to the six categories identified by the WHO (World Health Organization, 2012a). The hypothesis is:

a. The CFM samples are different from their originals

2.2. Methods

In order to determine the nature of CFM, two methods were used, physical examination and analytical techniques. The study compared each CFM with its original genuine sample, to determine if they were the same or different.

2.2.1. Sample collection

2.2.1.1. Counterfeit samples

The author of this study requested, officially through a letter (**Appendix 2.I.A**) to the MoPH, samples of different classes of identified CFM. The Ministry was able to provide five different CFM that were collected from undeclared local sources (**Appendix 2.I.B**). The author classified the samples as either essential or a life style medicine. A medicine was considered essential when the patient's life or health was affected without its use. A life style medicine was considered non-essential, when the patient's life or health would not be threatened without its use. Below is the list of the provided CFM:

1. Plavix[®] (Clopidogrel), essential medicine (for heart related problems)
2. Panadol[®] (Paracetamol), essential medicine (for pain relief)
3. Viagra[®] (Sildenafil), life style medicine (for erectile dysfunction)
4. Cialis[®] (Tadalafil), life style medicine (for erectile dysfunction)
5. Amoxil[®] (Amoxicillin), essential medicine (for bacterial infection)

2.2.1.2. Original medicine

The author contacted the agents of the above products through a university-accredited pharmacy, and ordered a box of each of the above listed medicines to be used as a reference. The Lebanese American University (LAU) - School of Pharmacy in Lebanon; is accredited by the Accreditation Council for Pharmacy Education (ACPE) in the USA. The selected pharmacy sites for pharmacy students at LAU, are selected based on the ACPE standards, and as a result are considered university-accredited pharmacies (Lebanese American University, 2015).

The analysis of the supplied CFM and original samples took place at the University of Brighton, School of Pharmacy and Biomolecular Sciences' laboratories.

2.2.2. Procedure

A three-stage process was used to compare each of the samples:

1. Visual inspection of the packaging material and dosage forms
2. Qualitative methods (Raman, NIR, and FTIR) to determine if the spectra of compared products were the same or different.
3. Tablet and capsule-dissolution test for assessment if CFM and original were the same or different, using the UV-vis spectra.

The physical examination is considered a visual and non-destructive method. In this study, it was used first to determine if the CFM, were the same or different from the original medicine, using the visual examination and then compared the results with the analytical techniques. The WHO recommended a tool for visual inspection of medicine (Tool for visual inspection of medicines, 2015), that indirectly covered both overt and covert anti-counterfeiting technologies, and it was partially adopted and used as a guide for the physical examination of this study.

Therefore, the author checked the integrity of the packaging, package insert, appearance of tablets, the features of the blister pack with indented or printed batch number, dates of manufacture and expiry date, in addition to the hologram on each box.

The label of the packaging was also checked, as to whether it included the list of active and non-active ingredients, name and address of the manufacturer, storage conditions, batch or lot number, expiry date of medicine and directions for use. The dimensions (width and length) of each tablet and capsules were also measured using a caliper. The weights were the average of 4 tablets and capsules. (**Table 2.3**)

The evaluated CFM samples were all compared with their originals and photos were also taken to show the comparison. (**Appendix 2.II.**) No attempts were made to identify any covert features on original packages, since resources to confirm them were not available.

The analytical techniques were used to determine if there was a difference between the original and CFM spectra, and to compare findings with the physical examination results. The study used qualitative analysis by comparing the spectrum of a CFM sample with that of the original medicine, therefore, requiring no or minimum sample preparations. The methods used were divided into; non-destructive and destructive, as described below.

2.2.2.1. Non-destructive analysis

Raman

The Raman analyses of the CFM and original tablets/capsules were carried out with a PerkinElmer Identichex. The instrument incorporates a line narrowed, 785 nm stabilized diode laser and charged coupled detectors. Medicines could be observed with Raman spectra between 3500 and 180 cm^{-1} . Eight scans of around 10 seconds duration were carried out for each sample, and the results averaged, with the laser power adjusted to suit each sample.

Near-infrared spectroscopy (NIR)

NIR spectroscopy was performed on all CFM and original medicines and their spectra were recorded with the use of a Perkin Elmer 100 series machine. The spectra were recorded over the wavelength range 10,000-4000 cm^{-1} using 8 scans. Tablets with coating were scraped and then their spectra taken. The spectrum of each CFM sample was compared to that of the original medicine. The mean correlation coefficient indicated the similarity with the original medicine. The limit to indicate if the sample was identical to original was set at 0.998. Higher values meant the samples couldn't be distinguished from the original. If the value was >0.95 was considered slightly similar, but <0.95 was dissimilar, therefore counterfeit (Vredendregt et al, 2006).

Fourier transform infrared (FTIR)

A Perkin Elmer Nexus FTIR fitted with an ATR accessory was used for all CFM and original medicines. Measurements were made in reflectance mode on a small amount of each CFM and original medicines. A spectrum was considered identical if correlation coefficient was greater than or equal to 0.99, less than or equal to 0.97, was considered different from the original, and counterfeit. The samples were measured through direct contact with the crystal surface to obtain spectroscopic data. Next, a small portion was directly placed on the attenuated total reflectance element. Identical pressure was used with all samples. Each spectrum was measured in the 4000–600 cm^{-1} range.

2.2.2.2. Destructive analysis

The methods below required simple sample preparations of the medicines; therefore, were considered destructive, for tablets and capsules were dissolved in distilled water for analysis.

Dissolution test

In this study, the reference used was the UV-vis spectrum of the original medicine to compare with the CFM (Guidance for industry, 1997; Dissolution Toolkit, 2010; United States Pharmacopeia, 2011; United States Pharmacopeia, 2015).

A paddle apparatus was used with an aqueous medium of pH7. Twelve dissolution tanks were prepared, filled with distilled water, and fixed at a temperature of 37°C and a paddle speed of 50 RPM. The CFM and original samples were each weighed (**Table 2.6.**) and then put in a tank at time 0 (t_0). Each CFM and its original were put in a separate labelled dissolution tanks. Samples were withdrawn (10 ml) from each tank after 45 min ($t_{45\text{min}}$) and after four hours ($t_{4\text{h}}$) from their respective tanks. Samples were then analysed by UV-visible spectroscopy. Each 10 ml sample withdrawn from each tank at $t_{45\text{min}}$ and $t_{4\text{h}}$ was replaced by 10 ml of distilled water in their respective tanks to maintain the same dilution.

UV- visible - Qualitative

A Perkin Elmer Lambda 25 UV-vis was used. Following the Pharmacopeial guidelines (Dissolution Toolkit, 2010; United States Pharmacopeia, 2011; United States Pharmacopeia, 2015), the 10 ml samples withdrawn from the dissolution tanks, were then diluted with distilled water up to 50 ml in a volumetric flask and then a 10 ml aliquot further diluted up to 100 ml with distilled water. All CFM and original samples were prepared using the same procedure. The samples were then examined by UV-vis spectroscopy to determine the difference in absorbance between the CFM and the original.

2.2.2.3. Advantages of methods used

Table 2.1, lists the analytical methods used, and describes the advantages behind using each instrument.

Method used	Reasons
a. Raman	(a) Non-destructive, requires no sample preparation (b) Samples may be scanned through the blister pack (c) No toxic chemicals or flammable solvents are necessary (d) Short (less than a minute) collection time required (Bell et al, 2000; Kaur et al, 2010)
b. NIR	(a) Non-destructive, requires no sample preparation (Siddiqui et al, 2013) (b) Rapid and very sensitive (Martino et al, 2010; Siddiqui et al, 2013) (c) Can be both qualitative and quantitative (Siddiqui et al, 2013) (d) Provides fingerprints of the whole matrix (e) Has a larger depth penetration into the sample surface, with the homogeneity of distribution of the API throughout the tablet can be determined (Blanco et al, 1996; Kaur et al, 2010)
c. FTIR	(a) Non-destructive technique (b) Provides a precise measurement, method that requires no external calibration (c) Can increase sensitivity – one second scans can be co-added together to ratio out random noise (d) Has greater optical throughput (e) Mechanically simple with only one moving part (Roggo et al, 2007)
d. Dissolution	(a) Widely accepted apparatus for dissolution test (b) First choice for solid oral dosage forms (c) Standardized (d) Easy to operate (e) Robust (f) Broad experience (Lawrence et al, 2002; Uddin et al, 2011)
e. UV-vis	(a) Low time and labour consumption (b) Excellent precision (Siddiqui et al, 2013) (b) Easy to use (c) Fast (speed of the analysis) (e) Cost effective (Lam, 2015; Wang et al., 2006)

Table 2.1. The reasons behind using the selected methods to analyse counterfeit and original medicines.

2.3. Results

2.3.1. Physical examination

Cursory inspection of the CFM samples did not suggest any problem, but a more detailed examination showed there were physical differences between the CFM and the originals on close scrutiny. The results were all qualitative and presented in **Table 2.2** showing that all CFM samples failed the physical examination, and were not identical to the original preparations.

Physical examination	Name of medicine				
	Panadol [®]	Amoxil [®]	Viagra [®]	Cialis [®]	Plavix [®]
Packaging					
Appearance	D*	D	D	D	D
Colour	S**	S	D	D	D
Font of print	S	S	S	D	D
Size of print	D	D	D	D	D
Missing imprints/information	Y ⁺	Y	Y	Y	Y
Additional imprints/information	N ⁺⁺	Y	Y	Y	Y
Expiry date on box	S	S	S	S	S
Features of blister	D	D	D	D	D
Expiry date on blister	S	S	S	S	S
Manufacturer	D	D	S	S	S
Tablet / Capsule					
Appearance	S	D	S	S	S
Shape	S	S	S	S	S
Colour	S	S	D	D	D
Imprint of logo	D	D	D	D	S
Imprint of number	NA [#]	NA	NA	NA	S
Package insert					
Information content	D	D	D	D	D
Font	D	D	D	D	D
Colour	D	D	D	D	S
Spelling errors	N	Y	N	N	N
Available	Y	Y	Y	Y	Y
Hologram	N	N	N	N	Y

*Different, **Same, +Yes, ++No, #Not applicable

Table 2.2. Comparison of counterfeit medicine with their original using physical examination

The photos of the physical differences and examples of the findings are described in **Appendix 2.II.**

Photo 2.1 below, shows the two boxes of Amoxil[®], and the differences observed, such as the different logo of manufacturer, and the missing “TM” next to Amoxil[®].



Photo 2.1. The left box of Amoxil[®] is the original and the right box is the counterfeit. The two boxes of Amoxil[®] were different in size, and the original had “TM” next to Amoxil[®], the CFM box did not, and the colour of the two boxes were different. The chemical name was spelled as “amoxycillin” on the original box, but was spelled “amoxicillin” on the counterfeit box. The strength (500mg) on the original box was printed in red, and was in black on the counterfeit box. The manufacturer’s name was different; GlaxoSmithKline was printed on the original box, and Beecham for the CFM .

Photo 2.2 shows the two boxes of Plavix[®], and the differences were evident when compared to the original, such as the print size of the name Plavix, and the strength location on the box, additionally, the two boxes had the hologram placed on them.



Photo 2.2. The left box of Plavix[®] is the original and the right box is the counterfeit, and both had the hologram placed on their boxes. The Plavix[®] looked different. The strength of Plavix[®] was next to Plavix[®] on the original box, and below Plavix for the counterfeit box. The Information on the boxes were different and not consistent with the original Plavix[®] box.

The CFM supplied by the MoPH were evaluated, according to the tool for visual inspection of medicine recommended by the WHO (**Appendix 2.III**) (Tool for visual inspection of medicines, 2015), and **Appendix 2.IV**, includes further explanation on the discrepancies found. **Table 2.3**, shows how the CFM tablets/capsules compared to their originals.

Medicine	L*	W**	Wt.+	Exterior colour	Inside colour	Tab/ Cap ⁺⁺	Comments
Panadol[®]-O[#]	17.6	7.5	601.4	White	White	Tab	
Panadol[®]-C^{##}	17.6	7.4	584.6	White	White	Tab	None
Amoxil[®]-O	23.8	6.9	465.6	Yellow/ burgundy	White	Cap	
Amoxil[®]-C	22.5	6.9	683.4	Yellow/ brownish	Yellowish	Cap	Obviously smaller
Viagra[®]-O	11.4	4.4	313.1	Deep blue	White	Tab	
Viagra[®]-C	11.4	4.8	340.4	Light blue	White	Tab	More bulging
Cialis[®]-O	12.3	4.9	372.3	Yellow mustard	White	Tab	
Cialis[®]-C	12.4	4.7	381.9	Light yellow	White	Tab	Different colour
Plavix[®]-O	8.6	3.9	257.4	Pink-orange	White	Tab	
Plavix[®]-C	8.5	3.9	254.6	Pink-brown	Brownish	Tab	Different colour
*Length in mm, **Width in mm, +Weight of tablet/capsule in mg, ++Tablet or capsule, #Original, ##Counterfeit.							

Table 2.3. Comparison of the dimensions and colour of tablets and capsules of counterfeit and original medicine.

As for the colour of tablets, **Photo 2.3** shows the two tablets of Panadol[®], and the two tablets looked the same, except the imprint of the original was more pronounced than the counterfeit.



Photo 2.3. The left tablet is the original Panadol[®] and the right tablet is the counterfeit. The original and CFM tablets of Panadol[®] looked the same, however the imprint was different.

Photo 2.4, shows the two tablets of Plavix[®] and the different colour of the counterfeit one, however the shape and imprint of the tablets were the same.



Photo 2.4. The left tablet is the original Plavix[®] and the right tablet is the counterfeit. The original Plavix[®] tablet was pink orange, and the counterfeit was pink brown.

2.3.2. Analytical techniques

The analytical results were based on the different spectra provided by Raman, NIR, FTIR, and UV-vis spectroscopy. Only Panadol[®] was identical to the original, as presented in (**Table 2.4**.) The table shows each CFM indicating whether the spectrum was identical to the original or not, the correlation was included, when provided. In addition to the above findings, the Raman spectrum of the hologram on the counterfeit package of Plavix[®] was identical to the spectrum of the hologram on the original package (**Appendix 2.V**). Please note that at the beginning of the study the term fake and counterfeit were used interchangeably when labelling the medicine. Unfortunately, at a later stage, the printouts of the spectra could not be changed to “counterfeit” instead of fake, or “original” instead of genuine and authentic.

Name	Raman Spectrum	NIR Spectrum	FTIR Spectrum	UV-vis ⁺ Spectrum
Panadol[®]				
With coating	Same	Same	Same	Same
Without coating	Same	Same	Same	Same
Correlation		0.9920 (P ⁺⁺)	0.9981 (P)	
Amoxil[®]				
Exterior Capsule	Same	Same	Same	Different
Correlation		0.9859 (P)	0.9977 (P)	
Viagra[®]				
With coating	Same	NA*	NA	NA
Without coating	Slightly different	Different	Different	Different
Correlation		0.8174 (F ^{**})	0.9398 (F)	
Cialis[®]				
With coating	Different	NA	NA	NA
Without coating	Different	Different	Different	Different
Correlation		0.5887 (F)	0.3311 (F)	
Plavix[®]				
Coated	Slightly different [#]	NA	NA	NA
Bare	Different	Different	Different	Different
Correlation	Coated=0.7146 Bare=0.9740	0.8282 (F)	0.6513 (F)	

⁺Sample after dissolution at Time (45min and 4hours),

⁺⁺Passed as the original,

*Not Applicable,

**Failed,

[#]Titanium dioxide present on the coating.

Table 2.4. The results of the different analysis used to determine if counterfeit medicine were the same as their originals.

2.3.2.1. Raman Spectra

Figures 2.1 - 2.6, show the Raman spectra of Panadol[®], Amoxil[®], Viagra[®], Cialis[®], and Plavix[®] respectively. According to Raman spectroscopy, both spectra of Panadol[®] and Amoxil[®] were identical to the original, however, the remaining counterfeit samples were not identical.

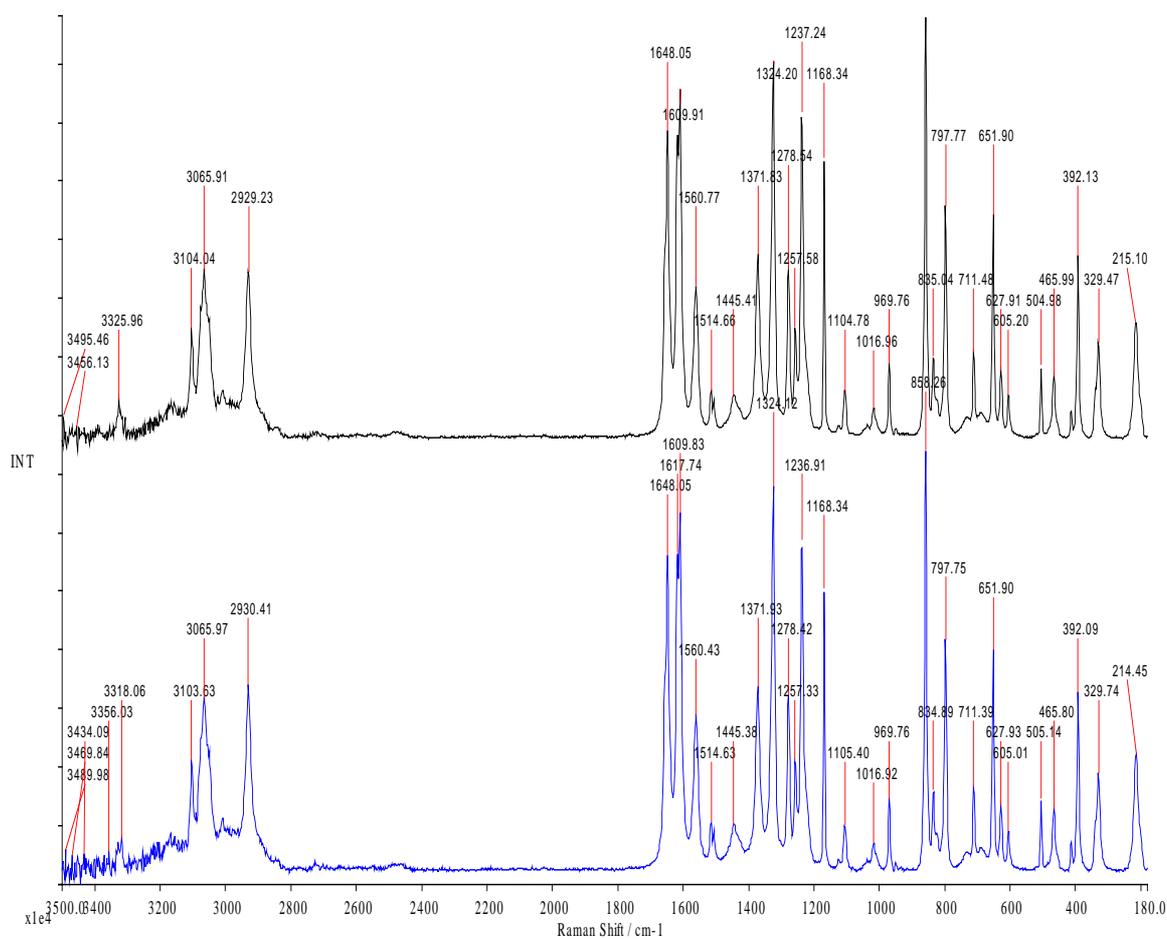


Figure 2.1. Raman spectrum of Panadol[®] bare tablet, top is the original and bottom is counterfeit. The spectra looked identical.

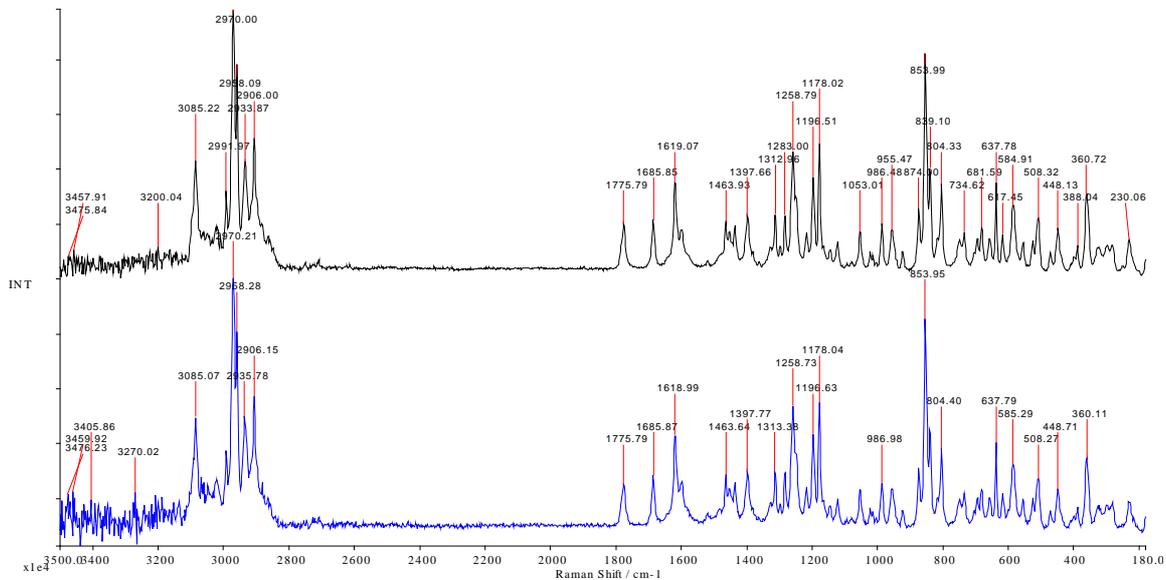


Figure 2.2. Raman spectrum of Amoxil® powder inside capsule, top is the original and bottom is counterfeit. The spectra looked identical.

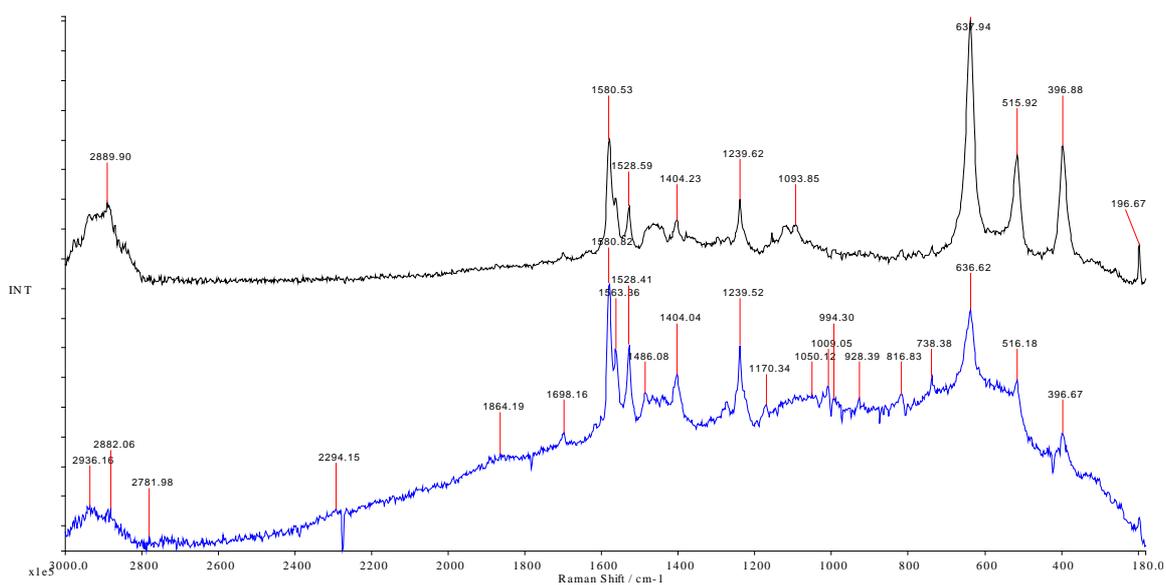


Figure 2.3 Raman spectrum of Viagra® coated tablet, top is the original and bottom is counterfeit. The spectra looked different.

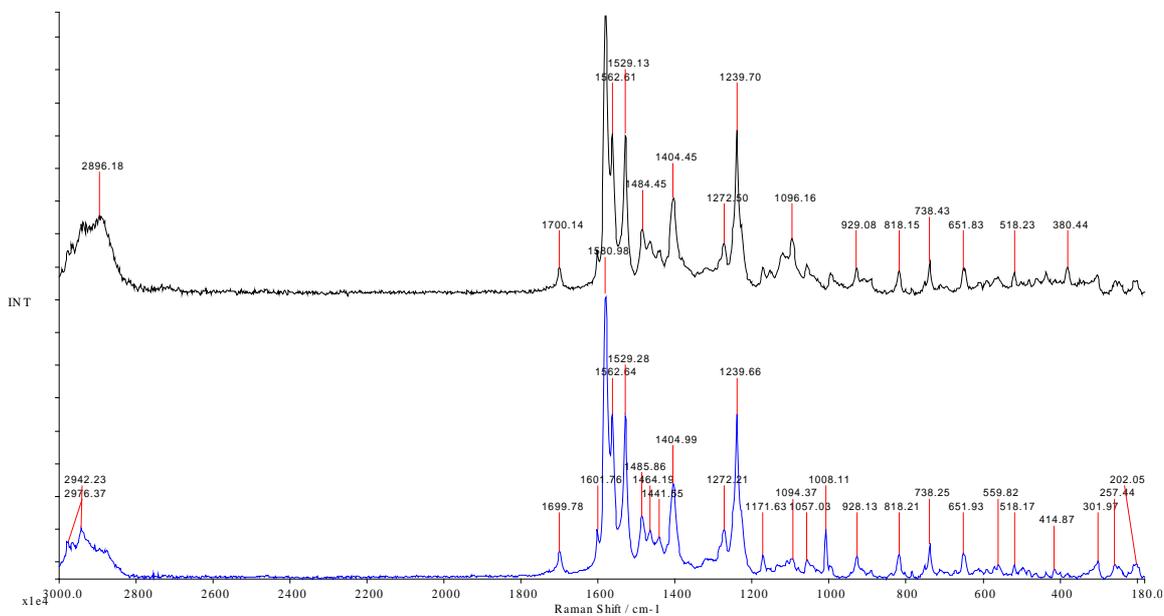


Figure 2.4 Raman spectrum of Viagra® bare tablet, top is the original and bottom is counterfeit. The spectra looked slightly different.

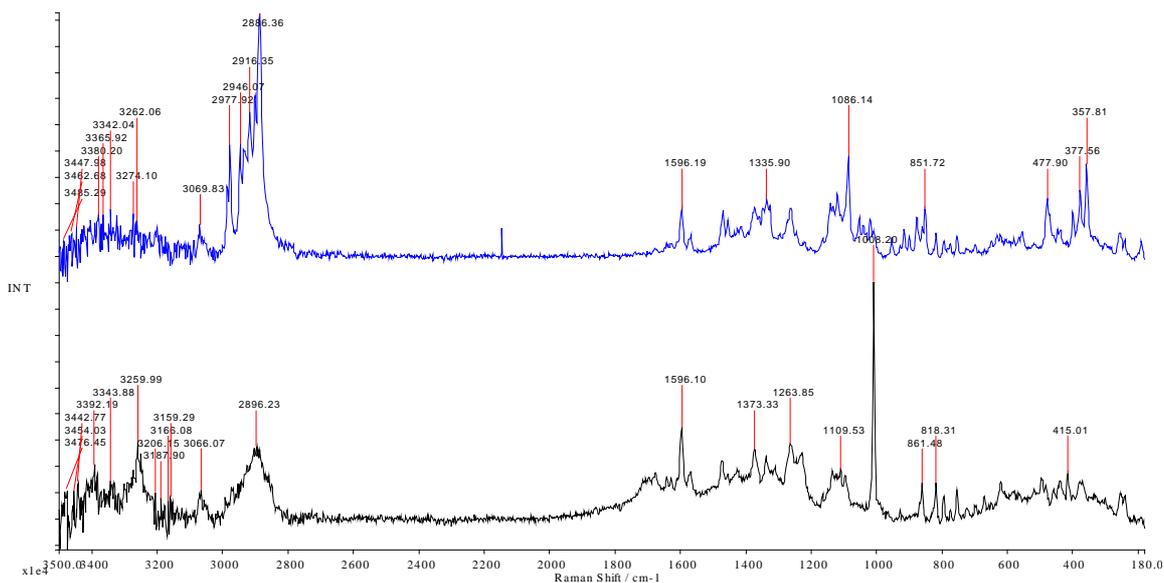


Figure 2.5. Raman spectrum of Cialis® bare tablet, the top is the original and the bottom is the counterfeit. The spectra showed that the CFM was not identical to the original.

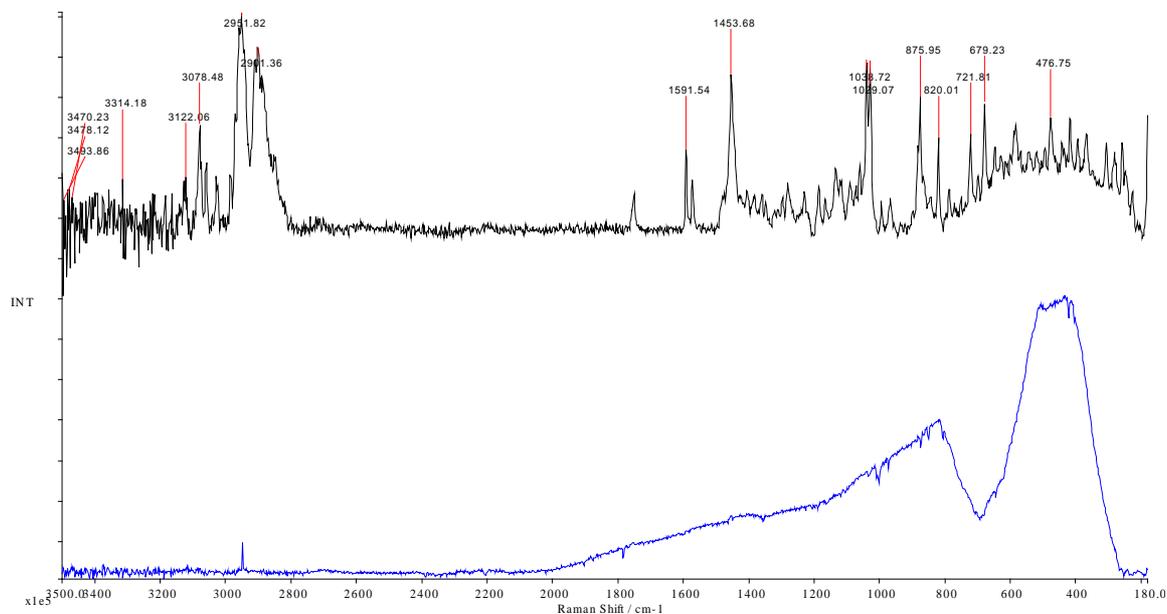


Figure 2.6. Raman spectrum of Plavix® bare tablet, the top is the original and the bottom is the counterfeit. The spectra showed that the CFM was not identical to the original.

2.3.2.2. NIR spectra

The NIR spectra, Figures 2.7-2.11 show the spectra of Panadol®, Amoxil®, Viagra®, Cialis®, and Plavix® respectively. The spectra of Panadol® and Amoxil®, were identical to their original, and the spectra for the rest of the CFM were not identical.

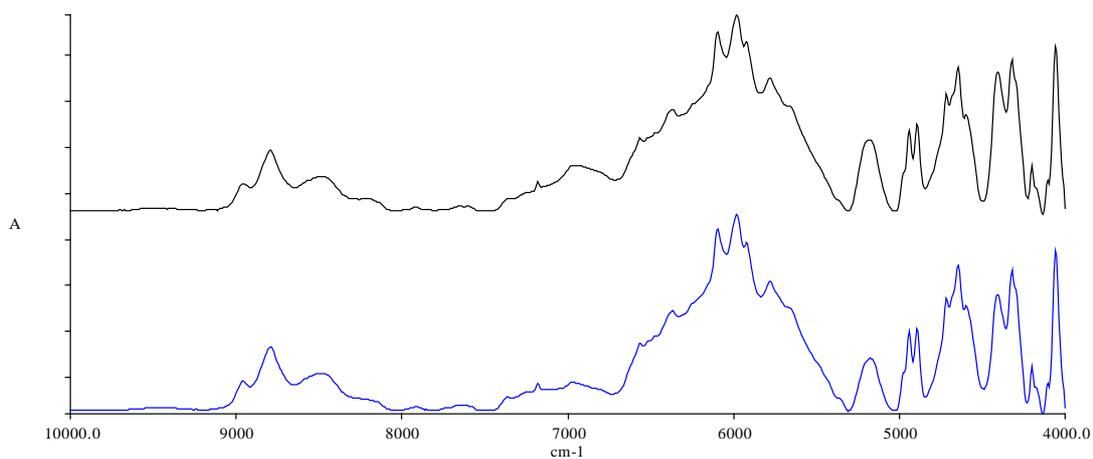


Figure 2.7 shows the NIR spectrum of the original Panadol® on top, and the counterfeit on the bottom. The spectra looked identical, with a correlation of 0.9920.

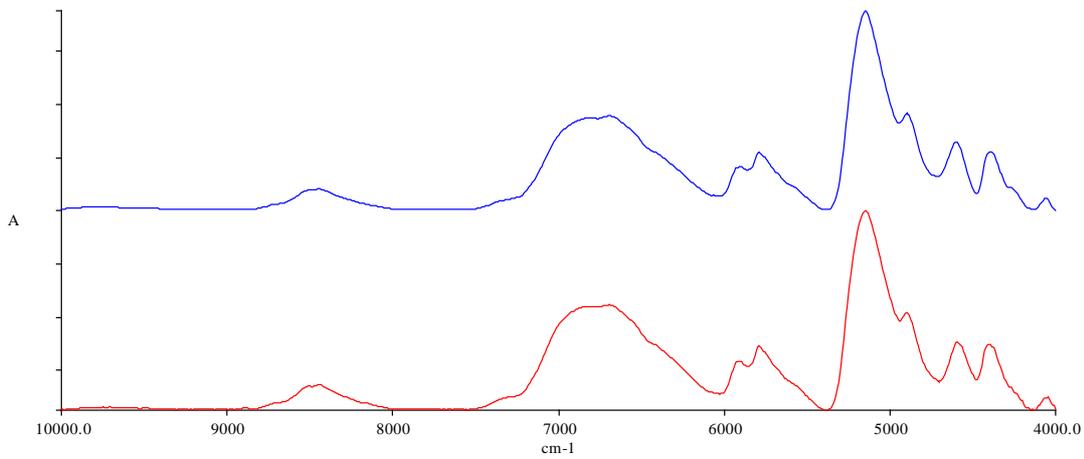


Figure 2.8. shows the NIR spectra of the original Amoxil[®] on top, and the counterfeit on the bottom. The spectra looked identical, with a correlation of 0.9859.

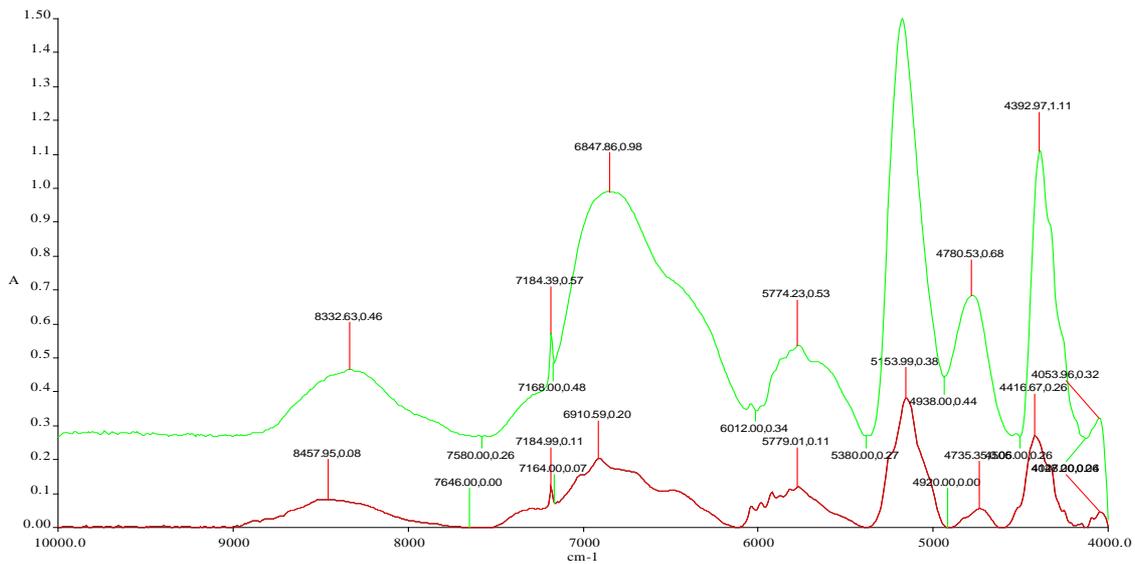


Figure 2.9 shows the NIR spectra of Viagra[®], the original on top and the counterfeit at the bottom. The two spectra were not identical, with a correlation of 0.8174.

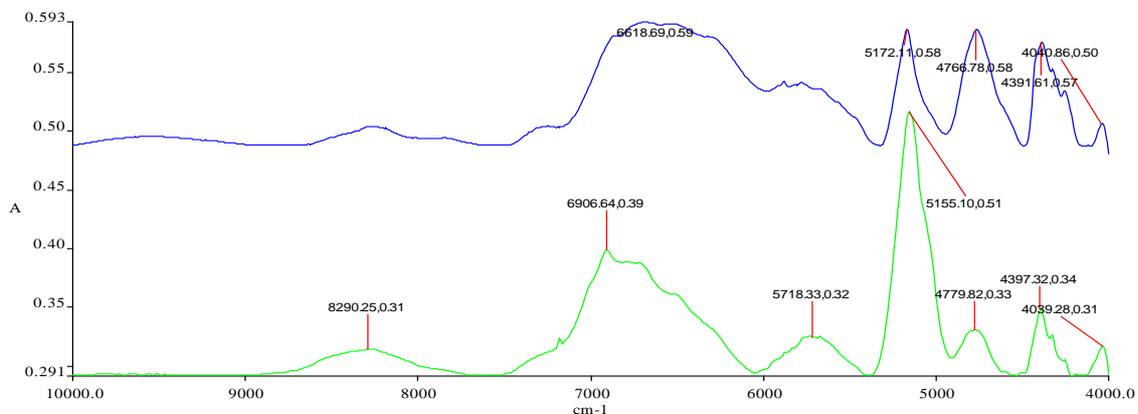


Figure 2.10 shows the NIR spectra of Cialis[®], the original on top and the counterfeit at the bottom. The two spectra were not identical, with a correlation of 0.5887.

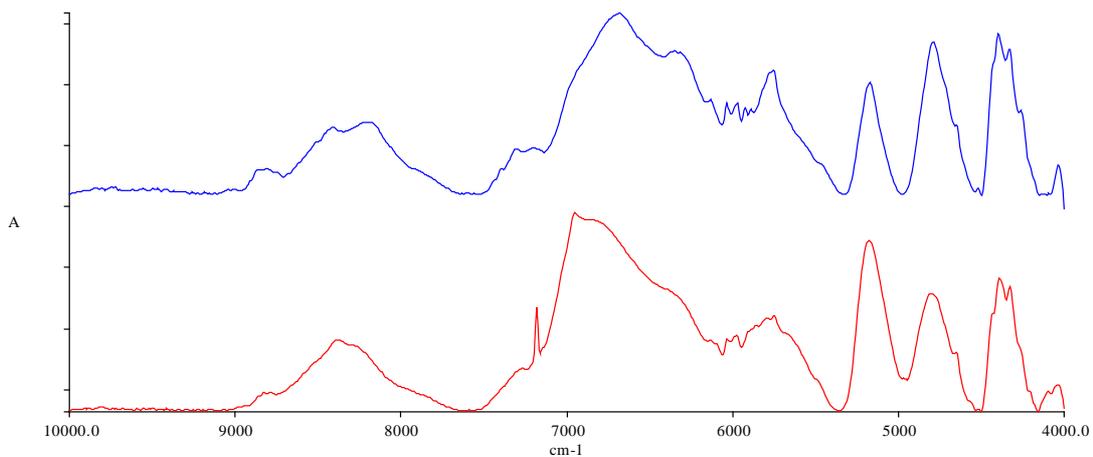


Figure 2.11 shows the NIR spectra of Plavix[®], the original on top and the counterfeit at the bottom. The two spectra were not identical, with a correlation of 0.8282.

2.3.2.3. FTIR spectra

The FTIR Figures 2.12-2.16 show the FTIR spectra of Panadol[®], Amoxil[®], Viagra[®], Cialis[®], and Plavix[®] respectively. The spectra of Panadol[®] and Amoxil[®], were identical to their original, and the spectra for the remaining CFM were not identical.

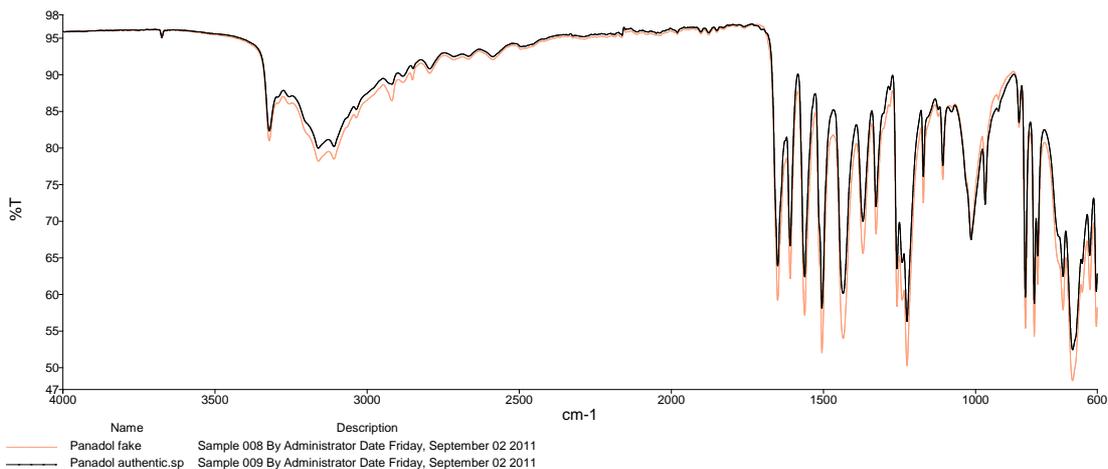


Figure 2.12. Shows the FTIR spectra of Panadol[®], the top green line was for the original and yellow line for the counterfeit (fake). Both spectra were identical, with a correlation of 0.998178.

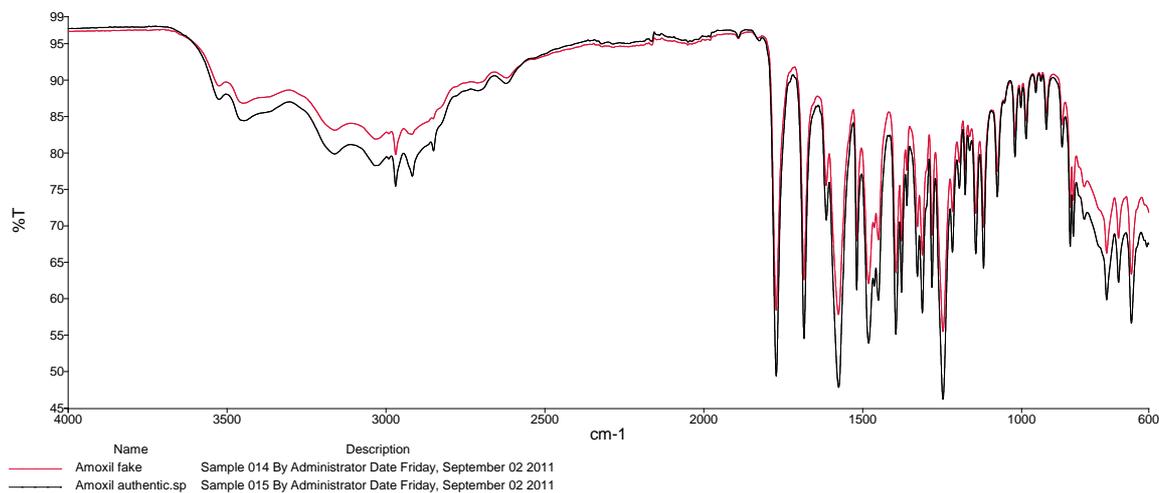


Figure 2.13 shows the FTIR spectra of Amoxil[®], the top green line was for the original and yellow line for the counterfeit (fake). Both spectra were identical, with a correlation of 0.997761.

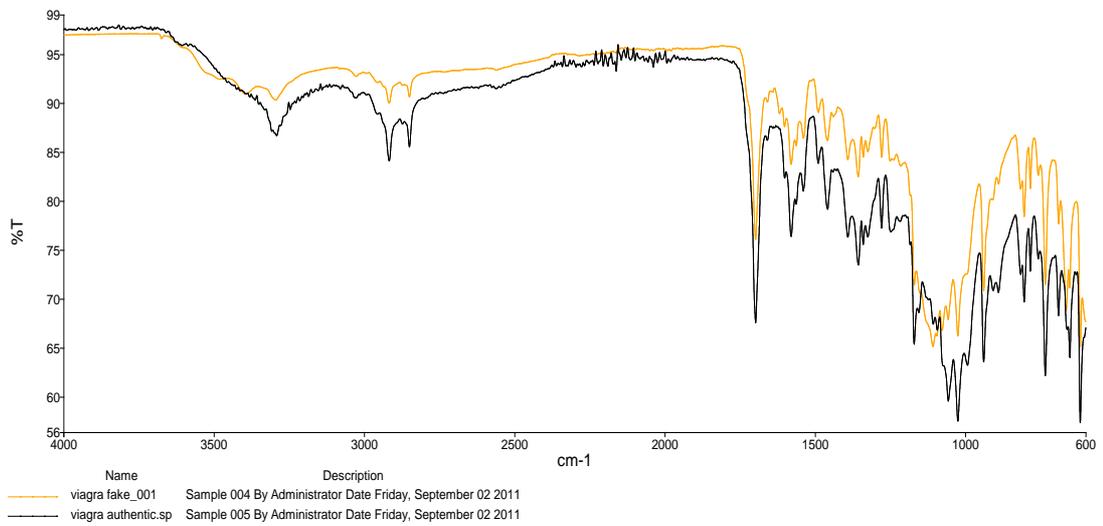


Figure 2.14. Shows the FTIR spectra of Viagra[®], the top for the original (authentic) and the bottom for the counterfeit (fake). The spectra were not identical, with a correlation of 0.939854.

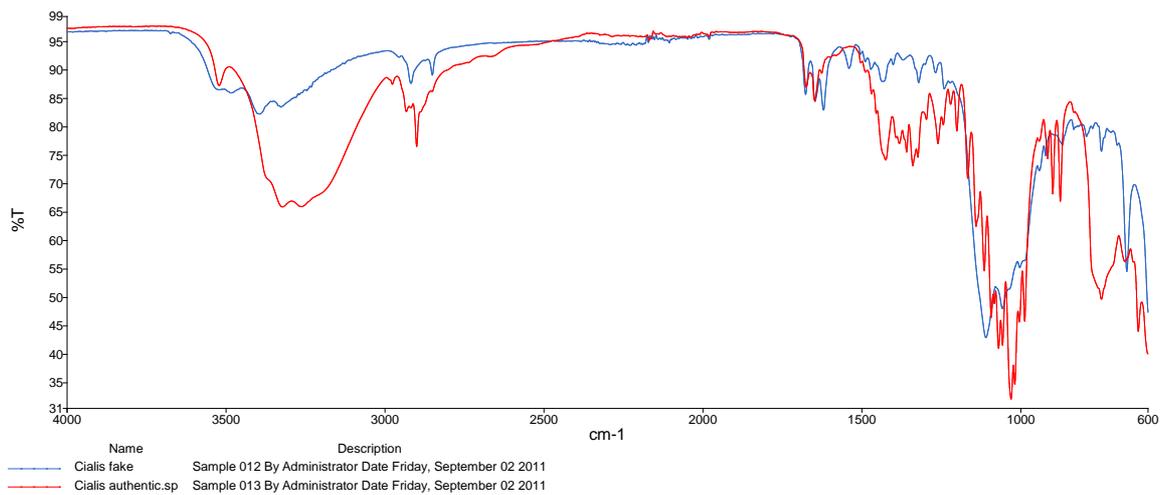


Figure 2.15. Shows the FTIR spectra of Cialis[®], the top for the original (authentic) and the bottom for the counterfeit (fake). The spectra were not identical, with a correlation of 0.331131.

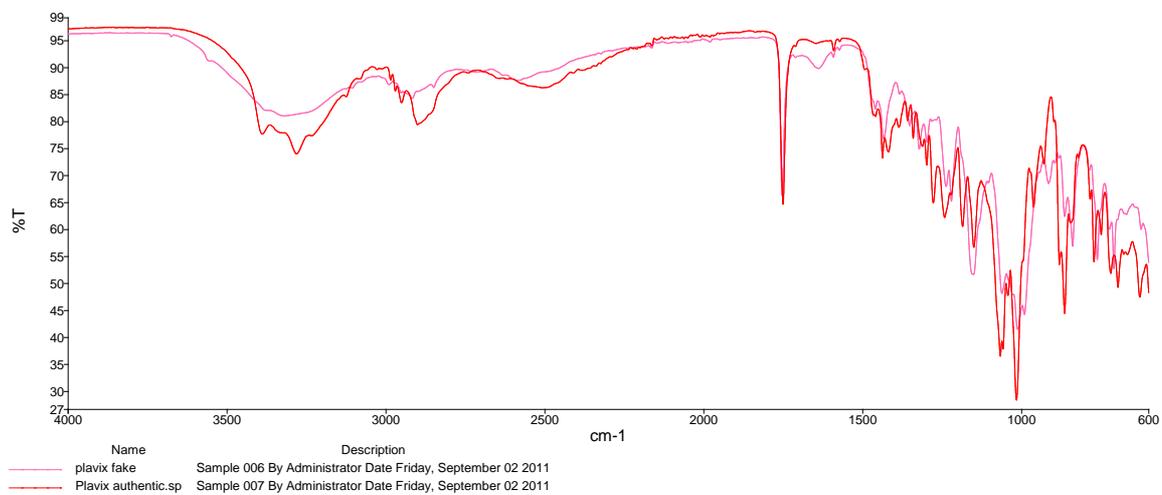


Figure 2.16. Shows the FTIR spectra of Plavix[®], the top for the original (authentic) and the bottom for the counterfeit (fake). The spectra were not identical, 0.651316.

2.3.2.4. Dissolution

Table 2.5 below, describes the process of the dissolution test, the timings when the samples were withdrawn, and the comments to describe what happened to the tablet or capsule after it was dropped into the respective tank.

Medicine	t ₀ *	t _{45m} **	t _{4h} ⁺	Comments
Panadol [®] -O ⁺⁺	Intact	Dissolved	Dissolved	Final solution clear.
Panadol [®] -C [#]	Disintegrated	Dissolved	Dissolved	Final solution not as clear as "O".
Amoxil [®] -O	Intact	Dissolved	Dissolved	Capsule floated for a minute before starting to go down the tank and dissolve, giving a pinkish solution.
Amoxil [®] -C	Disintegrated	Dissolved	Dissolved	Capsule immediately sank and started to dissolve.
Viagra [®] -O	Intact	Almost Dissolved	Dissolved	Final solution not completely clear
Viagra [®] -C	Intact	Tablet did not fully disintegrate	Dissolved	Tablet did not completely disintegrate, but solution was clear.
Cialis [®] -O	Intact	Turbid, almost dissolved	Dissolved, and turbid	Slow disintegration before dissolving, but turbid solution.
Cialis [®] -C	Disintegrated	Not dissolved	Not dissolved	Clear solution, but not fully dissolved
Plavix [®] -O	Intact	Dissolved	Dissolved	Clear solution
Plavix [®] -C1	Disintegrated	Dissolved	Dissolved	Clear solution
Plavix [®] -C2	Disintegrated	Dissolved	Dissolved	Clear solution
*Starting time, ** time after 45 minutes, +time after 4 hours, ++Original, #Counterfeit.				

Table 2.5. Dissolution timetable of differences between 45minutes and 4 hours

2.3.2.5. UV-vis spectra

Figures 2.17-2.21 show the UV-vis spectra of Panadol[®], Amoxil[®], Viagra[®], Cialis[®], and Plavix[®] respectively. The spectrum of Panadol[®] was identical to the original, with identical absorption to the original. The spectra for the remaining CFM samples were not identical. In reference to the Plavix[®] spectra (figure 2.21), in the normal UV spectra, there were similarities, and in order to show differences more clearly, the first derivative spectra (figure 2.22) were measured. These showed that the same compound was present in both samples, but in smaller quantity in the counterfeit Plavix[®].

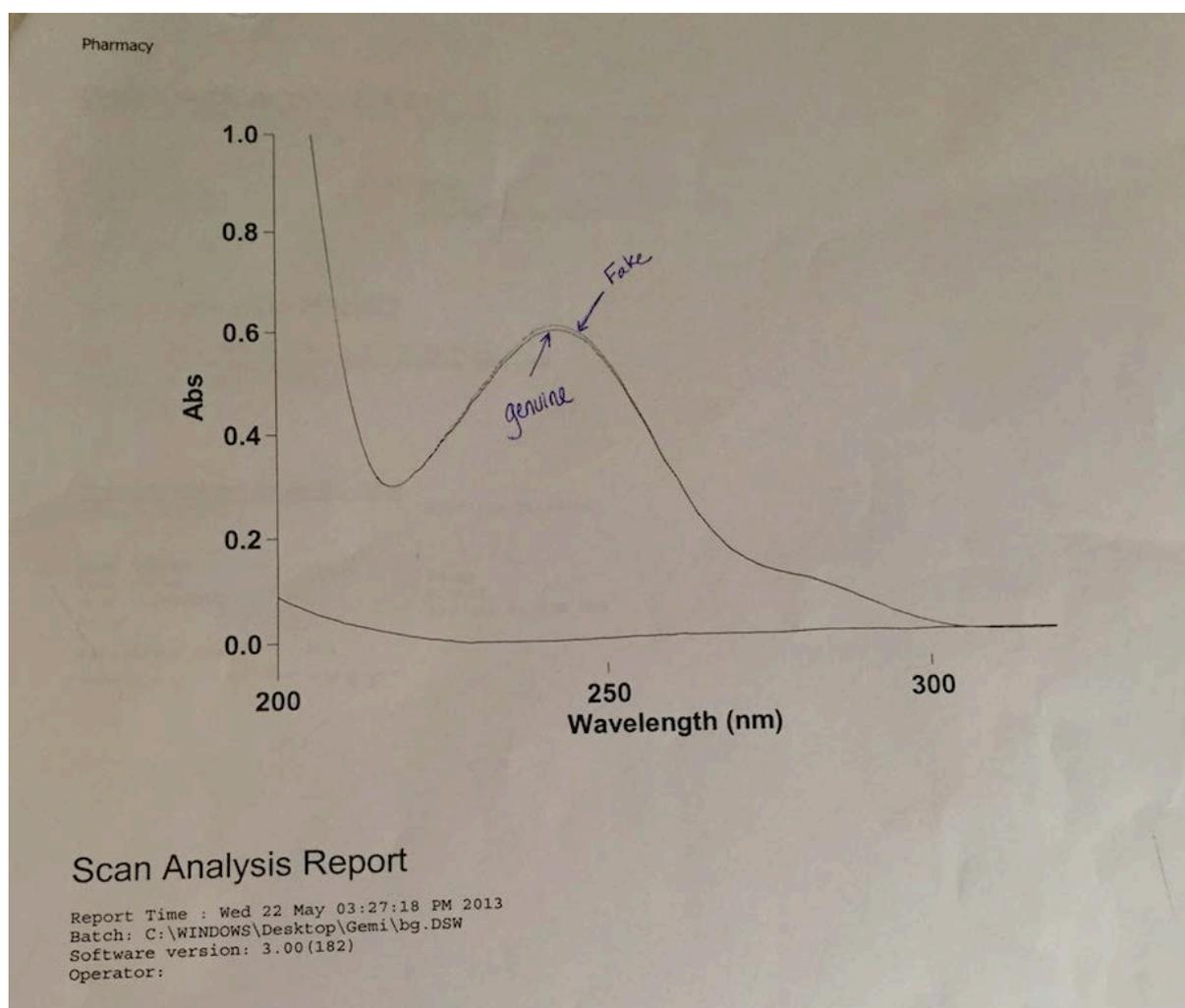


Figure 2.17 shows the UV-vis spectra of Panadol[®], the top for the counterfeit (fake), and the bottom for the original (genuine). The two spectra were identical.



Figure 2.18. Shows UV-vis spectra of Amoxil[®], the original (genuine) top, and counterfeit (fake) bottom. The spectra were different.

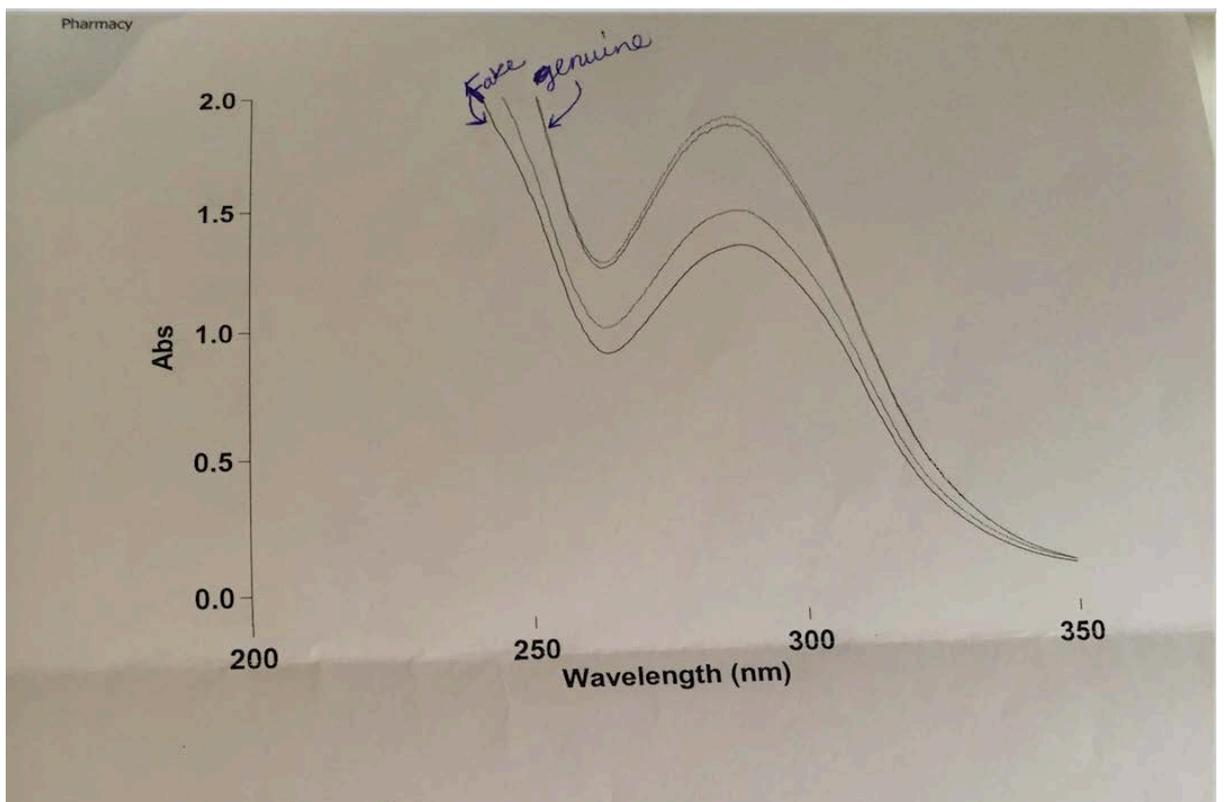


Figure 2.19, shows the UV-vis spectra of Viagra[®], Top the original (genuine), and bottom the counterfeit (fake). The spectra were different.

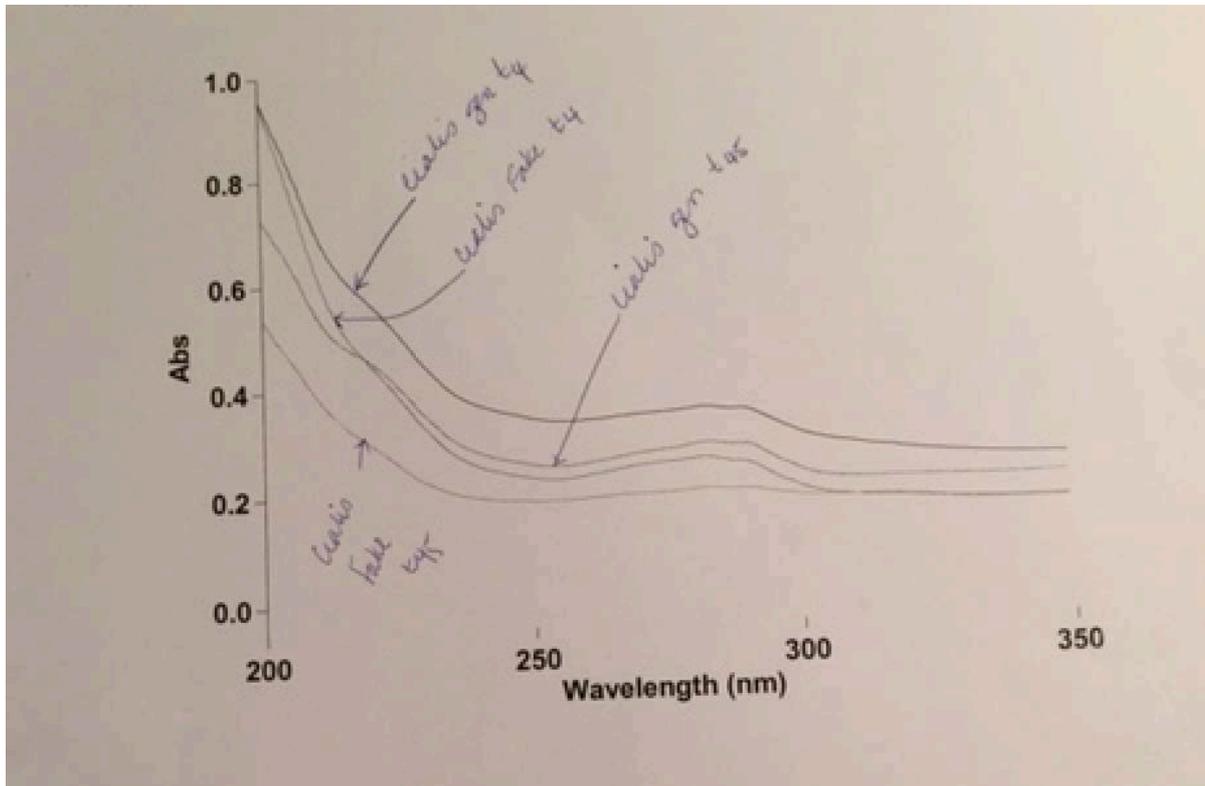


Figure 2.20, shows the UV-vis spectrum of Cialis® the spectra are identified as counterfeit (fake), and original (gen for genuine). The spectra were different.

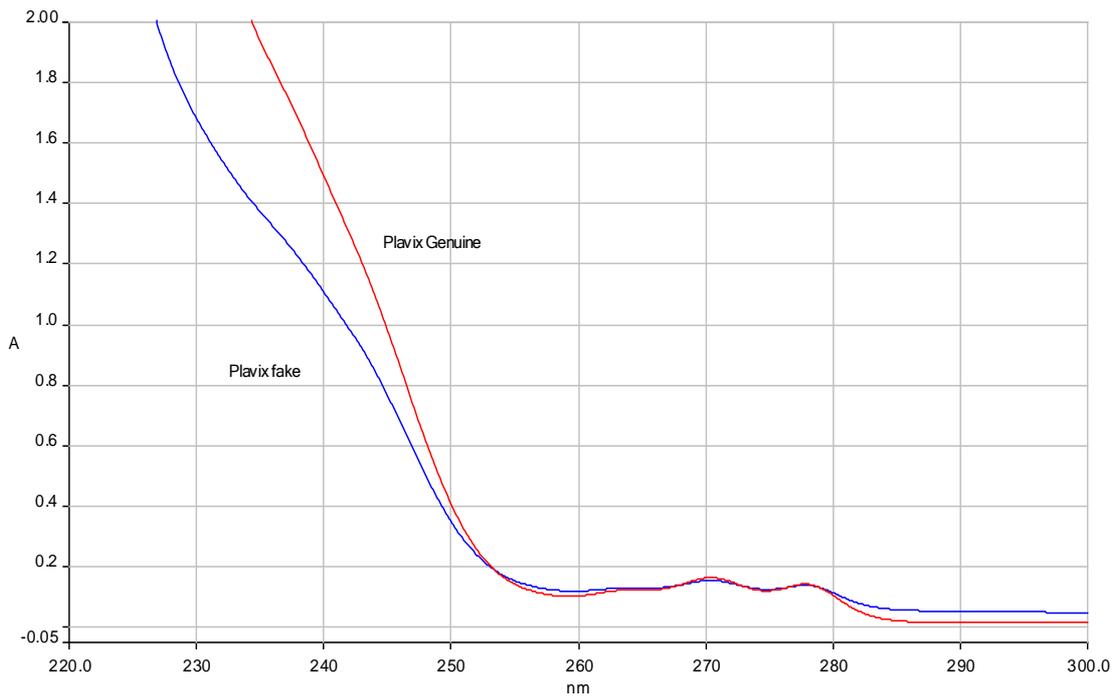


Figure 2.21. The normal UV-vis spectra of Plavix®, original (genuine in red) and counterfeit (fake in blue). The spectra were different.

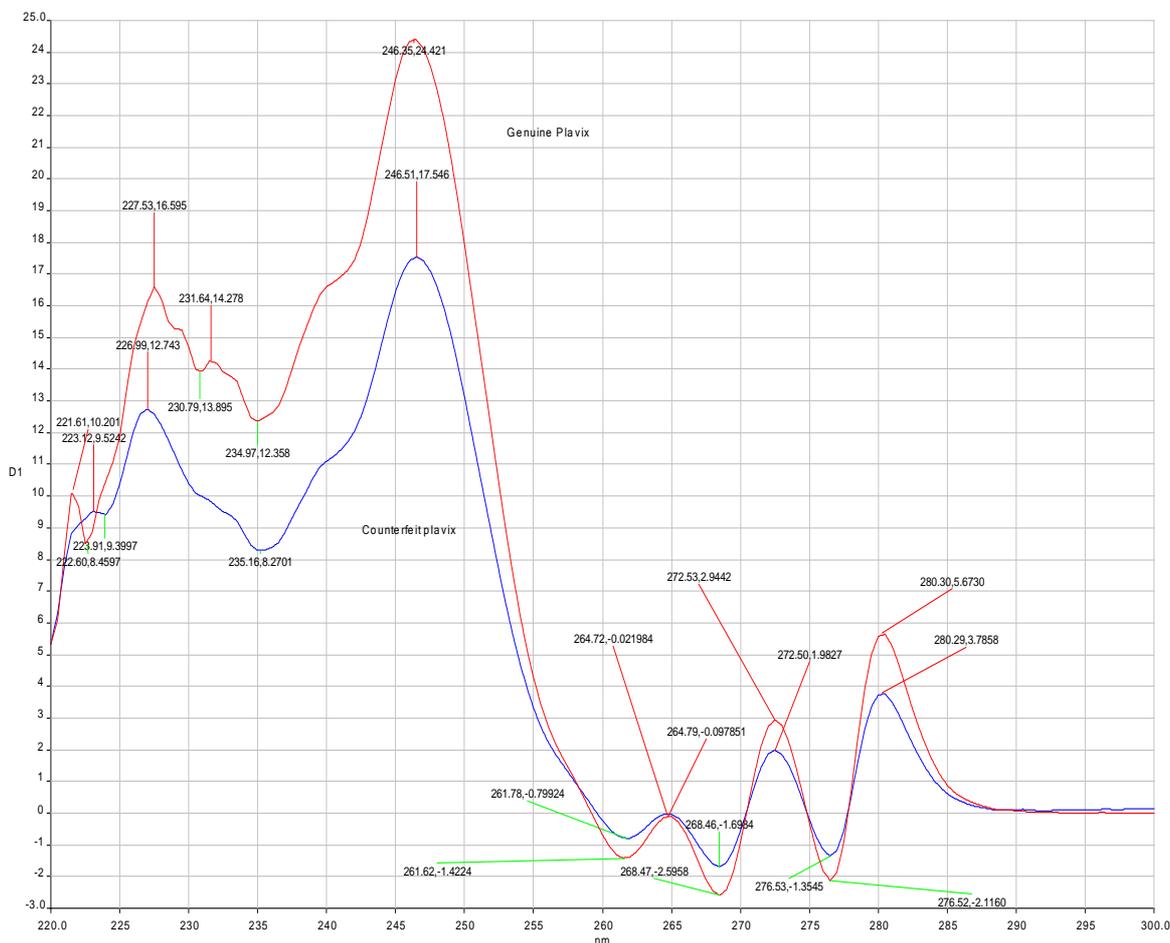


Figure 2.22. The UV-vis first derivative spectra of Plavix[®], original (genuine in red) and counterfeit (fake in blue). The spectra were different.

The results of the dissolution test and UV-vis spectra, were used to quantify the amount of medicine in each tablet/capsule, however, for Cialis[®], since it was insoluble, the UV spectra was not useful to use for calculating the amount of active ingredient present. The dissolution however, was performed to monitor any differences in disintegration of the tablets, and a disintegration apparatus was not used, as differences would be more apparent in the gentler conditions of a dissolution apparatus. The A1% values (absorbance of a 1% solution, in water) were used for Panadol[®], Amoxil[®], Viagra[®], and Plavix[®], to determine the amount of active ingredient present in each tablet and capsule, for the originals and counterfeits. The data were summarized in **Table 2.6**, and show that Plavix[®] contained 88% of the active ingredient. In addition, this was the only analytical test that matched with the physical examination results, and showed that counterfeit Amoxil[®] was actually counterfeit, and contained only 56% of the active ingredient in the capsule. Panadol[®], was the only CFM that gave identical results to the original tablets, and showed better absorbance than the original.

Name	A1%*	Absorbance	Peak	Amount of active ingredient mg/1000ml	% Active ingredient
Panadol [®] O ⁺	659 ^a	0.607	243nm	460.5mg	92%
Panadol [®] C ⁺⁺	659 ^a	0.616	243nm	467.4mg	93%
Amoxil [®] O	33.74 ^b	1.619	273nm	479.8mg	96%
Amoxil [®] C	33.74 ^b	0.944	273nm	279.8mg	56%
Viagra [®] O	198 ^c	1.886	292nm	47.6mg	95.2%
Viagra [®] C	198 ^c	1,323	292nm	33.4mg	66.8%
Plavix [®] O	848.3 ^{d,e}	0.313	271nm	77.5mg	103%
Plavix [®] C	848.3 ^{d,e}	0.270	271nm	66.8mg	88%

*A1%=The specific absorbance, is the absorbance of a 1% solution, in water,

⁺Original

⁺⁺Counterfeit

^a (Delvadiya et al, 2011)

^b (Patel et al, 2014)

^c (Albin et al, 2013)

^dMolar Absorption,

^e(Pimpodkar et al, 2009)

Table 2.6. Shows the amount of active ingredient present in each sample evaluated, using the absorbance of each medicine according to the dissolution results and UV-vis spectra.

According to the six categories of CFM, identified by the WHO (World Health Organization, 2012a), the CFM samples of this study fit 3 of them as listed in **Table 2.7**. Three of the CFM samples (Plavix[®], Viagra[®], and Amoxil[®]), fit the category of products with incorrect quantities of active ingredients, and in accordance with the WHO categories, the percentage of counterfeits in this category was higher than the other two categories of the remaining CFM samples.

No.	WHO* category	CFM** sample	WHO % ⁺
1.	Products with incorrect quantities of active ingredients (lower than indicated on label/bottle)	Plavix [®] , Viagra [®] , Amoxil [®]	20.2
2.	Products with correct quantities of active ingredients, with fake packaging (such as altered expiry date on expired medicines)	Panadol [®]	15.6
3.	Products with high levels of impurities and contaminants (such as talc powder, chalk, floor wax)	Cialis [®]	8.5

* (World Health Organization, 2012a),

** Counterfeit medicine,

⁺% of counterfeit medicine found in the category according to WHO.

Table 2.7. Classifying the identified counterfeit medicines according to the categories listed by the WHO.

Table 2.8, provides an overview of the overall methods used in this chapter to determine if the samples provided by MoPH were identical to or different than their originals. The table shows that counterfeit Amoxil[®] was the only CFM that passed all the analytical tests, except for the UV-vis analysis.

Parameters	Panadol[®]	Amoxil[®]	Viagra[®]	Cialis[®]	Plavix[®]
Physical examination	F*	F	F	F	F
• Packaging	F	F	F	F	F
• Tablet/capsule	F	F	F	F	F
• Package insert	F	F	F	F	F
• Hologram	None	None	None	None	P**
Analytical tests					
a. Raman	P	P	F	F	F
b. NIR	P	P	F	F	F
c. FTIR	P	P	F	F	F
d. Dissolution ⁺	93%	56%	66.8%	UK ⁺⁺	88%
e. UV-vis	P	F	F	F	F

*Failed the examination/test,

**Passed the examination/test,

⁺Amount of active ingredient present in tablet/capsule presented in percentages,

⁺⁺Unknown,

#Counterfeit medicine,

##Ministry of Public Health.

Table 2.8. Summary of the different methods used to analyse the CFM[#] provided by the MoPH^{##}

2.4. Discussion

The CFM supplied by the MoPH, were analysed by two methods, physical examination and spectroscopic analysis. The physical examination of the CFM supplied by the MoPH, showed that packaging was not identical to the original, and according to the WHO definition would be considered counterfeit. In order to confirm the findings of the physical examination, four analytical techniques were used for validation. The analytical techniques, Raman, NIR, FTIR, and UV-vis were used to demonstrate if the CFM and original spectra were identical or not to their original. This study demonstrated the sophistication of counterfeiters and the unreliability of visual examination, showing that the security devices or measures used on packaging do not always provide assurance as to the genuineness of the medicine. The results of this study supported other studies (Ricci et al, 2007; Sacré et al, 2010), and confirmed the necessity of using more than one validation method, to eliminate the chances of not identifying a CFM or falsely identifying a medicine as original. Analytical techniques should be required for more reliable evidence, and should be done prior to reaching pharmacies or patients. Additionally, CFM were further categorised according to the six identified categories by the WHO (World Health Organization, 2012a). Three of the CFM; Plavix[®], Viagra[®], and Amoxil[®] fit the category of medicines with incorrect quantities of active ingredients. Counterfeit Panadol[®] fit the category of medicines with correct quantities of active ingredients with fake packaging, and Cialis[®] fit the category of medicines with high levels of impurities and contaminants (World Health Organization, 2012a). Consequently, the hypothesis was true, as the identified CFM samples were different from their originals.

The visual inspection involved detailed analysis of different elements in the available packaging, leaflet and both the exterior and interior of the medicine dosage form (Jung et al, 2012). When evaluated closely, the study showed discrepancies between the CFM and their originals such as, inconsistency with packaging, labelling on boxes, font size of the medicines' names, leaflets, wrong name of manufacturer, and the different colours of tablets from their originals. Other studies showed that detected CFM were inconsistent between the box of medicine and the blister pack, the expiry date and/or the batch number; or manufacturer's name or country missing (Liang, 2006a; Mackey and Liang, 2011; Gaudiano et al, 2012; Jung et al, 2012). The visual inspection required close comparison of each CFM package with its original. The CFM samples would have passed as the originals, if it were not for the close inspection. This would explain why pharmacists would unknowingly dispense CFM. In support, a study showed that the packaging quality of

counterfeits has become sophisticated to the extent that they can be indistinguishable from their original (Dondorp et al, 2004). This comes in support with the PricewaterhouseCoopers report that not all products could be identified as counterfeit by visual inspection, as some required laboratory testing for verification (PricewaterhouseCoopers, 2003).

Different advanced techniques have been proposed for the detection of CFM. There were techniques that were based on destructive chemical tests, (Daraghmeh et al, 2001; Sacré et al, 2010), and others that were based on non-destructive tests, making use of imaging technologies outside the visible range (Ricci et al, 2007; de Veij et al, 2008; Holzgrabe and Malet-Martino, 2011). For cross validation, the qualitative analysis part of the study used three instruments; Raman, NIR, FTIR, and the quantitative analysis used dissolution and UV-visible spectroscopy, as these instruments were considered the most commonly used methods to identify CFM (Baratta et al., 2012; Deisingh, 2005; Martino et al., 2010; Ricci et al., 2007; Sacré et al., 2010; Tipke et al, 2008). The use of more independent techniques has proved to be powerful for the screening and characterization of CFM and original medicines. The spectroscopic methods used in the study depended on straightforward operational steps, that provided reliable, and fast results, as reported by similar studies (Sacré et al, 2010; Ortiz et al, 2013).

A study (Sacré et al, 2010) used Raman, NIR and FTIR spectroscopy, to investigate which of these techniques were the best for discriminating genuine from counterfeit and imitation samples, showed that for the Viagra[®] samples, the best results were provided by a combination of FTIR and NIR spectroscopy. On the other hand, the best results for the Cialis[®] samples were provided by the combination of NIR and Raman spectroscopy. These techniques permitted a clear discrimination between genuine and CFM (Sacré et al, 2010). This study demonstrated that Raman spectroscopy could not discriminate CFM Plavix[®] and Viagra[®], before scraping off the coating on the tablets, however, the NIR was able to detect and differentiate all CFM from their originals. The results of the Raman, NIR, and FTIR spectra were in agreement, showing that Panadol[®] and Amoxil[®] were identical to their originals; however, Viagra[®], Cialis[®] and Plavix[®] were not. The UV-vis spectra were able to show that Amoxil[®] and its original, were different and there was only 56% of the API in the counterfeit capsule. Moreover, studies have shown that amoxicillin is among the most widely counterfeited medicine in developing countries (Kelesidis et al, 2007; Wondemagegnehu and World Health Organization, 1999). The results of this study demonstrate the benefits of using more than one technique for detecting CFM.

It must be remembered that many pharmaceutical manufacturers coat the outer layer that covers each tablet, for recognition, and to mask the bitter tastes, giving it a specific colour and providing uniformity and brightness characteristic for each coat (Sohi et al, 2004). The coating process involves high-end technologies in addition to rigid quality control that rejects any physical imperfections (Sohi et al, 2004; Jung et al, 2012). Counterfeiters are expected to produce a coating that is indistinguishable from the original medicine (Jung et al, 2012), however, this study demonstrated that it is not always true, and this would probably differentiate the more sophisticated counterfeiters from the others who are less sophisticated (Benbasat, 1999; Deisingh, 2005; Newton et al, 2006a; Newton et al, 2006b; Lancaster, 2009). The study showed that Panadol[®] failed the physical examination, yet the spectra were indistinguishable from the original, raising the possibility that the medicine may have been stolen from the original manufacturer as a “Category Three: Products from current or former outsourced suppliers” (Berman, 2008). Other possibilities could be an API from an unknown source, the API manufactured without any consideration for good manufacturing practice (GMP), from damaged packages, or were expired medicines that were repackaged, as Panadol[®].

The Raman spectrum of the hologram on the counterfeit box of Plavix[®] was identical to the spectrum of the hologram on the original box of Plavix[®]. Based on the above information and data, the results could mean that the hologram on the counterfeit box was either: a) stolen from the source or supplier, b) passed to counterfeiters by insiders from the source/suppliers, or c) high quality counterfeit hologram. In this study, Plavix[®] failed both the physical examination and analytical tests, although it almost passed the Raman check.

After the January 2010 incident, it was reported that the head of the regulatory department at the Sanofi-Aventis said “the hologram on Plavix[®] was forged, therefore, it was difficult to differentiate between genuine and counterfeit medicine” (Ghosn, 2010). According to media reports, the Minister of Public Health revealed that counterfeiters used packaging that was nearly identical, and even used the same hologram (Zawaya, 2010). Additionally, many studies showed that counterfeiters could counterfeit holograms, making it very difficult to distinguish between the counterfeit and original (Newton et al, 2003; Newton et al, 2006b; Dondorp et al, 2004).

The findings of this chapter demonstrated that three of the CFM samples Plavix[®], Viagra[®], and Amoxil[®] fit the 20.2% of the CFM categorized by the WHO, counterfeit Panadol[®] fit the 15.6% category of CFM, and Cialis[®] fit the category of 8.5% of CFM (World Health

Organization, 2012a). The study would conclude that the best approach in detecting CFM, requires the use of minimum two analytical methods, however, it would be best to consider adding at least one quantitative method. Studies show that quantitative methods are used to determine the nature of the CFM problem, by identifying any impurities in the medicine preparation or dangerous ingredients that may harm patients, such as pathogens, rat poison, talc, powdered chalk, or unneeded medicinal substances (Newton et al., 2006a; Newton et al, 2006b). The counterfeit Amoxil[®] in this study, would support the importance of using more than one method, as other than the physical examination, it was only identified as counterfeit by using the quantitative analysis. The counterfeit Amoxil[®] was an example of the seriousness of CFM, and the risks that may develop from sub-therapeutic antibiotics, when the outcome could lead to resistance or even death (Kelesidis et al, 2007). As for the counterfeit Panadol[®], although it contained the correct quantity of active ingredient, it still would not be considered safe to use, since there are no good quality CFM, when the true identity and source are unknown (World Health Organization, 2015).

Identifying counterfeit and poor-quality medicines is crucial in a quality assurance system (Kaur et al, 2010). Since Lebanon is considered a developing country, that may not have the technical, financial or human resources required to inspect and regulate the medicine supply, it would be fitting to use simple and affordable analytical tools that can provide fast monitoring of medicine quality, and a high level of reliability to avoid any error in classifying CFM as an original when it is not. In fact, the findings of this study illustrated the need for the reactivation of the National Laboratory, to allow the regulatory authorities to regularly and randomly sample the medicines available in the country, for better control of the influx of CFM, and to reduce the risks related to CFM use.

This chapter demonstrated the nature of CFM in Lebanon, and the effect these findings may have on public health. The following Chapter (Three) will cover the extent of CFM in Lebanon.

2.5. Conclusion

This study is considered the first to describe the nature of CFM in Lebanon, as it described the different methods that could be used to determine if a medicine was the original or counterfeit. The physical examination, and analytical techniques used, described the nature of CFM in Lebanon, and confirmed that the CFM provided by the MoPH were counterfeit. The study demonstrated the vulnerability of pharmacists and patients in their ability to detect CFM, and the importance of using more than one analytical method, in addition to the visual examination, to detect CFM. Furthermore, the findings highlighted the seriousness of the problem and the harm CFM might have caused patients. Therefore, the MoPH and regulatory authorities should take appropriate measures to control the infiltration of CFM into the market, and reactivate the National Laboratory to regularly and randomly sample the medicines available in the country.

Chapter Three

The Extent of Counterfeit Medicine in Domiciles

3.1. Introduction

According to the WHO, no global study has been carried out to know the true extent of CFM (World Health Organization, 2015), and the biggest hurdle for those attempting to tackle CFM is understanding the scale of the problem (Siva, 2010). Consequently, as a follow up to Chapter Two that addressed the nature of CFM in Lebanon, this chapter aims at getting an approximate indication of the extent of CFM that will highlight the impact of its availability, and the risks associated with its use.

In order to address the problem of CFM in Lebanon, it is important to understand the extent of CFM to be able to recommend appropriate interventions that may help control its availability. The Chief of Lebanon's National Health Commission (NHC) reported to the WHO in 2004 that 35% of pharmaceuticals available in the Lebanese market were counterfeit (World Health Organization, 2015). However, it was not reported how the extent was determined, therefore, the reliability of the extent remains questionable. Moreover, the availability of CFM in Lebanon became more apparent to the public after the 2010 scandal (see Chapter One), (Lebanon Pharmaceuticals and Healthcare, 2010) yet, there were no official data by the MoPH, or the OPL to describe the extent of CFM, and the areas that were most at risk. The lack of resources to detect CFM and weak implementation of the law and regulations make it difficult to assess the true extent of CFM in Lebanon (Abou Jaoude, 2014).

Conversely, in 1982, a method of medication use evaluation (MUE) known as the "brown bag" review was developed in the USA, where pharmacists would periodically review all medicines used by patients at home (Larrat et al, 1990; Zermansky, 1996). The original project provided patients with brown super market bags, thus the name "brown bag" (Nathan et al, 1999). The idea behind the brown bag was to invite patients to bring all their medicines to the pharmacy or any specific setting, to be reviewed by a pharmacist. The review allowed pharmacists to identify prescribing or medicine related problems, risk factors, and patients' non-adherence, in addition to reduction of overall costs of patient care (Bradley et al, 1997; Nathan et al, 1999; Gurwitz et al, 2000; Franic and Jiang, 2006; Pham and Dickman, 2007).

There are different methods that can be used to detect CFM, as described in Chapter Two, such as the visual examination or the different analytical tools used for their analysis such as Raman, NIR, FTIR, and UV-vis. These methods are used for random sampling or to

verify if a medicine is counterfeit. Consequently, due to the nature of the MUE, requiring reviewing and evaluation of medicines used by patients at home, the author considered the possibility of identifying CFM after visiting the households. Identifying CFM would be through taking photos of all medicines being evaluated by the MUE, to be later compared by the author with the original boxes for each medicine. The literature search did not show any studies that used the MUE to identify CFM; therefore, the MUE was used since it would allow surveying a large sample of households and the medicines within. The aim of the study would be to provide an approximation of the extent of CFM by exploring the possibility of finding CFM in households, in various areas in Lebanon. Therefore, the hypotheses for this study are:

a. There are CFM in households in Lebanon

b. The household members are knowledgeable about their medicines

3.2. Methods

The MUE was used to determine the extent of CFM in Lebanon, to explore the possibility of identifying CFM in households.

3.2.1. Data collection form design

A data collection form (DCF) was designed by the author to explore the possibility of CFM being present in households (**Appendix 3.I**). The DCF, assessed: a) Demographics of household members, b) Knowledge of medicine used (indication) and effect (if medicine was working for them), c) Medicine purchasing information (source). Additionally, the DCF included a section for photos of medicines used in each household, upon patients' approval.

Therefore, the DCF was divided into three sections, firstly, general information and demographics, secondly, table for medicine information, and finally, checklist table of photos of medicine packages used. Section one was used to describe participants' background information, source of medicine, and medicines' storage. Section two was used to determine participants' information about their medicine, and expectations after their use. If participants' responses were accurate for the medicine indication (reason for use), and expectations after use (what to look for to know if it is working), then participants would be considered knowledgeable about their medicine. Section three was related to the checklist table of photos, to explore the possibility of CFM present in each household, indicating the photos that should be taken, for the author to compare at a later stage with their original.

There were 12 questions for sections one and two of the DCF; 6 open ended and 6 closed questions. One of the open ended questions (number 12) was in a table format related to medicine use; indication, duration and effect of medicine according to patients.

The DCF was written in English, and the interviewers asked all questions in English or Arabic depending on the houses visited. Translation of the answers into English was done at the time of the interview. Open-ended responses were recorded verbatim. The data collection took three months (from October 2010 until December 2010) to complete and the data entry took additional three months.

3.2.2. Ethical requirements

The study was approved by the Committee on Human Subjects in Research (CHSR) at the LAU (**Appendix 3.II**).

3.2.3. Setting and study population

The project was carried out by pharmacy students (interviewers) who were from different regions in Lebanon, therefore, were able to cover all five districts; Beirut, Mount Lebanon (ML), North, South, and the Bekaa. The author reviewed the DCF with interviewers, stressing and emphasizing on how to approach the public. The DCF was used to gather the required information from one family member or caregiver in each household. The interviewers were asked to take photos of each package of medicine available, after the consent of household members, in order for all medicines to be compared with a standard original by the author at a later stage. The author emphasized the need for interviewers to take a photo of the hologram on each box of medicine, when present.

Before initiating the project, the author visited four houses, as a pilot exercise, and to validate the DCF. The author chose two neighbours, one relative, and a friend's house. Participants visited by author were informed of the study's objective, and started the exercise after their verbal consent. The interview took around 50-65 minutes, as these were houses that had more than 30 medicines in total to be analysed. Therefore, based on the findings, the author decided to exclude herbal and Para-pharmaceutical products (i.e., cosmetics, vitamins, or dietary products) and focused only on prescription and over the counter (OTC) medicines. No modifications were required for the DCF.

Interviewers assured participants that the information they provided would be confidential and anonymous. The author informed interviewers that household members would be given the same objective used by author in the pilot exercise. Additionally, interviewers were unable to know if a medicine was CFM or not, without comparing each one with its original. Hence, interviewers were informed that if they saw anything of concern, to ask participants to check with or contact their physicians or pharmacists, for further advice.

3.2.4. Study samples

Convenience sampling was used in this study. Convenience sampling is used when the researcher takes a purely opportunistic approach and seeks information from a readily accessible sub group of the population (Baker, 2002), or when it involves selecting participants based on availability (Gehart et al, 2001). Convenience sampling can help develop hypotheses that may be tested and investigated further in future studies (Baker, 2002). This study used convenience sampling for the following reasons: firstly, safety of participant (to avoid going into “strangers” houses), secondly, easier to approach and visit households of family members, neighbours, and friends, and finally, convenience for interviewers (readily accessible, and based on availability).

The author asked the interviewers to choose houses of friends, family members, or neighbours. There was no selection criteria set, individuals willing to participate were welcomed, excluded for interviews was anyone below 18 years old, and households not using any medicines. Interviewers had to introduce themselves, state the purpose of the study, and the approximate time the exercise will take (around one hour). The DCF was used to gather the required information and various areas in Lebanon were visited to include the five districts.

3.2.5. Procedure

Participants were informed, before the interview started that the aim of the study was to evaluate what they knew about their medicines, and storage of their medicines (if they had medicine cabinets). With respect to participants’ autonomy and anonymity, verbal consent was obtained before participants agreed to participate, written consent was not required for this type of study, as per CHSR. The dates and times when these interviews took place were all documented. The study results were reported anonymously; hence participants were not vulnerable, as their responses could not be traced back to them.

Once the exercise was completed, the visual aspect of the physical examination, as detailed in Chapter Two, was adopted and the author evaluated the DCFs and photos, at a later stage, not during the visit to households. All photos were compared with the boxes or packages of the same medicine, using a university - (LAU) accredited pharmacy. The following were used to check for discrepancies between photos and original packages, if they had 1) different labelling/packaging, 2) no hologram, and or 3) both 1 and 2. A

medicine was considered counterfeit, if any of the three discrepancies were found. The author was not able to alert participants when a CFM was identified, for the nature of the study was anonymous.

3.2.6. Data analysis

Questionnaire responses were entered into the Statistical Package for Social Sciences (SPSS) (SPSS version 22.0.1) and descriptive analysis was undertaken.

3.3. Results

The sample included 150 households located in various areas in Lebanon. **Table 3.1** describes the geographical distribution of households, and the number of households visited in each region. The majority of households visited were in the Mount Lebanon region (53.3%), followed by Beirut and the least amount of houses visited were in the South and Bekaa (2.7%) and (2.7%) respectively. None of the houses visited refused to participate in the study.

Region	N*	%
Mount Lebanon	80	53.3
Beirut	34	22.7
North	28	18.7
South	4	2.7
Bekaa	4	2.7

Table 3.1. The number of houses visited according to the five regions in Lebanon

3.3.1. Demographics of household members

Table 3.2, shows that around 27.5% of households visited had 4 members living in the house, followed by 5 members in 25.3% of houses visited. The results show that 4% of the families in households had one infant/toddler, 24% had at least one child, almost 35% had at least one adolescent, almost 90% of the families included at least one adult (aged between 18-64) and almost one quarter had at least one elderly (aged more than 64 years old). Additionally, in 66% of the houses at least one family member had an undergraduate education, and 20% had a post graduate education.

Socio-demographic variables (N=150 houses)	N	%
Number of family members		
1	8	5.3
2	24	16.0
3	20	13.3
4	41	27.3
5	38	25.3
6	14	9.3
7	5	3.3
Infants & Toddlers (0 - < 2 Years old)		
0	144	96.0
1	6	4.0
Children (2 – 11)		
0	114	76.0
1	26	17.3
2	6	4.0
3	4	2.7
Adolescent (12-17)		
0	98	65.3
1	41	27.3
2	8	5.3
3	2	1.3
4	1	0.7
Adults (18 – 64)		
0	16	10.7
1	17	11.3
2	32	21.3
3	31	20.7
4	39	26.0
5	10	6.7
6	4	2.7
7	1	0.7
Elderly (> 64)		
0	111	74.0
1	23	15.3
2	16	10.7
Highest level of education of any member of the family (N=149)		
Primary school	5	3.4
Secondary school	9	6.0
Technical college	4	2.7
University	98	65.8
Graduate school	30	20.1
Other	3	2.0

Table 3.2. Demographics of the households visited

3.3.2. Knowledge of medicine used

Table 3.3 shows that of the 1972 medicines reviewed, participants were knowledgeable about the indications for 1818 (91%) of them. Additionally, participants knew what to look for, to know if the medicine was working for 1834 (93%) of them. No statistical differences were observed between patients' knowledge about their medicine and the regions of the households.

Region	(N=1972)*	Know about the medicines** (%)	Know what to look for+ (%)
Beirut	(N=425)	91.8	93.8
ML ⁺⁺	(N=1112)	88.9	91.6
North	(N=325)	91.4	95.7
South	(N=52)	90.4	96.2
Bekaa	(N=58)	93.1	94.8

*Total number of medicines reviewed,

**Patients' knowledge about indication,

+Participants' know what to look for to know if the medicine was working for them,

++ Mount Lebanon.

Table 3.3 Patients' knowledge about medicine use according to the five regions in Lebanon

3.3.3. Medicine purchasing

Table 3.4 showed that slightly more than half of participants went to the same pharmacy, and 17.2% got their medicines from different sources, such as the army, free samples or from abroad.

Question	(N=150)	%
Participants used the same pharmacy (N=150)		
Yes	82	54.7
No	68	45.3
Participants got their medicines from a different source other than a pharmacy (N=116)		
Yes	20	17.2
No	96	82.8

Table 3.4. Participants' use of the same community pharmacy, and other sources to get their medicine

3.3.4. Photographic data

There were a total of 2004 photos of medicines available in all 150 houses, and after excluding antiseptics, vitamins and herbal supplements the number of photos ended up with 1972, of which (9.2%) were locally manufactured and did not have a hologram placed on the box/package. **Appendix 3.3** describes the CFM found in each household according to the region in which they were.

The author compared the photos of the boxes or packages of all medicines found in households, with the boxes of the original medicines. Once a difference was detected the author took a photo of the original box of each identified CFM for documentation. **Table 3.5** described the households where CFM were detected, based on the 5 regions in Lebanon. Out of the 150 households visited, CFM were found in 49 households (32.7%). The extent of CFM varied among the five regions, according to the total number of houses visited in each region, and the highest percentages were in the following three regions; the Bekaa (15.9%), Beirut (12.4%), and ML (10.7%). Moreover, all of the identified medicines were bought from pharmacies. No statistical differences were observed between houses with CFM and the number of houses with CFM in each region.

Region	Number of houses with CFM* (n#/N%)	Number of medicines in houses with CFM	Number of CFM found** (n#/N%)
Beirut (N=34)	14 (41.2)	194	24 (12.4)
ML ⁺ (N=80)	20 (25)	308	33 (10.7)
North (N=28)	9 (32.1)	133	12 (9.0)
South (N=4)	3 (75)	38	3 (7.9%)
Bekaa (N=4)	3 (75)	44	7 (15.9%)
Total (N=150)	49 (32.7)	717	79 (11.0%)

*Counterfeit medicine,

Percentage of CFM according to the total number of **CFM found in that region, and total number of **medicines** in the households with CFM in that region,

⁺ Mount Lebanon.

Table 3.5. Counterfeit medicines found per household according to their regions

The extent of CFM varied when compared to the total number of medicines reviewed in each region. The region with the highest extent of CFM was the Bekaa (12.1%), followed by the south (5.8%) and Beirut (5.7%). The region with the least amount of CFM was ML (3%) (**Table 3.6**). Using the Chi Square test, statistical differences were observed between houses with CFM, and the regions of these houses, and were most prevalent in the Bekaa and South, $X^2=9.779$ (df=4) and $p=0.044$.

Region	Total number of houses	Total number of medicines	% CFM* in region
Beirut	34	425	5.6 ¹
ML**	80	1112	3.0 ²
North	28	325	3.7 ³
South	4	52	5.8 ⁴
Bekaa	4	58	12.1 ⁵
Total	150	1972	4.0⁶

*Counterfeit medicine,

**Mount Lebanon,

¹⁻⁵Shows the percentage of CFM in each region according to the total number of medicines reviewed in the study for each region (from Table 3.5, i.e., Beirut $24/425*100=5.6\%$),

⁶The extent of CFM in the whole country from Table 3.5 ($79/1972*100=4.0\%$)

Table 3.6. Detailed description of the CFM found according to regions and total number of medicines found according to that specific region

Photos of medicines were identified as CFM if the boxes: 1) had different labelling/packaging than their original, 2) did not have the hologram, or 3) had both 1 and 2. The majority of identified CFM did not have the hologram, 61 boxes of medicine (77.2%) and in addition, 22.8% had different packaging than the original, with 11 (61.1%) boxes of medicines that had both; different packaging and no hologram on their boxes (**Table 3.7**).

Counterfeit medicines detected*	%
Total number of medicines with no hologram	
N=61	77.2
Total number of medicines with different labelling/package	
N=18	22.8
• With hologram	
N=11	61.1
• Without hologram	
N=7	38.9

*Total number of counterfeit medicines found=79

Table 3.7. The number of detected counterfeit medicines without hologram and with different labelling/packaging

The below photos are examples of the identified boxes of CFM that had different packaging and/or no hologram. Photo 3.1 shows the different labelling of Aspi-Cor® (Aspirin) 81mg. The counterfeit Aspi-Cor had the hyphen tilted upward and the font size was larger than the original and therefore it was considered counterfeit.



Photo 3.1 shows on the left the original Aspi-Cor and on the right the CFM. The CFM had the tilted hyphen between Aspi and Cor, and a different font than the original.

As for medicines with different packaging than their original, **Photo 3.2** shows three Augmentin[®] packages, the top (a), the middle (b) and the bottom (c). Both (a and c) were identified as CFM and (b) the original. The discrepancies in (a) were the different packaging and manufacturer logo SmithKline Beecham (SB) than (b) “GlaxoSmithKline (gsk)”, also did not have the “TM” at the end of the name Augmentin, yet the hologram was present on the box. The colour of the box (a) looked different when compare to (b). The discrepancies for (c) were the larger font of the name Augmentin that filled the most part of the white area of the packaging, in addition to the absence of the hologram on the box. Both (a and c) did not have the gsk logo as a background on the white part of the box. Finally, boxes (a and c) misspelled the chemical name as “amoxycillin” instead of “amoxicillin” as seen in (b) on the original box.



a



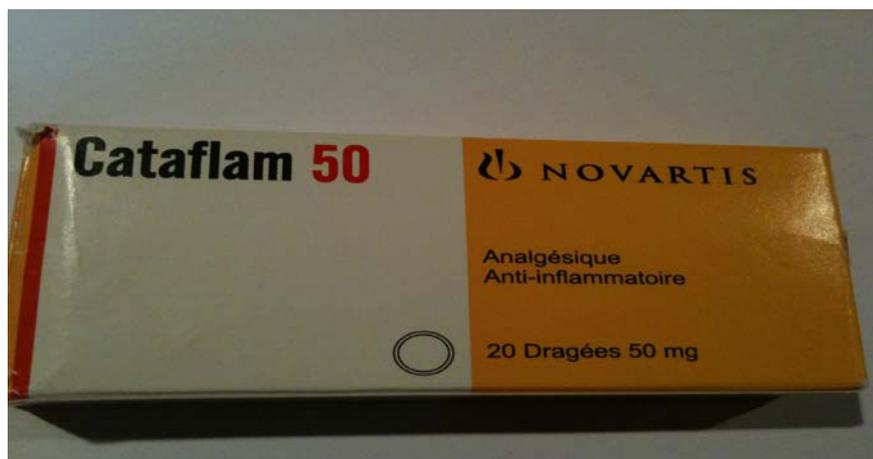
b



c

Photo 3.2 shows the picture of 3 boxes of Augmentin®. The top (a) and the bottom (c) were identified as CFM, and the middle photo (b) the original.

Photos 3.3, shows (a and b) as the one box of counterfeit Cataflam[®] and (c) the original. The differences for this box were (1) the labelling of the packaging for (a) was different from (c); as the chemical name was missing and the description of the medicine was in French only, versus three languages in (c), (2) the hologram was missing, and (3) the “®” was placed before the name (i.e., [®]Cataflam) not after the name Cataflam, (i.e., Cataflam[®]) as shown in (b). The manufacturer’s name (Novartis) filled the yellow part on the upper right corner of the original box (c) but not for the counterfeit.



a



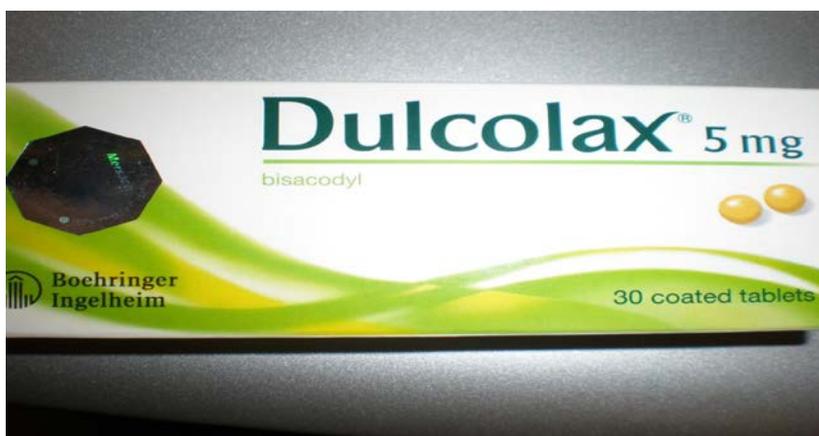
b



c

Photos 3.3 Shows (a and b) as counterfeit Cataflam[®] and (c) the original.

Photos 3.4, shows another example of the different packaging and labelling for the medicine Dulcolax[®]. The box on top (a) was the counterfeit and (b) was the original. The following were observed: 1) the name Dulcolax was more elongated on the original box (b), 2) the chemical name bisacodyl was missing for (a) and was printed under Dulcolax[®] for the original (b), and 3) The hologram was on the counterfeit box (a).



Photos 3.4 shows the two packages of Dulcolax[®] (a), the counterfeit, and (b) the original. The original box had the hologram on it, and the chemical name under Dulcolax[®].

The CFM found in this study were identified for chronic and acute uses, and are described in **Table 3.8** according to four categories (**Appendix 3.II** describes the CFM according to visited regions). The majority of medicines were from category 3, followed by category 4. Some of the medicines could go up a category or down a category depending on the disease state of the patient.

No.	Category Description	Number found*	Medicine name
1.	A medicine without which it would lead to death, but the effects of which are routinely monitored and dosage adjusted.	6	Januvia, Sintrom, Glucophage, Diamicron, Glucophage, Avandia
2.	A medicine without which the patient would suffer long-term consequences, but no symptoms would arise if activity were decreased, i.e., a calcium channel blocker antihypertensive.	4	Acotral (TG), Elantan, Apo-acetazolamide, Lipodar,
3.	A medicine without which it would not lead to death, but symptoms would become more severe.	52	Profinal XP, Yomesan, Atarax, Cataflam, Profinal XP, Di-antalvic, Daflon, Apo-ranitidine, Mosar, Ranicux, Amoxil, Clonac plus, Adol, Xyzal, Nurofenflash, Disflatyl, Atarax, Ceclor, Augmentin, Clarinase, Ercefuryl, Cataflam, Augmentin, Lomotil, Profinal XP, Julmentin, Atepadene, Douzabin, Migrastop, Uvamin, Profinal XP, Di-antalvic, Mobic, 123, Spasmo-cibalgine, Ercefuryl, Augmentin, Cataflam, Rantag, Dulcolax, Ercefuryl, Ercefuryl, Aerius, Cyclovex, Spasmo-cibalgine, Dulcolax, Nexium, Ranidine, Immodium, Lansomid, Flector EP, Algophene

*Number of counterfeit medicine found in each category

Table 3.8. The categories describing the counterfeit medicine found in households

Continue Table 3.8

No.	Category Description	Number found*	Medicine name
4.	A medicine without which the patient would not die nor would there be rapid onset of symptoms, for example an antidepressant.	17	Aspi-cor, Tofranil, Ferricure, Decalcit. Actonel plus, Anafranil, Apo-allopurinol, Ferricure, Tolexin Ge, Gynotardiferon, Ginvapast, Mebo, Xanax, Actonel plus, Xanax, Pazolam, Biafine,

*Number of counterfeit medicine found in each category

Table 3.8. The categories describing the counterfeit medicine found in households

Due to the nature of the MUE methodology, participants were asked how did they know if the medicines they were using were working for them. **Table 3.9** shows the identified CFM that did not have the expected therapeutic effect, according to participants. The results were further described as percentage of medicines without therapeutic effects, according to regions. The ML region had more participants that reported no therapeutic effect with the medicines used, however, in comparison to the number of CFM found in the region, the south had the highest percentage (33.3%) of reported medicines without therapeutic effect.

Region*	CFM**	Participants' response	% ⁺
Beirut	Decalcit [®] (Calcium and Vitamin D)	Did not know if effective	4.2
	ML	Cataflam [®] (Diclofenac)	Not effective
	Mebo [®] ointment (β-sitosterol)	Not effective	
	123 [®] (Acetaminophen, Caffeine, Codeine, Phenylephrine)	Not effective	
	Anafranil [®] (Clomipramine)	Did not know if effective	
	Apo acetazolamide	Did not know if effective	
	Diclofenac	Not effective	
South	Nexium [®] (Esomeprazole)	No response	33.3
Bekaa	Ranitidine	Did not know if effective	14.3
Total		9	11.4

*All regions except for the North since patients did not report anything,

**Counterfeit medicine,

+Percentage of counterfeit medicine,

++Only identified CFM are included in this table.

Table 3.9. Participants' response to how well the medicine worked for them⁺⁺ according to each region.

3.4. Discussion

The study involved visiting households in various areas in Lebanon, to explore the incidence of CFM present in the households visited. The presence of CFM was evident in one third of the 150 households visited, and the extent of CFM in households varied among the five regions visited. Although the majority of households visited were in ML and Beirut than in the South and Bekaa, the extent was lowest in the ML region (3%) and highest in the Bekaa (12.1%), and the extent for the whole country was calculated as 4%. The majority of medicines in this study, when compared their photos with the original packages, were considered CFM due to the absence of the hologram on the medicine boxes. Differences in packaging for the identified CFM would have been less evident, without the photo comparison to their originals. The majority of the identified CFM fit the description that categorized them as medicines without which it would not lead to death, but symptoms would become more severe. Therefore, the hypotheses were true, as there were CFM present in households, and patients were knowledgeable about their medicines.

The main cities in Lebanon are Beirut (capital), Tripoli (north), Sidon (south), Zahle (Bekaa) and Tyre (south) (Ministry of Finance, 2013). Statistics show that 49% of the Lebanese population live in the two governorates, Beirut and Mount Lebanon, and the rest of the population were distributed among the remaining governorates; North (20.3%), Bekaa (13%), and South Lebanon including Nabatiyeh (17.6%) (Lebanon in Figures, 2008). The results of this study were in concurrence with the statistics, where the number of houses visited was the highest in Mount Lebanon and Beirut.

The number of people in the households ranged from 1-7, which may explain the large number of medicines reviewed, additionally, more than half of households visited had an under graduate education, leading to conclude that the sample of this study was an educated sample. According to the central administration for Statistics (CAS) and world fact book of the Central Intelligence Agency (CIA) on literacy in Lebanon; 87.4% of the 15 years old and over, could read and write and 93.1% of the total population who were males and 82.2% of female were educated (Lebanon in Figures, 2008; Central intelligence agency, 2014). These statistics would explain the high level of education among participants in this study.

The majority of participants were knowledgeable about their medicines and knew what to look for when deciding if the medicine was working for them or not. Therefore,

participants were considered well informed and that could be due to the high level of education among participants. The sample was highly educated, and may be considered a limitation to this study, as a result, future studies may consider visiting households with lower levels of education that may lead to different findings. In addition, the number of houses visited in the South and Bekaa was low, and this is probably due to the low number of interviewers from those regions. A larger sample may have provided a better representation of the region. Therefore, further investigation of these two regions would be required to give a better indication of the CFM prevalence.

More than half of the visited household members reported to go to the same pharmacy for their medicines, which would suggest continuity with a specific pharmacy/pharmacist. Using the same pharmacy encourages the development of pharmacist patient relationship and trust, that would lead to better counselling, and follow-up on patients' treatments, and eventually prevention of CFM use, and even detecting problems if a medicine was counterfeit. Studies show that the pharmacists' interaction and counselling with patients; increased patients' knowledge and satisfaction (Farris et al, 2000; Okamoto et al, 2001; Garjani et al, 2009). Future studies may need to consider carrying this exercise in pharmacies, for on the spot verification of each package with its original, in addition to reviewing medicine use.

The medicines reviewed in this study were similar to the documented reports of the medicines available on the Lebanese market. Almost 91% of the reviewed medicines in this study were imported medicines and 9% were locally manufactured medicines. Therefore, the medicines reviewed were a close representation of the medicines available on the market; 90% were imported medicines and 10% were locally manufactured medicines (Karam, 2004; Investment Development Authority of Lebanon, 2013).

In order to describe the extent of CFM, all the photos taken were compared with the boxes or packages of the same medicines at a university accredited pharmacy. It should be noted that it was not an automatic alert for interviewers, when the hologram was not present on boxes, as locally manufactured medicines and some imported medicines do not have the hologram on their boxes, as its use in Lebanon is not mandatory. As a result the author relied on the physical appearance of the packages according to the photos taken, to differentiate between the CFM and a standard original. This identification was not feasible while evaluating each medicine in households since the original was not available to compare with. The packaging could be counterfeit when the print or finishing of the

product was different; the label may also have incorrect directions on how to use the medicine (Feldschreiber, 2009). The comparison of medicine photos, and actual packages of the corresponding originals, showed discrepancies in packaging features such as; different fonts, prints, colours, misspelling, in addition to missing the hologram on the identified CFM, however, some of the packages were difficult to differentiate if the photos and the originals were not closely compared. This was the reason for taking 6 photos for each box of medicine, to compare all sides in order not to mislabel a medicine as CFM.

In support, the analysis of the CFM Chapter (Two) described the difficulty in distinguishing CFM from their original, and the only way the author could differentiate the two was by putting them next to each other and comparing the packages from all 6 sides. However, a limitation here is the possibility that the identified CFM was old, and there might have been changes in the packaging by the manufacturer that could also explain the differences. Moreover, according to the official site of the Lebanese Pharmaceutical Importers Association (LPIA), the hologram should guarantee the legal importing, shipping and storage of the pharmaceuticals, to assure the public that it came directly from the producer, as per the imprint on the hologram “from producer to consumer” (Lebanese pharmaceutical importers association. 2015). The findings of this study would suggest that the hologram failed to provide this guarantee to patients, as two thirds of the identified CFM in this MUE, had different packaging, and also had the hologram on their boxes. The holograms might have been stolen, or counterfeited (Feldschreiber, 2009). Additional methods should be considered to assure, and guarantee patients that the available medicines in pharmacies are safe, and effective.

The majority of CFM in this study belonged to the category that would not immediately alert that something is wrong with the medicine, but symptoms may become more severe. However, this is assuming that these medicines did not contain toxic or poisonous material that could lead to patients’ harm (Alubo,1994; Deisingh, 2005). According to Medicines and Healthcare Products Regulatory Agency (MHRA, 2012). For counterfeiters this would be an area they would focus on since it would be less likely to link to counterfeiting.

The findings of this study also revealed that a small percentage of participants did not find the identified CFM effective, and were asked to refer to their pharmacists and physicians to identify the reasons. Additionally, 5 out of 8 medicines belonged to category 3 (A medicine without which it would not lead to death, but symptoms would become more

severe). Participants may not have been aware of the availability of CFM, as a result, would not be expected to check or monitor the medicines' effect. When a medicine is not effective, participants may continue to take it hoping it will work with continuous use, may stop taking it, or may choose to check with their pharmacist or physician for advice, although no studies were found to support this. Moreover, CFM may contain the same amount of active ingredient or less, or a placebo, therefore, even if patients were aware, may not be able to suspect anything for a while, and continue to take it. This can be supported by the findings in Chapter Two, when the spectra of counterfeit Panadol[®] was identical to the original. Even if a CFM had the correct ingredient, it still may not be safe and effective since counterfeiters do not abide by the GMP; therefore, chances are it may cause more harm than good (Menkes, 1997; Syhakhang et al, 2004b; Kelesidis et al, 2007).

The different categories of CFM found in this MUE, demonstrated the impact that CFM may have on patients' and public health. The problem with the study's findings was the difficulty of identifying the counterfeits when the packaging was very similar to the original. As a result the MoPH and regulatory authorities would need to consider more strict supervision and regulations, or use different methods to control the availability of CFM in the country. In addition, collaboration between MoPH, OPL and pharmaceutical companies would be necessary to educate all parties involved in handling medicine as well as the public, and help control the availability of CFM.

A report commissioned by the "Brand Protection Group" (PricewaterhouseCoopers, 2003) indicated that counterfeit products were available all over Lebanon, with prevalence in the Bekaa Valley, Akkar in the North, the South and southern eastern suburbs of Beirut. This could also be explained by the higher incidences of organized crime in the Bekaa, and the reported sites producing CFM that were sold across Lebanon (Cilluffo, 2000; Stewart, 2010; IRACM, 2014; Naharnet, 2014). Additionally, areas with weak law enforcement or where the authority of law enforcement officials is weak, there would be an increase in production and sales of counterfeits (PricewaterhouseCoopers, 2003). Similarly, this study showed that the households in the Bekaa and South regions were more prone to have CFM than others. The extent of CFM in Lebanon through this study would accept the hypothesis that there are CFM available in households, describing the extent as 4% for the whole country and as high as 12% in the Bekaa. The results of this study showed the extent of CFM in Lebanon, and as a result the public and the pharmacists would need to become aware of these findings in order to be more vigilant and alert. The study's participants were well informed about their medicines therefore, once properly educated about medicine use

and CFM, it might be easier for them to report any unusual developments after using their medicine, especially if it was counterfeit. Education without awareness towards CFM may not deter people from the use of CFM.

This study was able to explore the possibility of finding CFM in households, providing a rough estimate of the extent of CFM in Lebanon. However, future studies may need to consider investigating each region separately, to provide a representative sample of the population in that region.

This chapter addressed the extent of CFM in Lebanon and provided the prevalence of CFM in the different regions: Beirut, Mount Lebanon, North, South, and the Bekaa. After understanding the nature of CFM from Chapter One, and determining the extent of CFM in this chapter, it would be important to assess public and pharmacist awareness, experience, and views of CFM. As a result, public awareness would be addressed next, in Chapter Four, Public attitude in Chapter Five, and pharmacist awareness and attitude in Chapter Six.

3.5. Conclusion

This study is considered to be the first to use the MUE to demonstrate the extent of CFM in domiciles. The study demonstrated the reality of the situation and the magnitude that CFM may have on public health and the threats associated with its use. Collaboration between the MoPH, OPL, pharmacists, and parties involved in the pharmaceutical supply chain would be considered a necessity, to control the influx of CFM, in order to prevent CFM from reaching patients. Educating all stakeholders would also be considered essential to control and prevent CFM use.

Chapter Four

Public Awareness Towards Counterfeit Medicine in Lebanon

4.1. Introduction

Consumers in counterfeiting may be considered the actual force behind the counterfeiting business (Chan et al, 1998). In recent years, it has become increasingly difficult for patients and even pharmacists to identify CFM, especially in situations where the treatment responses are subjective (Nsimba, 2009). The previous chapter of this study (Chapter Three-counterfeit medicine in domiciles) showed that slightly more than a third of the households visited in Lebanon had suspected CFM, with an extent of 4% for the whole country, and a prevalence as high as 12.1% for the Bekaa region. When the public is not aware or does not have adequate understanding of CFM, and their potentially serious adverse effects, the public would be more likely to be affected by their use. As a consequence, medicines that lack efficacy or cause unusual adverse effects are rarely reported, since the outcome is usually attributed to the disease and not to the use of CFM (IFPMA, 2011). Therefore, this chapter will be addressing public awareness towards CFM in Lebanon.

The literature review found limited studies addressing public awareness and knowledge towards CFM, and most of the studies were on exploring and combating CFM in developing countries (Lybecker, 2007; Tipke et al, 2008; Sengaloundeth et al, 2009). A study in Nigeria aimed to establish the factors that have contributed to availability of CFM, used a combination of questionnaires and interviews of stakeholders that were considered relevant to the study; regulatory and non-regulatory agencies in Nigeria. The results showed that 100% of respondents indicated that the laws were not properly enforced, and 60% considered the penalties to be too light. Almost two thirds of respondents had the view that the major public laboratory for quality control analysis was not adequately equipped to cope with the volume of requests of imported products. The high cost of medicines was considered a reason why CFM were available by 71% of respondents, and 43% indicated that greed of regulatory officials contributed to the availability of CFM. Ignorance and the low level of literacy were considered the contributing factor to the problem of CFM and the reason why people used CFM. The main findings of the study included the need for the government to implement the existing laws, and increased funding for the central laboratory to analyse more suspected CFM. In addition, the study addressed the need to ensure that all medicines of both locally and imported medicines, to be registered and offenders should be prosecuted (Erhun et al, 2001).

Another study in Poland conducted a survey on 377 laypersons using a questionnaire, to gain information on the understanding of the CFM problem. The sample was chosen during a generally accessible mass event, and provided a proportional representation of different social groups. The results addressed the objectives of the study and revealed that majority of participants were aware of the scale of CFM, and related threats. However, slightly more than half were not willing to buy prescription or expensive medicines outside a pharmacy, if it was not accessible. Additionally, the study reported that majority of respondents did not know the procedure for reporting suspicious medicines, and did not know what to do in such cases. The study demonstrated the need to increase public awareness addressing the threats related to CFM, and illegal medicine (Binkowska-Bury et al, 2013). The study set the ground for further studies of CFM in Poland.

An online survey in 2004 commissioned by the National Consumer League (NCL), a private non-profit advocacy group that represents consumers on market place in the USA and abroad, was conducted to determine consumers' knowledge about and experience about CFM, in addition to questioning about purchasing prescriptions online. There were 1013 participants, aged 18 years or older. The survey revealed that only 4% of respondents reported to have bought prescription medicines that they suspected to have been counterfeit. The study evaluated participants' experience with CFM, and purchasing prescriptions online (National consumer league, 2004). The study did not address what participants knew about CFM.

The limited number of studies in the literature addressing public awareness and knowledge towards CFM, and the fact that no studies were found in Lebanon addressing the same topic, determined the need for this study. However, it is worth mentioning that an awareness campaign about CFM took place in 2008 (International Pharmaceutical Federation, 2015a), and targeted the public, pharmacist and healthcare professionals in Lebanon. Some of the approaches used were television advertisements, print press, radio advertisements, billboards, posters, conferences, and brochures, yet there have been no published outcomes regarding the success of the campaign.

A questionnaire was developed as an assessment tool to determine public awareness towards CFM in Lebanon. Before formulating and developing the questionnaire, a thorough literature review was conducted to find studies and reports on CFM in Asia, Europe, Africa and USA and how the public dealt with CFM and related issues. An electronic search was done through PubMed, Scopus, Cochrane Library, ScienceDirect,

and MedlinePlus databases by using the following key terms: counterfeit, counterfeit drug/medicines, public health, public awareness, public awareness and surveys, pharmaceuticals and fake medicine/drugs, substandard medicine/drugs, poor quality medicine/drug and patients, counterfeit drug/medicines and patients, counterfeit drug/medicines and public, counterfeit drug/medicines and health. The search started from October 2009 to November 2010 for the questionnaire development. The author decided to keep the years of research open in order to get an overview of the topic. The search revealed many terms related to CFM such as substandard, sub-therapeutic, falsified medicines/drugs, and the literature was used when relevant.

As a result, the aim of this study was to determine public awareness towards CFM in Lebanon, after the 2008 campaign, using a questionnaire. The hypothesis was:

a. The public are aware of CFM

Therefore, the study assessed the following:

- a. Respondents' experience with CFM**
- b. Respondents' views of awareness campaigns**
- c. Respondents' knowledge on how to report CFM**
- d. Respondents beliefs on who is responsible for availability of CFM**

4.2. Methods

The literature evaluation revealed the types of counterfeiting and the classes of medicines that were targeted by counterfeiters, which led to the questions on the type of medicines used by patients and how they could differentiate CFM from their original (Erhun et al, 2001; Kelesidis et al, 2007; Mackey, and Liang, 2011). Additionally, the literature discussed and displayed “how” counterfeiting was produced, “where” (in what conditions, backyards, substandard labs...) and by “whom” that led to the question on the parties involved in the process of counterfeiting (Erhun et al, 2001; Cockburn et al, 2005; Morris and Stevens, 2006; Newton et al, 2006b; Mackey, and Liang, 2011). Furthermore, the literature mapped the supply chain of counterfeiting originating with the raw material, manufacturer, passing by the transit countries and ending up in the consumer countries. In turn, this led to the question on the source of CFM (Koh et al, 2003).

4.2.1. Questionnaire design

The questionnaire used different types of questions: multiple-choice, close ended, and open-ended. The open-ended questions were used to elicit a response pattern by respondents using their own words. These questions allow respondents to reflect on their own perceptions and feelings, therefore, providing the author with answers that may not have been considered, in order to give further depth and insight. The close ended and multiple-choice questions were used to offer a limited number of responses for respondents to choose the best according to them. Ranking questions were also used to determine the relative importance of each option for respondents.

The questionnaire consisted of 25 questions, and was divided into three parts; **Part I**) General information and demographics. **Part II**) Medicine use, consisted of 2 multiple-choice questions and one open-ended, to determine if participants were using any sort of medicine (to provide an idea on respondents’ medicine use and commitment with a pharmacy, that may lead to continuity and better communication with pharmacists, especially for medicine use). **Part III**) Awareness of CFM, consisting of 22 questions, three of which were open-ended. The awareness, experience and views section of the questionnaire, started with general questions before focusing on more specific questions to address the objective. The questionnaire was initially written in English, and was translated into Arabic according to a standardized process to validate the translation (Sperber, 2004). Translation of the answers into English was done at the time of data entry. Face validity of

the questionnaire was assessed through experts in the field of pharmacy before it was piloted (Hardesty and Bearden, 2004; Broder et al, 2007).

4.2.2. Ethical requirements

The study was approved by the Committee on Human Subjects in Research (CHSR) at the LAU, and the School of Pharmacy and Biomolecular Sciences Research Ethics Committee at University of Brighton (**Appendix 4.I**). With respect to respondents' autonomy and anonymity, verbal consent was obtained before individuals agreed to participate, written consent was not required for this type of study, as per CHSR. The dates and times when the questionnaires were administered were all documented. The questionnaire did not include respondents' personal information hence their responses could not be traced back to an individual.

4.2.3. Procedure

Before starting the study, the author and an assistant (surveyor) piloted the questionnaire for validation content, at a mall in Beirut, on 13 members of the public. The pilot questionnaire (**Appendix 4.II**) was shortened and simplified, for according to respondents, it was long (32 questions) and time consuming (12-15 min), and some questions were not straightforward. Few respondents preferred to have the surveyor read the questions for them, and write down their answers (may have been illiterate). For the open-ended questions, their answers were reported verbatim. The final questionnaire (**Appendix 4.III**) was modified and resulted in 25 questions.

4.2.4. Setting and study population

The study was based in Lebanon, and the aim was to administer the questionnaires in different locations in Lebanon. The inclusion criteria were any individual 18 years old and above, willing to participate in the study, and who could speak and read English or Arabic. Respondents had the freedom to choose between Arabic or English questionnaires.

A convenience sample was used, as it was based on the availability and willingness of members of the public to participate. The surveyors approached the public in shopping malls and public places, such as supermarkets, shops, and the street, in different areas in Lebanon, and were asked to fill out the questionnaire. These places were chosen for the

diversity of people that may be present, and the easy access to the public in such places. Areas visited were the North, South, Beirut, and Mount Lebanon, and respondents were identified according to the area of living such as city, village, or town.

The surveyors stated the purpose of the study, and the approximate time it would take to fill out the questionnaire (around 10-15 minutes). The data collection took six months (From August 2010 until December 2010), and five month for data entry.

4.2.5. Data analysis

Data were entered on an Excel sheet, and analysed using Triple One, Version 2 (Matrix, 2015). Descriptive analysis was performed for the questionnaire where frequencies and percentages were reported for all categorical variables. Bivariate analyses were performed and included the use of the Chi-square and Kruskal-Wallis (KW) tests. Content analysis was used to analyse the open-ended responses. This involved reading the questions, identifying recurring ideas and categorizing all responses to similar ideas or answers to allow numerical analysis.

4.3. Results

The majority of respondents who were willing to participate were the young age group, and more of the older age groups refused to participate. The reason given was lack of time or not interested.

4.3.1. General information and demographics

The sample included 464 respondents, a descriptive analysis showed that 62% were males; the largest percentage of respondents was 20 years old and younger (29.4%), followed by the age group 21-30 (26.5%), and 31-40 (22.8%). More than half of respondents lived in the city, and almost half of respondents reported to have a university or graduate education, therefore the sample was well educated (**Table 4.1**). In order to describe the study sample, KW test was used; $H= 65.75$, $p < 0.05$, showing that the majority of the educated sample were the younger group age 18-20.

Demographic Variables	N	(%)
Gender (N=460)		
Male	285	(62.0)
Female	175	(38.0)
Age (N=456)		
18- 20	134	(29.4)
21-30	121	(26.5)
31-40	104	(22.8)
41-50	79	(17.3)
51-65	18	(4.0)
Type of residence (N=463)		
City	244	(52.7)
Town	113	(24.4)
Village	106	(22.9)
Highest level of Education (446)		
Primary school	56	(12.6)
Secondary school	117	(26.2)
Technical school	47	(10.5)
University	164	(36.8)
Post graduate	62	(13.9)

Table 4.1. Respondents' general information and demographics

4.3.2. Medicine use

Table 4.2 shows 52.6% of respondents reported going to the same pharmacy to get their medicines or pharmacy related products. The reason for going to the pharmacy was reported by 76.3% of respondents to obtain their medicine, and by 53.4% of respondents to obtain medicine for acute or chronic diseases.

Questions related to medicine use	N	(%)
Do you go to the same pharmacy (N=458)		
Yes	241	(52.6)
Sometimes	130	(28.4)
No	87	(19.0)
Reason for going to the pharmacy (N=459)		
For medicine	350	(76.3)
For para-pharmaceutical products*	11	(2.4)
For both**	98	(23.3)
Indication for medicine use⁺ (N=464)		
Acute/Chronic diseases	248	(53.4)
Vitamin deficiencies	6	(1.3)
No answer	210	(45.3)

*Products such as cosmetics, or vitamins,

**Respondents listed medicine and para-pharmaceuticals,

⁺The author classified indications as; acute/chronic, vitamin deficiencies, and no answer, based on respondents' responses.

Table 4.2. Whether respondents go the same pharmacy, and their reported reasons

4.3.3. Awareness of counterfeit medicine

The majority of respondents (93.4%) reported to have heard of the term “counterfeit medicine”, and using the Chi Square test, statistically significant relationships were observed between responses and respondents' level of education. The results revealed that the higher the educational level of respondents, the less they had heard of the term CFM, $X^2= 19.93$ (df=4), $p<0.05$.

The analysis of an open-ended question on comparing between CFM and authentic (original) medicine; showed that the majority of respondents (48.6%), reported that they did not know or did not answer. Almost one third of respondents thought that original medicine was more effective than CFM, and only 3.7% of respondents reported that the original medicine would have the hologram on the package (**Table 4.3**). No statistically significant relationships were observed between responses and respondents demographics.

Questions	N	(%)
Compare quality of CFM* to authentic medicines		
Don't know/No answer (N=463)	225	(48.6)
Original more effective (N=464)	138	(29.7)
Irrelevant comments (N=464)	44	(9.5)
CFM have poor quality (N=464)	25	(5.4)
Authentic has hologram (N=464)	17	(3.7)
CFM has more SE** (N=464)	9	(1.9)

*Counterfeit medicine, **Side effects

Table 4.3. Description of how respondents compared CFM with original medicine

The source of awareness for the majority of respondents was TV (84.4%), and out of those who responded, (55.1%) reported to have learned from the advertisement (**Table 4.4**). No statistically significant relationships were observed between responses and respondents' education, gender, and age.

Questions	N	(%)
Source of CFM* awareness (N=232)		
TV	391	(84.4)
Neighbours	44	(9.5)
Pharmacy	38	(8.2)
Billboards	37	(8.0)
Other	36	(7.8)
Unsure	13	(2.8)
Seen a CFM advertisement/campaign in the past 24 months (N= 462)		
No	259	(56.1)
Yes	169	(36.6)
Unsure	34	(7.4)
Learned from the advertisement (N=283)		
Yes	156	(55.1)
No	64	(22.6)
A little	44	(15.5)
Unsure	19	(6.7)

*Counterfeit medicine

Table 4.4. Source of CFM awareness and related benefits

Table 4.5, presents how respondents differentiated between CFM and original medicines, showing that 41.9% reported to look for the hologram, and almost one third did not know or had no answer.

Questions related to CFM* awareness	N	%
Differentiation of a CFM from the original medicine (N=464)		
Look for a hologram	195	41.9
Don't know	133	28.6
Medicine effect	99	21.3
Pill colour	63	13.5
Package (box) colour	50	10.8
Other	40	8.6
Label/Write up	38	8.2

*Counterfeit medicine

Table 4.5. Describes how respondents differentiated between CFM and original medicine

Using the Chi Square test, statistically significant relationships were observed between responses and respondents' education, and gender. For education, the higher the level of education, the less respondents who reported not to know, $X^2=15.58$ (df=4), $p<0.05$. Also, statistical significance was observed with respondents who reported to look for the hologram; and it was directly related to the level of education, $X^2=10.73$ (df=4), $p<0.05$. As for gender, more females reported to look for the hologram (49.7%), $X^2=6.98$ (df=1), $p<0.05$.

The questions that addressed how respondents dealt with suspected CFM showed that 5.5% of respondents suspected that a purchased medicine was a CFM, whereas a 10.1% knew of someone that suspected they purchased a CFM, no statistically significant relationships were observed between responses and respondents' education, age or gender. For the action taken after the suspicion of purchasing a CFM; the most common reported response was to tell the pharmacist (47.5%). Respondents indicated that after reporting the incidence of buying CFM, 40.2% who reported the suspected CFM, were able to return the medicine and 18.3% were told that nothing could be done (**Table 4.6**). No statistically significant relationships were observed between responses and respondents' demographics.

Questions related to CFM* Awareness	N	%
Differentiation of a CFM from the original medicine (N=464)		
Ever suspected that a purchased medicine was counterfeit (N=457)		
Yes, I have	25	5.5
Yes, someone I know has	46	10.1
No	386	84.5
Action taken after the suspicion of a CFM (N=101)		
Told the pharmacist	48	47.5
Nothing	21	20.8
Told the doctor	18	17.8
Other	9	8.9
Told insurance	5	5
What happened after reporting**(N=82)		
Returned medicine	33	40.2
Checked package	16	19.5
Cannot do anything	15	18.3
Refused to return medicine	12	14.6
Other	6	7.3

*Counterfeit medicine,

**Pharmacists' responses, as reported by respondents, after they reported the CFM.

Table 4.6. Describes how respondents dealt with a suspected CFM

Respondents were further asked how to avoid buying CFM, and the majority reported by getting the medicine from a trustworthy pharmacist (83.4%), whereas 37.5% reported by making sure the hologram was present (**Table 4.7**).

How you avoid getting a CFM* (N=464)	N**	%
Get the medicine from a trustworthy pharmacist	387	83.4
Make sure the hologram is present	174	37.5
Buy the medicine from a different country	20	4.3
Other	14	3

*Counterfeit medicine,

**Totals are more than 100% because more than one answer was possible

Table 4.7. Describes how respondents avoid buying CFM

Statistically significant relationships were observed between responses and respondents' level of education, age, and gender. For education, statistical significance was observed with respondents who chose the presence of the hologram, and was directly related to the education level, $X^2=16.04$ (df=4), $P < 0.05$. According to age, statistical significance was observed with participants who reported a trustworthy pharmacist, and was considered the least by the youngest group, $X^2=11.12$ (df=4), $P < 0.05$. Statistical significance was also observed with gender as more female respondents chose the presence of the hologram, $X^2=13.58$ (df=1), $P < 0.05$, however, more male respondents chose a trustworthy pharmacist, $X^2=6.23$ (df=1), $P < 0.05$.

Furthermore, respondents were asked to rank the most important factor they would consider when buying a medicine. Less than half of respondents reported the effectiveness of medicine (46.7%) as the most important factor, followed by the name of the medicine, and the price of medicine ranked 4 (4.2%) (**Table 4.8**).

Decision to buy according to	(N=456)
Effectiveness of medicine	213 (46.7)
Name of medicine	153 (33.6)
Country of origin	71 (15.6)
Price of medicine	19 (4.2)

Table 4.8. Describes the number 1 factor respondents consider when buying a medicine

When respondents' demographics were compared using Chi Square test, statistical differences were only observed with age. And according to the different age groups, age groups 41-50 and 51-65 both ranked the name of medicine 1st, (40.3% and 44.4%) respectively, $\chi^2=38.38$ (df=12) and $p<0.001$. For the source of CFM, **Table 4.9** shows that 33.3% of respondents' thought CFM originated from the Arab countries, and 30.4% thought from China. No statistically significant relationships were observed in respondents' responses and their demographics.

Country of origin of counterfeit medicine (N=187)	N	%
Arab Countries	62	33.2
China	57	30.4
Europe/USA	23	12.3
Lebanon	19	10.2
3rd world countries	15	8.0
India	6	3.2
Far East	5	2.7

*Counterfeit medicine

Table 4.9. Respondents' responses to where they believed CFM* originated.

When respondents were asked an open-ended question about who they believed to be responsible for the availability of CFM, 58.2% reported wholesalers, followed by customs (52.2%) (**Table 4.10**).

Who is responsible for the availability of CFM	N	%*
Wholesalers	270	58.2
Customs	242	52.2
Manufacturers	172	37.1
Pharmacists	169	36.4
Other	34	7.3

*Percentage is more than 100% since more than one answer was possible.

Table 4.10. Respondents reported believe on who is responsible for the availability of counterfeit medicine in the country

Results revealed that the only statistical significance was observed between responses and respondents' level of education. The majority of participants who reported to believe wholesalers were involved in the supply chain of CFM, were those with higher education, $X^2=12.47$ (df=4) and $p=0.01$.

When participants were asked about education and awareness towards CFM, the majority of respondents (85.3%) reported to believe education as part of the solution to stop CFM, and 81% reported that the public should be educated about CFM, followed by pharmacists, and the government. The awareness campaign as reported by participants should be done through the TV (85.3%) (**Table 4.11**).

	N	%
Education as part of the solution to combating/stopping CFM* (N=463)		
Yes	395	85.3
Maybe	52	11.2
No	16	3.5
Whom should be educated** (N=464)		
The public	376	81
The pharmacists	166	35.8
The government	153	33
The wholesalers	116	25
The physicians	105	22.6
The nurses	89	19.2
How the awareness campaign should be done** (N=464)		
Through TV	396	85.3
Through billboards	278	59.9
Through the news	265	57.1
Through radio stations	201	43.3
Through leaflets	181	39

*Counterfeit medicine,

**Total is more than 100% since more than one answer was possible.

Table 4.11. Education and methods of awareness campaigns against CFM

For participants who chose education as a solution to stop CFM, statistical significance was observed between responses and respondents' different age groups, and was inversely

related, $X^2=19.94$ (df=8), $p<0.05$. No statistically significant relationships were observed in respondents' responses on who should be educated and their demographics.

According to **Table 4.12**, respondents reported to believe that the MoPH (73.7%) should be involved in the CFM campaign, and (44%) thought that the campaign should be done twice a year. Conversely, 53.2% of respondents reported to believe the best way their pharmacist could educate them about CFM to be through leaflets, pamphlets or brochures.

Question	N	%
Who should be involved in the awareness campaign*(N=464)		
Ministry of Public Health (MoPH)	342	73.7
The Lebanese order of Pharmacists (OPL)	195	42
Pharmacists	144	31
Physicians	114	24.6
The Lebanese Pharmaceutical Imports Association (LPIA)	87	18.8
Wholesalers	34	7.3
Other	11	2.4
How often should the campaign be done (N=434)		
Twice a year	191	44
Once a year	39	9
Every other year	8	1.8
Other	196	45.2
How would you like to learn about CFM** from your Pharmacist* (N=464)		
Leaflet/Pamphlet/Brochure	247	53.2
Seminars	145	31.3
Workshops	69	14.9
Other	27	5.8

*Total is more than 100% since more than one answer was possible.

**Counterfeit medicine

Table 4.12. Questions related to the educational and awareness campaigns

Finally, when participants were asked an open ended question about the role of officials in controlling the availability of CFM, 58.9% of respondents reported to believe that officials should provide strict supervision and control of conduct of responsible authorities (MoPH, pharmacists, wholesalers, importers...) (Table 4.13).

Role of officials in controlling availability of CFM* (N=372)	N	%
Strict supervision/control of conduct**	211	58.9
Impose severe punishment (prison/fine)	77	21.5
Increase public awareness	54	15.1
License withdrawal/Closure of pharmacy	16	4.5

*Counterfeit medicine,

**Conduct of wholesalers, importers, pharmacists, etc...

Table 4.13. The role of officials in controlling the availability of counterfeit medicine

The only statistical significance was observed between responses and respondents' age, for the majority of age group 21-30 years (28.7%) considered strict supervision/control of conduct, and was reported the least by the age group 51-65 years, with $X^2=25.59$ (df=12), $p<0.05$. No statistically significant relationships were observed between responses and respondents' level of education and gender.

4.4. Discussion

The aim of this study was to determine public awareness towards CFM in Lebanon, to determine the perceived need for additional educational and awareness campaigns. This study was based on a questionnaire administered to the public in various areas in Lebanon such as the north, south, Beirut, and Mount Lebanon. The hypothesis of the study was true, and the aim of the study was met as the results revealed that majority of respondents had heard of the term “counterfeit medicine”, but did not know how to identify CFM. When asked to differentiate a CFM from its original, respondents reported to look for the hologram. The majority of respondents reported that a trustworthy pharmacist would be the best way to avoid buying CFM. Moreover, participants reported to believe that wholesalers, followed by customs were involved in the supply chain of CFM. Respondents considered education to be part of the solution to stop and limit availability of CFM. However, the administration of the questionnaire at public places might have affected the provided information, rather than if respondents were answering at their own leisure with more time to think about their answers.

According to the United Nations Educational, Scientific and Cultural Organization (UNESCO), “Lebanon’s rates of access to education and youth/adult literacy are amongst the highest in the Middle East. About 90% of its youth and adult population is literate, with few gender disparities” (UNESCO, 2013). The study showed that respondents of this questionnaire, were mostly males, and most of respondents were less than 40 years old, and lived in the city. The study population may not appear to be diverse enough; as respondents were reported to be mainly from the city, when there are three main cities in Lebanon; Beirut (capital), Tripoli (north) and Saida (south). The areas visited were the North, South, Beirut, and Mount Lebanon, and the three main cities were among the areas visited. However, knowing which city may have demonstrated a better insight into the level of awareness at specific geographical regions, and would have provided a better reference for targeted future awareness and educational campaigns. The questionnaires did not ask for respondents’ income bracket, future studies may consider evaluating if this might be a factor in the use of CFM.

The large number of respondents was in the age groups 18-20 and 21-30, and almost half of respondents reported to have reached university or post-graduate level. As a result, the sample would be considered more representative of the 18-30 age group of the Lebanese population. In addition, the reason for the high number of young participants could be that

they were easier to approach, and usually are less inhibited about expressing their opinions and views whether positive or negative, and may be more willing to take risks. Future studies could investigate public awareness with an older age group.

In Lebanon, medicine is available in pharmacies, hospitals, centres sponsored by MoPH and dispensaries, making it slightly more difficult for counterfeiters to use the market or streets as sources for CFM. The majority of respondents in this study went to the same pharmacy to get their medicine, although it is not enough to generalize, however, it would suggest commitment and continuity with a specific pharmacy and pharmacists. In addition, going to the same pharmacy would help develop patient-pharmacist relationship, that would lead to better patient counselling and education (O'Neil and Poirer, 1998), therefore, better chances of detecting CFM (Rajapandian et al, 2013). Unlike a study in the town of Cotonou, that evaluated purchasing practices and habits of 600 randomly selected households, where the majority of respondents reported to having purchased medicine at least once from a pharmacy. Additionally, more than half purchased medicine at least once from health centres, and around one third of respondents reported to have purchased medicine at least once from private clinics and illicit markets (Abdoulaye et al, 2006a). Not restricting the availability of medicines to only pharmacies, makes it much more difficult for members of the public to avoid buying CFM. Therefore, the restricted availability of medicine in Lebanon to pharmacies would be considered a positive path, in the right direction of controlling the availability of CFM.

As for the term counterfeit medicine, the majority of respondents had heard of the term, however, the term was heard more among those with primary education. The reason could be that, the higher the education level, the better would be their socioeconomic status, therefore, would be less likely to have heard of CFM, or to look for or buy CFM. There would be speculation as whether participants really knew or were reporting educated guesses. A study revealed that highly educated individuals were less likely to buy counterfeits (Chapa et al, 2006), one view could be that those individuals are more aware of global issues, and therefore, are less likely to buy counterfeits, in order not to put their own interests above others (Carpenter and Lear, 2011). Participants with lower levels of education, may have lower socioeconomic status, and as a result may be more likely to consider buying cheaper medicines, and thus may have heard of CFM more than participants with higher education. Thus, the influence of education and socio-economic status on awareness towards CFM could be further investigated in future studies.

When participants were asked to compare CFM with the original, lack of awareness was evident when almost half did not know or did not answer, and hologram was considered by a very small percentage of participants. Although, by the time the study was carried out, there had been two campaigns conducted highlighting the use of the hologram on medicines (Lebanese pharmaceutical importers association, 2015), the results would indicate that these awareness campaigns had not reached all members of the public or they had not had the desired impact.

The NCL survey (National consumer league, 2004) showed that more than half of respondents agreed that there was no way to tell if a prescription medicine was counterfeit or the original. These answers demonstrated a gap in respondents' knowledge towards CFM, when the majority of this study's respondents did not answer or know how to compare CFM with their original, and the need to address this gap in their knowledge through awareness.

Respondents' awareness towards CFM was mostly through TV, and half of them learnt from the advertisements. A study has shown that TV only campaigns were superior in evoking cognitive responses, most probably due to the larger number of senses stimulated, as well as the forced exposure associated with television as a delivery medium, in comparison to print, and the Internet (Dijkstra et al, 2005). This would support why respondents reported TV as the source of awareness towards CFM.

Moreover, the study showed that for differentiating CFM from original, less than half of respondents reported to look for the hologram, and almost one third reported they did not know or did not answer. Respondents with higher levels of education looked more for the hologram, as they could be more aware of technologies and the purpose behind using holograms, therefore, reported to look for it. Moreover, female participants reported to look for the hologram than male respondents, as studies show them to be more observant and cautious in general (Kanin et al, 1970; Wertz, 1993; Hausman, 2000; Eckel and Grossman, 2008).

According to the NCL survey (National consumer league, 2004) a small percentage of respondents reported to have purchased prescription medicine that they suspected to have been counterfeit, and those respondents who thought they have received a CFM, were most likely to report the problem to the pharmacists who dispensed their prescription. However, the results showed that almost one third failed to report to anyone (National consumer

league, 2004). The lack of awareness and understanding of the risks, and consequences related to CFM use, might have been one of the reasons why some respondents did not report. In this study, a small percentage reported to have dealt with a suspected CFM, or someone they knew did. Almost half of respondents reported their cases to the pharmacist, and less than half of the pharmacists returned the medicine. According to respondents'; the pharmacist was the logical choice for them, and that could be for a number of reasons: firstly, the pharmacy might have been the source of the suspected CFM, secondly, pharmacists are the most accessible, thirdly, pharmacists are easy to communicate with, fourthly, pharmacists may be able to provide a quick assessment, and finally, pharmacists are trusted healthcare professionals. The results demonstrated the need to explain how and whom to report to when suspecting CFM, and why should they report it. Consequently, a clear reporting system should be known to all stakeholders, in order to make sure any suspected case is reported, acted upon, and followed up by responsible authorities. Similarly, the study in Poland showed that a very small percentage of respondents knew the procedure for reporting suspicious medicines, and majority were not aware of the necessity to report them (Binkowska-Bury et al, 2013).

Furthermore, to avoid buying CFM, participants reported to buy their medicine from a trustworthy pharmacist. And that would be the more logical response, due to the trust placed in pharmacists, as HCP whose duty is to provide, safe and effective medicines to their patients. This finding was reported more by the more educated respondents who may be more aware of the role of pharmacists, although a trustworthy pharmacist was considered the least by the youngest age group of the highly educated, and that could be explained by the general fact that younger people have less health problems than older age groups. Therefore, the younger age groups would deal less with pharmacists, as a result, may not appreciate or understand the role of the pharmacist, as a trusted HCP, who can have a positive influence on the outcome of their health (Cerulli, 2001; Posey, 2003). According to the NCL survey (National consumer league, 2004), more than half of consumers said they would tell a pharmacist if they suspected a CFM, which demonstrated people's trust in their pharmacists. In pharmacy practice, the trust people place on pharmacists brings with it a huge responsibility to provide safe and effective medicines (Shahverdi et al, 2012; Taleb and Madadha, 2013). Future studies could evaluate the methods used by respondents to decide if a medicine was CFM.

In order to assess the vulnerability of participants to buying CFM, they were asked to rank the factors they would consider when buying a medicine. As the majority of participants

were educated, slightly less than half ranked the effectiveness of medicine first, followed by the brand name. The results revealed that the older age group, ranked first the brand name of the medicine, and it could be that they trusted more the brand of the medicine, and as a result the effectiveness would follow. Interestingly, the price ranked last by participants, and since the majority of respondents were educated, they probably had better socioeconomic status, and price was not considered high on their list. The Cotonou study investigated the price and efficacy of medicines (Abdoulaye et al, 2006a), and found that more than half of respondents thought the cost of the medicines reflected the guarantee of its efficacy. Studies reported that leading brands in the market; are viewed by consumers as superior due to greater brand publicity, and market share (Tauber, 1981; Reddy et al, 1994).

Another key point is when participants reported to believe that wholesalers were responsible for the availability of CFM. Participants with higher education reported this mostly, and that could be due to their logical conclusion of the role that wholesalers play in supplying medicine to pharmacies. And this would be important to address in order to emphasize the importance of having a tight control on the supply chain starting with the source of the raw material, to the manufacturer site until it reaches the patient, to limit infiltration of counterfeiters through weak points of the supply chain. Several studies have reported where CFM appeared in the legal supply chain (Cockburn et al, 2005; Himbolt, 2006; Maruchek et al, 2011; Taylor, 2011), therefore the need for the tight control.

As part of the solution to stop and limit the availability of CFM, participants reported to believe that education could be a part. The younger age group mostly reported education, as they may have better appreciation for education as an awareness tool to stop and limit CFM. Furthermore, educating the public was considered by majority of respondents, followed by pharmacists, and the government, their choices may be reflected by who they considered to be the most affected or involved with CFM. The public; represent the patient who would be using the medicine, therefore, the weakest link in this chain. Followed by the pharmacist; who would dispense the medicine, and makes sure the it is safe and effective. The government, who imposes strict control over which of the medicine, should be available on the market, to guarantee that only safe and effective medicines reach pharmacies, to be dispensed to patients. Education is considered the first step in the counterfeit prevention programs (Harvey, 1988).

In addition, respondents of this study chose TV as the first choice to use as a source of awareness, similar to the Cotonou study (Abdoulaye et al, 2006b). The respondents in the Cotonou study also referred to the following, as the most convincing sources of information; television, followed by radio, posters, and then health professional (Abdoulaye et al, 2006b). Additionally, participants of this study reported that MoPH should be involved in the CFM campaign. After the initial Cotonou study, an evaluation of the results of the new 9 months campaigns, that was suggested by the initial study, (Abdoulaye et al, 2006a), showed that respondents found the campaign to be effective in increasing their awareness. Likewise, continuous awareness campaigns may be beneficial in the control of CFM use in Lebanon. Repeated exposure to campaigns seem to be associated with good results, such as a decrease in buying from illicit vendors due to increased awareness, especially when using several types of exposure (TV, print media and billboards) (Abdoulaye et al, 2006b), however, the messages should be clear and specific (Dumesnil and Verger, 2009).

Notably, more than half of respondents agreed for regulatory authorities to have strict supervision and control on all responsible parties that deal with or handle medicine, in order to control the availability of CFM. Furthermore, respondents believed the MoPH should be involved in the awareness campaigns, probably because the MoPH in Lebanon is the authoritative and responsible body when it comes to decisions related to healthcare.

This study is the first to address public awareness towards CFM in Lebanon. The results showed a gap in the public's understanding towards CFM, demonstrating the need for additional educational campaigns that would clarify and add to the public's knowledge and understanding of CFM.

The study's questionnaire did not have enough questions to address respondents' attitude towards CFM, therefore, the following chapter will address more extensively the public's attitude towards CFM, and pharmacists who deal with CFM.

4.5. Conclusion

The study is the first in Lebanon to address public awareness, experiences and views regarding CFM. The findings demonstrated the gap in respondents' knowledge, suggesting that the previous awareness campaigns might not have reached all respondents; therefore, more efforts should be put on using different approaches than what was used before. Additionally, the need to establish a well-structured CFM reporting system for the public. Moreover, the government and regulatory authorities should implement and enforce the law, and prosecute counterfeiters, collaborators and accomplices in order to limit counterfeiting. In conclusion, public awareness and education would have a crucial role in helping decrease the demand for CFM, and as a result contributing to limit their availability and use.

Chapter Five

Public Attitude Towards Counterfeit Medicine in Lebanon

5.1. Introduction

Counterfeiting is not limited to medicine; counterfeit products (CFP) are also available such as cosmetics, clothes, car parts and food (Ang et al, 2001; Penz and Stottinger, 2005). The problem with the availability of CFP is not only related to the manufacturers that produce them, but also to the public demand for such products. Chapter Four of this study demonstrated the need for additional educational campaigns to fill in the gap of the knowledge related to CFM, however, the study did not have enough questions to assess the attitude of the public regarding CFM. This chapter was added to address the public attitude towards CFM in Lebanon.

Explaining human behaviour in all its complexity is a difficult task, and concepts referring to behavioural dispositions such as social attitude and personality trait have played an important role in the attempts to predict and explain human behaviour (Campbell, 1963; Sherman and Fazio, 1983; Ajzen, 2005). Attitude is considered to have a vital role in the choices people make regarding their own health and security, their families, friends, and nations (Greenwald and Banaji, 1995). Attitude is a term that refers to a person's overall evaluation of oneself, other persons, objects and issues. The attitude would refer to how positively or negatively a person views an object of judgement (Petty et al, 1997). The evaluation could be based on emotions, beliefs, past experiences and behaviours, (Breckler, 1984; Zanna and Rempel, 1988), and whether they are internally consistent or ambivalent (Kaplan, 1972).

Although the Theory of Planned Behaviour (TPB) is not the focus of this study, yet it is one of the widely researched models that links beliefs and behaviour (Ajzen, 1991; 2005), and is considered an extension of the Theory of Reasoned Action (TRA), a model for the prediction of behavioural intention, to determine the difference between attitude and behaviour (Fishbein and Ajzen, 1975). The TRA was related to voluntary behaviour, however, the TPB, included perceived behavioural control, when it appeared that behaviour was not only voluntary and under control (Ajzen and Fishbein, 1980; Armitage and Conner, 2001). The TPB predicts deliberate behaviour, since behaviour can be deliberate and planned, however the prediction of intentions is expected to vary across behaviours and situations (Ajzen, 1991).

Important to realize that counterfeiting activities could be decreased by hindering the suppliers of counterfeits, and by reducing the public demand for them (Chakraborty et al,

1996). Although the industry is putting efforts to limit the production and sales of CFP, fashion counterfeiting is increasing due to the demand by consumers for upscale brands and the perceived price advantage in comparison to brand products (Bloch et al, 1993; Casabona, 2006). The literature search revealed that consumers with economic needs or concerns were found to have a supportive attitude and satisfaction of counterfeiting, and seek CFP because of the price of such products (Tom et al, 1998). The reasons for consumers' positive attitude regarding buying counterfeits are the economic and hedonic benefits (Ergin, 2010). Research from social psychology demonstrated that attitude influenced behaviour, including the consumer's choice (Furnham and Valgeirsson, 2007). Addressing the demand part for the CFM problem was important in developing countries, where high and unaffordable medicine prices were linked with counterfeiting (Bird, 2007). Nevertheless, the factors that influence people to buy CFM are not understood, and few studies have addressed the public attitude towards CFM.

A thorough literature review was conducted on public attitude towards CFM, but very limited studies addressed this area (Bird, 2007; Furnham and Valgeirsson, 2007; Marcketti and Shelley, 2009; Ergin, 2010; Sugita and Miyakawa, 2010; Alfadl and Hassali, 2013; Alfadl et al, 2013). In addition, no studies on public attitude towards CFM in Lebanon were found.

A study at a university in the USA used a selected sample of 244 from four sophomore to senior-level undergraduate fashion and apparel undergraduate classes. The study used a 19-item questionnaire on concern for apparel industry issues, knowledge of counterfeiting, and attitude towards counterfeit items, intention to purchase, and willingness to pay more for genuine products. The findings suggested that consumers' willingness to pay more for genuine products directly increased with greater concern, knowledge and attitude towards CFP. Statistical analyses significantly and positively suggested a relationship among concern, knowledge, attitude and behavioural intent. The results suggested that educational and marketing campaigns that would make the effects of counterfeiting more evident, and personally relevant to consumers, might be effective means to reinforce consumers' beliefs about the negative consequences of CFP (Marcketti and Shelley, 2009).

A study in Turkey surveyed 385 adults between the ages of 18-35, to address the nature of the demand for counterfeits. Their findings showed that the four motivators for consumers to buy counterfeits were: perceived prestige, brand popularity, degree of product availability, and low prices (Ergin, 2010). The study only included participants 35 years

old and under, comparing the results with the older age groups, with different socioeconomic factors may have revealed different results. Therefore, their motivations might have been different due to higher levels of education and or income.

Another study in Sudan, examined the influence of certain factors on consumers' behaviour towards CFM, and used face-to-face structured interviews to collect data from 1003 members of the public (Alfadl and Hassali, 2013). The study found that motivation and subjective norm (i.e., society and peer pressure) were positively and significantly related to purchase intent of CFM. The findings showed that Sudanese consumers might have been motivated to buy CFM, because legitimate medicines may not have been accessible or affordable to them. Thus, the non-accessibility and non-affordability of legitimate medicines might be considered the main reason that encourages the behaviour of buying CFM in developing countries (Alfadl and Hassali, 2013).

And a study in Cotonou, Benin that utilized a questionnaire, evaluated several aspects of medicine purchasing behaviour in randomly selected households. The findings showed that 86% of respondents thought that medicines acquired from street shops were of good quality, and indicated the need for new campaign messages for targeted groups. They also indicated the necessity to have legitimate medicines to be more accessible and affordable to consumers, to simplify dispensing procedures, and to be followed by appropriate professional counselling (Abdoulaye et al, 2006a).

Consequently, a questionnaire was developed as an assessment tool to determine public attitude towards CFM and CFP in Lebanon. A thorough literature review through PubMed, Scopus, Cochrane Library, ScienceDirect, and MedlinePlus databases took place using the following key terms: counterfeit, counterfeit drug/medicines, counterfeit products, counterfeit items, fake items, fake products, consumer attitude, public health, public attitude, public attitude and surveys, pharmaceuticals and fake medicine/drugs, substandard medicine/drugs, poor quality medicine/drug and patients, counterfeit drug/medicines and patients, counterfeit drug/medicines and public, counterfeit drug/medicines and health, counterfeit drug/medicines and consumers, fake drug/medicines and consumers, substandard drug/medicines and consumers. The literature search was not restricted to a time frame, the author kept the years of research open due to the limited number of studies on attitude and CFM.

The aim of this study was to determine public attitude towards CFM, and analysis of findings by demographic factors. Accordingly, the study used the questionnaire to assess:

- a. Respondents extensive views on attitude towards CFM**
- b. Respondents extensive attitude towards pharmacists who deal with CFM**
- c. Respondents attitudes towards CFP**

5.2. Methods

A questionnaire was developed to assess public attitude towards CFM in Lebanon. It consisted of 30 questions.

5.2.1. Questionnaire design

The questions were mostly adapted from the study by Furnham and Valgeirsson (Furnham and Valgeirsson, 2007). This questionnaire consisted of 30 questions divided into three parts; Part 1) General information and demographics, Part 2) Questions on CFP, to determine respondents' attitude to counterfeiting in general, and Part 3) Questions on CFM. Most of the questions in the questionnaire were designed as closed questions. The questions related to attitude towards CFP and CFM were divided into three sections, quality and value, risk, and experience, to determine participants' perceptions.

This questionnaire used Likert-type scale statements as well as open-ended, closed, and multiple-choice questions. The Likert-type scale statements were used to measure the extent to which respondents held a particular attitude or perspective, where a given statement had a range of different responses (i.e., strongly agree/disagree, very willing/unwilling, etc...) (Cohen et al, 2000), and as a result measured psychological variables such as attitudes, abilities, sensitivity, personality traits, etc... (Bertram, 2007). A four-point scale was used to produce an ipsative (forced choice where no indifferent option is available) (Bertram, 2007), with 4 indicating the respondent strongly agreed with the statement and 1 indicating the respondent strongly disagreed, or 4 indicating the respondent was very willing and 1 indicating the respondent was very unwilling to perform an act. The forced choices were used to ensure respondents expressed an opinion or attitude answer on important preference question, for a more precise and insightful perspective on specific issues. There were questions where respondents were given a five-point scale, to determine if respondents were indifferent, with 5 indicating the respondent strongly agreed with the statement and 1 indicating the respondent strongly disagreed, however 3 reflected a neutral/unsure response. Likert scales falls within the ordinal level of measurement (Pett, 1997; Friedman and Amoo, 1999; Blaikie, 2003; Hansen, 2003; Jamieson, 2004; Bertram, 2007). Face validity of the questionnaire was assessed through experts in the field of pharmacy before it was piloted (Hardesty and Bearden, 2004; Broder et al, 2007).

The questionnaire was written in English, and translated into Arabic according to a standardized process to validate the translation. Translation of the answers into English was done at the time of data entry.

5.2.2. Ethical Requirements

The study was submitted and approved by the Research Ethics Committee, at University of Brighton School of Pharmacy and Biomolecular Sciences (**Appendix 5.I**).

The author obtained verbal consent before individuals agreed to participate, respecting respondents' autonomy and anonymity. The dates and times when the questionnaires were administered were all documented. The questionnaire did not collect personal data from participants, hence ensuring anonymity.

5.2.3. Procedure

The author piloted the questionnaire for validation content, on 10 members of the public (shoppers) at a supermarket in the ML area. Respondents took around 6-10 minutes to fill out the survey, and found the questions to be simple and straightforward, and the format was easy to follow. Therefore, the author did not change the questionnaire, and used it for the study (**Appendix 5.II**).

5.2.4. Setting and study population

The study was based in Lebanon, and trained pharmacy students (surveyors), carried out the survey. The inclusion criteria were any adult above 18 years old, who could speak or read English or Arabic, since the survey was available in those two languages.

The study used a convenience sample, and the approach was based on the willingness of members of the public to participate, since they were approached in shopping malls and other public places in different areas in Lebanon. Public places, were chosen for the diversity of the members of the public that may be present in such areas, and the easy access to them in such places.

Surveyors introduced themselves; stated the purpose of the study, and the approximate time it would take to fill out the questionnaire (around 10 minutes). Surveyors assured

respondents that the information they provide would be anonymous. Data collection took three months (from April 2011 to June 2011) to complete, and data entry an additional three months.

5.2.5. Data analysis

Questionnaire responses were entered on an Excel sheet, and analysed using Triple One, Version 2 (Matrix, 2015), an automated statistical reporting tool and descriptive analysis was undertaken, where frequencies and percentages were reported for all categorical variables. Bivariate analyses were also performed and included the use of the Chi-square test. The t-Nullity test (a regression test) was also used to determine linear relationships. The t-student test was used for determining any statistical differences between the sample means.

5.3. Results

More of the younger age groups were willing to participate than the older groups. The sample included 385 respondents; more than half were females (56.5%) and were relatively young (49.8% were under 30) with Almost 60% being from the Mount Lebanon region. The majority of respondents (78%) had at least an undergraduate level of education (Table 5.1).

	Total (N=385)
	N (%)
Gender	
Male	161(43.5)
Female	209(56.5)
Age	
21-30	191 (49.8)
31-40	62 (16.2)
41-50	74 (19.3)
50 and above	56 (14.6)
Region	
Mount Lebanon	229 (59.6)
Beirut	77 (20.1)
North	63 (16.4)
Bekaa	10 (2.6)
South	5 (1.3)
Years lived in Lebanon	
Less than 10 years	56 (14.5)
10-20	47 (12.2)
20-30	148 (38.4)
30-40	38 (9.9)
40 years and above	96 (24.9)
Education	
Secondary and below	54 (14.0)
University	223 (57.9)
Graduate	78 (20.2)
Technical / Others	30 (7.8)

Table 5.1. Respondents' general information and demographics

5.3.1. Respondents' willingness to buying counterfeit products

To determine respondents' willingness to buying CFP, the questionnaire included a list of products to choose from, given good price and quality. Respondents reported to be more willing to buy counterfeit CDs (75.6%), videos (72.5%) and pens (71.7%), followed by clothes (58.4%), and the remaining products they were less willing to buy (**Figure 5.1**).

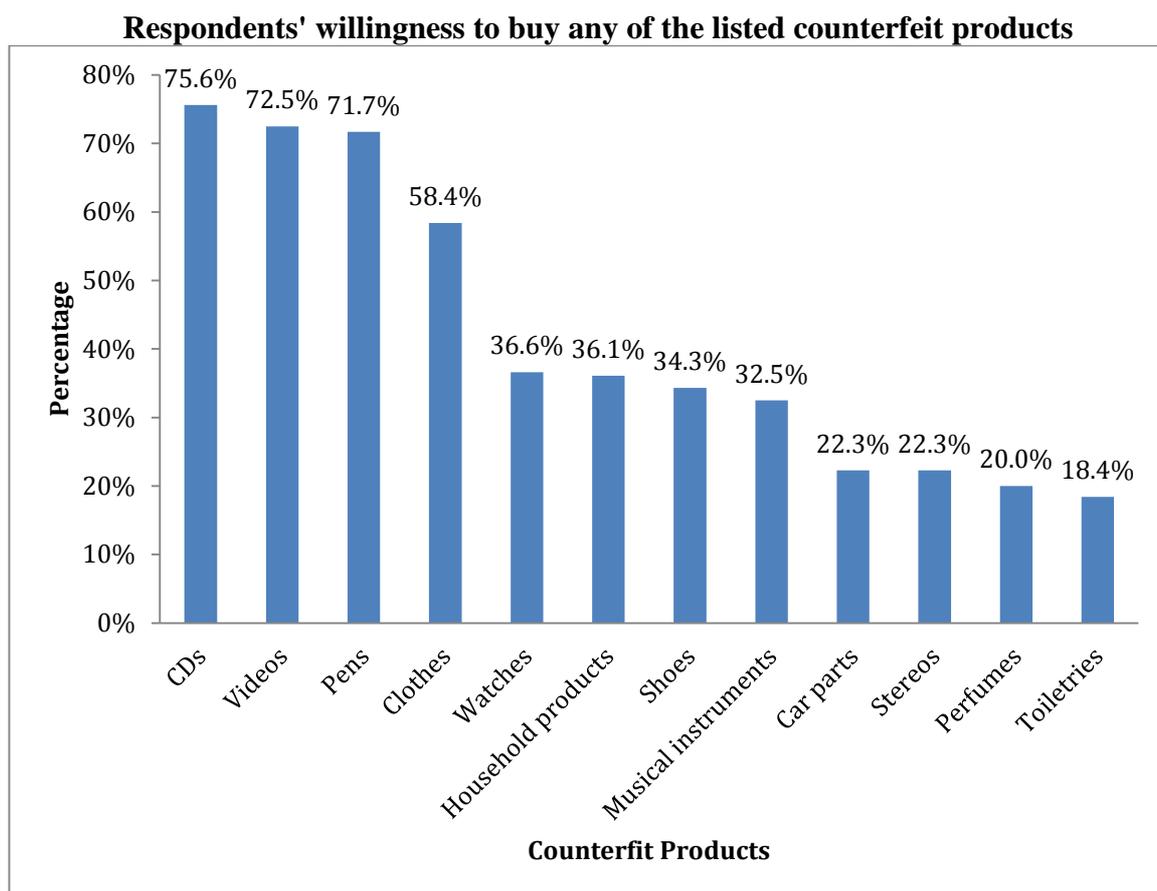


Figure 5.1. Respondents' reported willingness to buying specific counterfeit products

5.3.2. Public's attitude towards counterfeit products

In order to determine the public attitude towards CFP, statements describing the quality and value, risk and experience with CFP were used to assess their attitude. In order to determine respondents overall attitude, data from the questionnaire were analysed and summarized in **Table 5.2**, after dichotomizing the answers to strongly agree/agree and strongly disagree/disagree. The results revealed that only 11.7% of respondents reported to believe that CFP were as good as the original ones, and about 64.7% reported that many branded products were overpriced. Moreover, 62.6% believed that CFP could be dangerous, 52.5% of the respondents reported to believe they could easily spot CFP, and 67.3% reported that they knowingly bought CFP in the past. No statistically significant differences were observed between responses and respondents' level of education, gender, age, and area of living, ($P>0.05$).

Statement	Strongly Agree/Agree N(%)	Strongly disagree/disagree N(%)
Most counterfeit products are as good as the originals	45 (11.7)	251 (65.2)
Many branded (original) products are highly priced; while counterfeit products are of better value	249 (64.7)	70 (18.2)
Counterfeit products can be very dangerous	241 (62.6)	58 (15.1)
It is easy to spot counterfeit products by their quality and price	202 (52.5)	87 (22.6)
I have knowingly bought counterfeit products in the past	259 (67.3)	67 (17.4)

Table 5.2. Respondents' attitude towards counterfeit products

5.3.3. Public's attitude towards counterfeit medicines

The questionnaire also used statements describing the value, danger, and experience with CFM, to determine respondents' attitude towards them. Data from the questionnaire on CFM were analysed, and summarized in **Table 5.3**, after dichotomizing the answers to strongly agree/agree and strongly disagree/disagree. A minority of respondents (6.2%) believed that CFM were as good as the originals, and 46% believed that original medicines were highly priced, and CFM were of better value. Almost (81%) were aware of the danger of CFM. Furthermore, less than half of respondents believed that they were not able to differentiate a CFM from the original and 12.5% have knowingly bought CFM in the past (**Table 5.3**). No statistically significant differences were observed between responses and respondents' level of education, gender, age, and area of living, ($P>0.05$).

Statement	Strongly Agree/Agree N(%)	Strongly disagree/disagree N(%)
Most counterfeit medicines are as good as the originals	24 (6.2)	320 (83.1)
Many branded (original) medicines are highly priced; while counterfeit medicines are of better value	177 (46.0)	119 (30.9)
Counterfeit medicines can be very dangerous	310 (80.5)	42 (10.9)
It is easy to spot counterfeit medicines by their quality and price	171 (44.4)	86 (22.3)
I have knowingly bought counterfeit medicines in the past	48 (12.5)	288 (74.8)

Table 5.3. Respondents' perception regarding counterfeit medicine

5.3.4. Public's attitude towards pharmacists

In order to determine respondents' attitude towards pharmacists who dealt with CFM, the questionnaire included different statements describing pharmacists who deal with CFM. A small percentage of respondents (14.3%) agreed that pharmacists dispensing CFM were clever; a higher percentage (21%) agreed that they were good businessmen/women. Moreover, almost 81.3% and 83.1% agreed that those pharmacists were unprofessional and unethical respectively, whereas 79.5% believed that the pharmacists did it for the money, and 78.4% for the big profit. Finally, only 14.5% agreed that pharmacists would dispense CFM for the quality is acceptable (Figure 5.4). No statistically significant differences were observed between responses and respondents' level of education, age, gender, or area of living ($p>0.05$).

Statement	Strongly Agree/Agree N(%)	Strongly disagree/disagree N(%)
Pharmacists that knowingly dispense CFM are very clever	55 (14.3)	286 (74.3)
Pharmacists that knowingly dispense CFM are good businessmen/women	81 (21.0)	257 (66.8)
Pharmacists that knowingly dispense CFM are unprofessional	313 (81.3)	41 (10.6)
Pharmacist that knowingly dispense CFM are unethical	320 (83.1)	39 (10.1)
Pharmacists carry CFM in their pharmacy because it is easy money	306 (79.5)	29 (7.5)
Pharmacists carry CFM in their pharmacy for the big profit	302 (78.4)	32 (8.3)
Pharmacists carry CFM in their pharmacy because the quality is acceptable	56 (14.5)	209 (54.3)

Table 5.4. Respondents' perception of pharmacists who deal with counterfeit medicine

To check the internal consistency of respondents' answers to this questionnaire, and the reliability of their responses, Cronbach's alpha coefficient was used. The acceptable value of alpha coefficient according to the literature; has ranged from 0.9 down to 0.6 (Nunnally et al, 1967; Bland and Altman, 1997; Clark and Watson, 1995; Tavakol and Dennick, 2011; DeVellis, 2012). The following questions were used to check for consistency and

reliability; questions 23, 25, and 26 (Pharmacists that knowingly dispense CFM are very clever, Pharmacists that knowingly dispense CFM are unprofessional, and Pharmacist that knowingly dispense CFM are unethical), the alpha coefficient value for all the items was 0.69. And for questions 18, 22 and 29 (Most counterfeit medicines are as good as the originals, I have knowingly bought counterfeit medicines in the past, and pharmacists carry CFM in their pharmacy because the quality is acceptable), the alpha coefficient value for all items was 0.64. The alpha coefficient value for both groups of questions was >0.6 , although the value was < 0.7 , the results of the survey would be considered reliable and consistent, since the test used only 3 items.

5.3.5. Comparison between public's attitude towards CFP and CFM

Responses to questions (13-17) and (18 to 22) were compared to determine if respondents' attitudes towards CFP and CFM were related. The t-nullity test was used to determine the relationship between the compared statements. When comparing the two statements; CFP can be very dangerous and CFM can be very dangerous, the t-nullity test confirmed that the slope is statistically different from 0, $t(383) = 7.10$, $p < 0.05$. Comparing the two statements; CFP are as good as originals with CFM are as good as originals, the t-nullity test confirmed that the slope is statistically different from 0, $t(383)=8.89$, $p < 0.05$. When comparing the two statements; many branded (original) products/medicine are highly priced; while CFP/CFM are of better value, the t-nullity test confirmed that the slope is statistically different from 0, $t(383)=9.07$, $p < 0.05$. The t-nullity test also confirmed that the slope is statistically different from 0, when comparing how easy it is to spot CFP and CFM since, $t(383)=6.09$, $p < 0.05$. Respondents reported knowingly purchasing more CFP in the past than CFM, and the t-nullity test confirmed that the slope is statistically different from 0, $t(383)=3.16$, $p < 0.05$.

Additionally, the t-test was used to compare the mean value for the statements related to CFP and CFM, to determine if people responded differently to the two statements.

Comparing the two statements; CFP are as good as originals with CFM are as good as originals showed statistical significance with $t(768)=-7.91$, $p < 0.05$, indicating that respondents responded differently to the two statements, and disagreed more that CFM were as good as the originals.

When comparing the two statements; many branded (original) products/medicine are highly priced; while CFP/CFM are of better value, showed statistical significance with $t(768)=-5.44$, $p<0.05$, indicated that respondents responded differently to the two statements, and agreed more that CFP were of better value than they did for CFM.

When comparing the two statements; CFP and CFM can be very dangerous, showed statistical significance with $t(768)=5.50$, $p<0.05$, indicated that respondents responded differently to the two statements, and agreed more that CFM were more dangerous than they considered CFP.

Respondents who reported knowingly purchasing more CFP in the past than CFM, showed statistical significance with $t(768)=-20.84$, $p<0.05$, more people buying CFP and few people who knowingly bought CFM in the past.

And when comparing how easy it is to spot CFP and CFM, no statistically significant difference were observed between spotting CFP and CFM, with $t(768)=-1.46$, $p>0.05$. The t-Test paired two sample also did not show statistically significant differences between spotting CFP and CFM, with $t(384)=1.73$, $P>0.05$.

5.4. Discussion

The results were able to demonstrate respondents' reported attitude towards CFP, and their awareness of the risks related with such products. The majority of respondents were willing to buy many of the listed CFP, and more than half of respondents could easily spot CFP by their quality and price. With respect to CFM, the results revealed that respondents reported agreeing that the original medicines were highly priced, and CFM were of better value, and that CFM are of risk, in addition less than half could easily spot CFM by their quality and price. Finally the majority of respondents reported that they believed that pharmacists who knowingly dispensed CFM were unethical and unprofessional.

Respondents in the study provided a close representation of the population, according to the central administration for statistics (CAS) (Lebanon in Figures, 2008) and world fact book of the CIA (Central intelligence agency, 2014). According to these references, the age group (25-54) represents 44.1% of the population, and 6.9% for the age group 55 and above (Lebanon in Figures, 2008; Central intelligence agency, 2014). About 90% of Lebanon's youth and adult population are literate, with few gender disparities (UNESCO, 2013). Almost 50% of the population lives in the governorates of Beirut and Mount Lebanon, 20% in the North, 13% in the Bekaa, and about 18% in the South. (Ministry of finance, 2011) Respondents of this study were mostly from the Mount Lebanon, Beirut, and the North, and the highest percentage of respondents received at least a university degree, indicating an educated sample. Almost half of the respondents reported to be in age group 21-30, and the majority of respondents were females.

The sample represented more the younger age group, who were also the more educated, and this may have contributed to the overall attitude of respondents. Therefore, future studies may need to consider assessing the attitude towards CFM using older age groups and lower levels of education. Additionally, this study, investigated respondents' general background, but excluded religion, and political inclinations, although may be predictors of willingness to buy counterfeits. However, including such questions would have discouraged people from participating, due to the sensitivity towards these topics in the Lebanese culture, coupled with the political instability of the country.

The majority of respondents in this study were willing to buy counterfeit pens, clothes, CDs and videos, and less likely to buy personalized products. In a similar study (Furnham, and Valgeirsson, 2007), respondents also seemed less likely to buy personalized

counterfeits such as perfumes and toiletries. Another study found a positive relationship between value consciousness “a concern for paying lower prices, subject to some quality constraint” and attitude toward counterfeit CDs (Lichtenstein et al, 1990), for participants in this study, their willingness to buy counterfeit CDs and videos might have been due to the obvious price advantage in comparison to the original product (Bloch et al, 1993; Albers-Millers, 1999). Other studies have also shown that, the better the quality, or expected performance of a counterfeit, the more likely people were willing to buy the counterfeit. Respondents of this study also reported to believe that CFP were inferior to the originals as most of respondents did not consider CFP to be as good as the original, however, agreed that the originals were highly priced, and CFP were of better value. As for risk, most agreed that CFP could be very dangerous. In support, different studies reported that people realized that counterfeits were inferior to originals (Prendergast et al, 2002; de Matos et al, 2007; Penz and Stöttinger, 2008; Commuri, 2009).

This study shows that experience might have been the source of awareness and the base behind respondents’ responses, for slightly more than half of them reported being able to easily spot CFP by quality and price, and that the majority knowingly bought CFP in the past. Many people knowingly buy CFP and this is referred to as non-deceptive counterfeiting, therefore, counterfeiters sell CFP to satisfy consumers’ demand (Arellano, 1994; Kim and Karpova, 2010). A closer look at respondents’ attitude towards CFP in relation to their background revealed no statistically significant association with respect to education, age, gender, and area of living.

With respect to respondents’ attitudes towards CFM, less than half agreed that original medicines were highly priced and CFM were of better value, yet the high majority agreed that CFM could be very dangerous. A study with similar findings reported that, when the authors considered the variability in what products people were prepared to buy, results showed that in comparison to the listed products, people were by far less willing to buy CFM than the other CFP (Furnham, and Valgeirsson, 2007). Although, respondents may believe that CFM were inferior to their original, however their superior prices might compensate for the lower quality and efficacy (Ang et al, 2001). This could be the case for the members of the public with low socioeconomic status, when the price of a CFM could be an attractive alternative, especially when risks are not known and understood. Participants of this study considered CFM to be dangerous demonstrating their ability to realize the increased danger associated with CFM, however, it was not easy for respondents to spot CFM by their quality and price. A study reported that consumers are

not affected by low quality and poor material, since they do not consider counterfeits as inferior when they are under budget constraints (Ang et al, 2001).

A 2012 study in Sudan, examined the influence of certain factors on consumers' behaviour regarding CFM, and found that motivation and subjective norms were positively and significantly related to purchase intent of CFM, but not attitude. Additionally, the findings suggested that Sudanese consumers might be motivated to buy CFM when medicines are inaccessible and/or unaffordable, and these were considered the main contributors to buying CFM in developing countries (Alfadl et al, 2012). Therefore, controlling the cost of medicine needs to be considered, and evaluated by pharmaceutical companies, MoPH and health authorities. If cost is considered one of the reasons why people buy CFM, then re-evaluating the cost would be an option to address. Cost would be an aspect to address in decreasing the demand and availability of CFM, "It could take away a lot of the incentive for counterfeiting" (Burki, 2010).

Less than half of respondents believed it was easy to spot CFM by their quality and price. The study in Turkey, showed that respondents would not hesitate to buy the original products if they could afford them (Ergin, 2010). Again more affordable medicines or generics could be an alternative to CFM. However, with the sophistication of counterfeiters, patients should realize the importance of choosing the appropriate source of their medicine. Cheaper medicine does not necessarily mean it is CFM; therefore, education about generics would also be necessary. Studies reported that patients were confused and not sure if "generic brands" of medicines were in fact counterfeits (d'Astous and Gargouri, 2001). Many studies also reported that, lack of patients' knowledge about CFM led them to have more of a negative attitude towards generic medicines (Bang et al, 2000; Liang, 2006b; Marcketti and Shelley, 2009). The more knowledgeable people become about CFM and generics the stronger they would feel about the positive benefits of generic medicine (Ajzen and Fishbein, 1980). Generics of essential medicines have a global public health benefit, because they are less expensive and more accessible to people (Newton et al, 2011). It would be crucial at this time to remember that, as per the WHO definition, that generic medicine can also be counterfeited; therefore, education and awareness are important. Consequently, according to Chapter Four of this study, respondents of the public awareness survey reported that the best way to avoid buying CFM, was going to a trustworthy pharmacist.

Moreover, in this study, the majority of respondents reported to disagree that pharmacists who dispensed CFM were clever, or good businessmen/women, however agreed that those pharmacists were unprofessional and unethical, and were dealing with CFM for the profit and easy money. Respondents' reported answers reflected the negative attitude they had towards pharmacists who dealt with CFM. This view could have a negative impact on the patient-pharmacist relationship, and the trust between them. Doubting the credibility or the professionalism of pharmacists would damage the trust placed in pharmacists, and would jeopardize pharmacists' trustworthiness, especially if the people suspected or knew of pharmacists who were selling CFM. The public needs to be assured that pharmacists as HCP do care about patients' safety, and well-being. The MoPH and OPL could have a role in maintaining control of the pharmacy practice, and improving the image of pharmacists, in addition to the continuous educational campaigns that address CFM.

The comparison between respondents' responses to CFP and CFM statements, demonstrated that respondents considered CFM to be more dangerous than CFP indicating awareness towards the associated risks with CFM. Additionally, respondents disagreed more with the statement related to CFM being as good as originals when compared to CFP. Respondents disagreed more with the statement that the price of CFM was better than its original, than for CFP, suggesting that respondents did not consider CFM equally with CFP. Respondents disagreed more with the ability to spot CFM by their quality and price, than they did for CFP and this demonstrated awareness towards the difficulty of differentiating CFM from originals. Respondents bought more CFP in the past than they did CFM, and this finding further indicates that participants were more cautious with CFM purchases, yet the need still remains for additional educational campaigns to increase awareness and knowledge about the risks related to CFM use.

The study showed that respondents reported to have a more positive attitude towards CFP than CFM, and a negative attitude towards pharmacists who dealt with CFM. Respondents' attitude towards CFP and CFM according to the t-Nullity test were related, however, respondents had a more negative attitude towards CFM than CFP. Additionally using the t-test, statistical significance was observed and participants responded differently for CFP than CFM, however the only insignificant finding was with the easiness of spotting counterfeits, indicating how difficult it is becoming to differentiate between the counterfeits and originals with the sophistication of counterfeiters. This was supported by the results reported in Chapters Two and Three.

The results suggest the need for educational campaigns, emphasizing the risks and consequences associated with CFM, in addition to addressing the public demands for CFM. Considering the difficult and challenging economic situation in Lebanon, pricing of medicines may be the reason behind the demand for counterfeits. Therefore, in order to reduce its effect on the demand and supply equation, re-evaluating the prices of medicine by MoPH, pharmaceutical companies, and OPL may be one option, in addition to introducing more affordable alternatives such as generics. Respondents considered pharmacists who dealt with CFM unethical and unprofessional, and would carry CFM for the big profit and easy money. Furthermore, the study demonstrated the need to provide educational programs that would highlight pharmacists' role as healthcare professionals, and the vital role they have in preventing the use of CFM. However, more studies should address the public's perception, and attitude towards pharmacists, and their role with CFM.

According to the TPB, behaviour can be deliberate and planned, however the prediction of intentions is expected to vary across behaviours and situations, the study supports the theory, as participants' attitude towards CFP was different than CFM. The TPB is guided by three considerations; behavioural beliefs, normative beliefs, and control beliefs (Ajzen and Fishbein, 1980; Ajzen, 1991; Ajzen, 2005; Kim and Karpova, 2010). The behavioural beliefs gave the negative attitude towards CFM and the more favourable attitude towards CFP. The normative belief is more of the perceived social pressure or the subjective norm, and control belief is to perceive behavioural control; to buy or not to buy (Ajzen and Fishbein, 1980; Ajzen, 1991; Ajzen, 2005.;Kim and Karpova, 2010). The TPB could explain why campaigns only provide information that do not help change behaviour much, rather campaigns that focus on attitudes, perceived norms and control would have better results in changing the behaviour (Ajzen and Fishbein, 1980).

In addition, understanding the public attitude and cultural influences is critical to developing effective campaigns towards CFM. As an example, according to Hong Kong's IP director, in Chinese culture the importance of face is used, "People buy fashion and accessories because of peer pressure, so that's a good toll to use in the other direction" so they say "You are what you wear; if you wear fake clothes you're a fake person" (Bowman, 2008). A message that may work in one part of the world may fail in another. According to secretary general of the Italian anti-counterfeit trade association Indicam, scare or shame would not work with Italians, rather the focus would be on education such as "you're ruining the Italian economy and supporting crime" (Bowman, 2008). For those that do not know much about the economy they could be educated, however, it would be a

long process. Future studies may consider evaluating public attitude, subjective norms and perceived behavioural control, in addition to the cultural influences towards counterfeiting in general and CFM in particular.

Henceforth, educational campaigns should continue to address awareness, however, more should focus on the social and financial risks of CFM. The study would suggest for the MoPH, and regulatory authorities to implement and enforce the law against offenders, and to use extreme legal measures.

As a follow up to public awareness towards CFM in Chapter Four, this chapter included more description of public attitude towards CFM, according to quality, value, risk and experience with CFM. The following Chapter (Six) would be describing pharmacists' awareness and attitude towards CFM, as the healthcare professionals who buy and dispense medicine to patients.

5.5. Conclusion

The study demonstrated the need for educational campaigns that focus on the risks and consequences associated with CFM, and why the public would demand CFM, in order for the public to make an informed decision. The MoPH and pharmaceutical companies may need to consider re-evaluating the pricing of medicines to decrease the public demand for counterfeits. Respondents considered pharmacists, who dealt with CFM unethical and unprofessional, and carried CFM for the big profit and easy money. Therefore, the educational programs should also highlight the pharmacists' vital role in providing safe and effective medicine.

Chapter Six

Pharmacist Awareness and Attitude Towards Counterfeit Medicine in Lebanon

6.1. Introduction

Pharmacists have always been compassionate listeners and caregivers (Vogt and Finley, 2009), like many other healthcare professionals (HCP). However, pharmacists in particular, are able to identify, prevent and resolve medicine-related problems, and improve patients' health outcomes (Cerulli, 2001; Posey, 2003). Pharmacists ought to have patients' well-being and safety as their primary concern, consequently; pharmacists' unique duty is to guarantee that safe and effective medicines are dispensed to and used by patients (General Pharmaceutical Council, 2015). It would not be enough to provide sophisticated pharmaceutical services (Hepler and Strand, 1990), when the safety and efficacy of treatments may be compromised by the availability of counterfeit medicine (CFM). Counterfeit medicines are documented to cause serious consequences that range from infectivity, to more serious outcomes such as antibiotic resistance with resulting effects on patients' morbidity and mortality (Dondorp, et al, 2004; Deisingh, 2005; Luu, 2005; Newton et al, 2006a; Newton et al, 2006b).

The previous Chapters (Four and Five) of this thesis assessed public awareness and attitude towards CFM, and this chapter will also assess what Lebanese pharmacists know about CFM, and their experiences of them.

The primary problem with CFM is the significant risks they pose to public health and safety. Counterfeit medicine has raised questions as to where pharmacists stand with respect to the trust placed in them, since they are considered the key to patient safety with regard to medicine (Besançon. 2008). With the availability of CFM, it has become challenging for pharmacists to ensure and assure patients that their medicines were safe and effective. This could be accomplished provided pharmacists are aware of CFM, their availability in their market (country), and the measures to be taken by pharmacists, and the regulatory authorities to safeguard patients.

The differences between a developed country and a low to middle income country are their regulatory abilities, and the limited enforcement of regulations that may be due to constraints by limited government power (Lowe and Montagu, 2009). The practice of pharmacy in Lebanon is controlled through the Ministry of Public Health (MoPH), by the laws and regulations on who can practice pharmacy, the conditions that a pharmacy should follow, in addition to laws governing prescribing and dispensing of medicine (Lebanese Order of Pharmacists, 2014a). Medicines in Lebanon are only available in pharmacies and

dispensed by registered pharmacists (Lebanese Order of Pharmacists, 2014a). This is unlike other developing countries, where products may be dispensed by different types of retailers such as product sellers, general stores, or by doctors (Lowe and Montagu, 2009).

In Lebanon, there are more than 6900 registered pharmacists; 19 pharmacists for every 10,000 members of the public, in a country that has a total area of 10,452 square kilometres, with a population close to 6 million (Karam, 2004; Central intelligence agency, 2014; Lebanese Order of Pharmacists, 2014b; NationMaster, 2014). Furthermore, there are 2806 registered pharmacies, a ratio four times the normal ratio considered worldwide, according to the Lebanese Order of Pharmacists (OPL) (Lebanese Order of Pharmacists, 2014b; Lebanese Order of Pharmacists, 2015). The continuous increase in the number of pharmacists every year lead to the decrease in pharmacists' minimum wages to USD1350/month. The OPL proposed to restrict the number of schools of pharmacy, and students admitted to the schools of pharmacy in Lebanon, to control the over saturation of pharmacists in the country (Lebanese Order of Pharmacists, 2014b).

In order to address CFM, the OPL in collaboration with MoPH, International Pharmaceutical Federation (FIP)-WHO Eastern Mediterranean Regional Office Pharm Forum and the Conférence Internationale des Orders de Pharmaciens Francophones, in 2008 launched a campaign on CFM. They published a guide for pharmacists, in addition to leaflets, posters, and brochures for pharmacists, doctors and the public on CFM (International Pharmaceutical Federation, 2015a). All were actively involved in raising awareness of CFM, through the media, billboards, and conferences (Chauve, 2008).

A study in California, USA (Law and Youmans, 2011) examined pharmacists' knowledge of CFM, impact of technology and barriers to pharmacists' involvement, and potential roles that pharmacists can undertake. Their sample represented a diverse distribution of practice sites. The results revealed that of the 155 respondents, almost two thirds reported belief that CFM posed a problem to the profession. However, two thirds of respondents reported no experience with CFM, and since the USA is a developed country, the likelihood of pharmacists encountering CFM would be expected to be low (The World Bank, 2015) due to less CFM prevalence. Additionally, pharmacists reported identifying CFM by alerts from the Food and Drug Administration (FDA), recall notices from the district managers, in addition to labelling and altered tablets. Pharmacists reported believing that lack of awareness and resources were barriers to detecting CFM, and most indicated a lack of knowledge regarding new technologies (Law and Youmans, 2011).

More than half of respondents reported that pharmacists were responsible and had a role in educating patients about CFM. The findings concluded that many barriers were hindering opportunities for pharmacists to get involved, in addition to the methods to identify CFM, such as improved communication between officials (FDA, Board of pharmacy) and pharmacists, to provide more resources and dissemination information, in addition to educational programs (Law and Youmans, 2011). The study addressed the issues present in the USA, however, there was no definition of CFM by respondents, to determine if all were evaluating the same thing, and this was evident with respondents (15.9%) who did not know if they had ever encountered CFM, in addition to the two thirds reporting having no experience with CFM. Since the USA is a developed country, the likelihood of pharmacists encountering CFM would be expected to be low.

A recent study in Jordan (Taleb & Madadha, 2013), a developing country, used a questionnaire, to identify pharmacists' awareness and the contributing factors of CFM in Amman, Jordan, using a descriptive cross sectional design. The study included a convenience sample of 100 Jordanian pharmacists from 3 different areas of pharmacy; community (75%), industrial (17.7%), and quality control (6.5%). The data collection was by a self-reported questionnaire, with 62 Jordanian pharmacists completing the questionnaire. The majority (76%) were aware of the CFM problem and the current laws and regulations in Jordan. However, around one third of the community pharmacists did not believe that there were penalties for trading of CFM, and according to the authors it was a serious problem, since community pharmacists were the main targets for counterfeiters. This might explain why half of respondents did not think counterfeiting was a serious problem, and reported to believe that it would be difficult for CFM to invade the Jordanian market. Additionally, 37% of respondents reported encountering CFM cases themselves, however it was not clear what the authors meant by it. The study suggested that the fight against CFM is a shared responsibility among all parties involved, however, this would be best achieved through awareness campaigns (Taleb & Madadha, 2013). The questions in the questionnaire used by the study were mostly related to the CFM laws and regulations, with few questions on the respondents' experience, rather than awareness towards CFM. The study did not ask how respondents would define, or identify a CFM, to determine awareness. The study highlighted the difference between awareness and knowledge, indicating the lack of knowledge towards the seriousness of CFM that could be further evaluated and addressed in educational campaigns.

There are many questions related to CFM, with few precise or definite answers. There is a gap in the literature in documenting pharmacists' knowledge, attitude and involvement in controlling and limiting the availability of CFM, and their role in educating the public and community about CFM. Additionally, a literature search did not reveal any work related to pharmacists and CFM in Lebanon.

Consequently, a questionnaire was used as a tool to assess Lebanese pharmacists' awareness and attitude towards CFM. The questionnaire was developed by the author and following a literature search. The methodology of the literature search for the questionnaire development followed the same search used in Chapters Four and Five, with an attempt to identify the issues practising pharmacists have encountered when dealing with CFM. Additional key terms used were; pharmacists and counterfeit medicine/product/drug, healthcare professionals and counterfeit medicine/product/drug, pharmacist awareness/attitude and counterfeit medicine/product/drug, pharmacist awareness/attitude questionnaires/surveys, pharmacist role and counterfeit/fake medicine/product/drug, pharmacist role and medicine/product/drug, pharmacist duty and counterfeit/fake medicine/product/drug, pharmacist responsibility and counterfeit/fake, pharmacist and fake medicine/product/drug, pharmacist and poor quality medicine/product/drug, and pharmacist and substandard medicine/product/drug. The literature search was not restricted to a time frame, was open and focused mostly on literature describing reports on CFM and how it was dealt with in different parts of the world. The emphasis was on how pharmacists dealt with CFM, and their reported experiences (Chakraborty et al, 1996; de Guzman et al, 2007; Besançon, 2008; Edelstein et al, 2008; Newton et al, 2009; Sengaloundeth et al, 2009; Law and Youmans, 2011; Shahverdi et al, 2012; Binkowska-Bury et al, 2013).

The purpose of this study was to assess the awareness and attitude of Lebanese pharmacist towards CFM and counterfeit products (CFP), and to explore the relationship between respondents' responses and their demographics. Therefore, the hypothesis is:

a. Pharmacists are aware of CFM

Accordingly, the objective was to assess pharmacists':

- a. Experience and views towards CFM**
- b. Attitude towards other pharmacists that dispense or deal with CFM**
- c. Attitude towards CFP**

6.2. Methods

The study is based on a questionnaire to assess the awareness and attitude of Lebanese pharmacist towards CFM and CFP.

6.2.1. Questionnaire design

The questionnaire was divided into three parts; **Part I**) Professional responsibility which consisted of questions that described pharmacists' professional responsibilities and knowledge about CFM. There were 23 questions in total, 6 open ended or qualitative questions, 8 multiple-choice questions, and 9 Likert-type scale statements. **Part II**) Questions about counterfeit products with 7 questions total; 3 multiple-choice questions, and 4 Likert-scale type statements. **Part III**) Demographic data, consisting of 6 questions, 5 close ended and one open ended. The open-ended questions required the interpretation of responses and were coded before being processed for computer analysis (Babbie, 2008). The purpose of part I was to determine the professional background, awareness of CFM, and attitude towards pharmacists who deal with CFM. Part II, was to determine the attitude towards counterfeiting in general. Part III was to determine the relationship between respondents' demographics and the provided answers. Face validity of the questionnaire was assessed through experts in the field of pharmacy before it was piloted (Hardesty and Bearden, 2004; Broder et al, 2007). There were no questions in the questionnaire on attitude towards CFM in order not to offend pharmacists.

The questionnaire was written in English and Arabic, and respondents had the freedom to choose the language they preferred to answer in. The data collection took three months (from April 2011 to June 2011) to complete and the data entry took additional four months.

Before carrying out the study, the questionnaire was piloted. The author administered two questionnaires in the Mount Lebanon (ML) area to determine how pharmacists would respond to the questionnaire and the topic. The author informed pharmacists of the study's objective and both were willing to participate in the study. Both pharmacists were French educated and English was their third language. They found the questions to be clear, easy to follow, but it was long, and took them around 15-20 minutes to complete.

The author trained pharmacy students (surveyors) to assist in carrying out additional pilot questionnaires and requested that they document the number of pharmacists who refused to

participate, and any comments made related to the study. The author explained the objective of the questionnaire with emphasis on how to approach pharmacists, when asking for their participation. The author emphasised that the questionnaire was voluntary and pharmacists should not be pushed or forced to participate. The ten additional pharmacists did not report having any problem with the questions, however, found the questionnaire long. Respondents reported that they would have preferred for the Yes/No questions to include a third option (Not sure). In addition, the majority of respondents thought the CFP questions were for medicine, and responded accordingly, based on their feedback at the end of the survey. They were surprised on how the questionnaire would ask pharmacists such questions and did not realise the questions were for counterfeit products in general. Furthermore, they were sceptical about other pharmacists being honest in their responses to questions.

The pilot questionnaire (**Appendix 6.I**), included 40 questions; and based on the pilot results was shortened to 36 questions and at this point; Part II was added to the questionnaire titled “Questions about counterfeit products”, and Part II became Part III. In addition, the author added a third option (Not sure) for the Yes/No questions when appropriate, questions were further simplified, and put in a table, and became easier to follow and answer. Once the final questionnaire (**Appendix 6.II**) was modified and ready to use, it was translated into Arabic and independently back translated for verification (Sperber, 2004).

6.2.2. Ethical requirements

The study was approved by the Research Ethics Committee, at University of Brighton School of Pharmacy and Biomolecular Sciences (**Appendix 6.III**). The same approach used for Chapters Four and Five, was used with pharmacists who participated in the study, using verbal consent, and respecting respondents’ autonomy and anonymity.

6.2.3. Setting and study population

The aim was to survey community pharmacists in different cities/areas in Lebanon, such as Beirut, Mount Lebanon, the North, South, and Bekaa. Surveyors were asked to step aside or leave the pharmacy, and return for the questionnaire after 30 minutes, to give the pharmacists some privacy when filling it out. When finished, surveyors would ask

pharmacists to place their completed questionnaire in an envelope with other questionnaires, for further reassurance of the anonymity of the process.

6.2.4. Study samples

An opportunistic/convenience sampling was used in this study. The convenience sampling involved selecting pharmacists based on pharmacists' willingness to participate (Gehart et al, 2001). The inclusion criteria were any practising pharmacist willing to participate and could speak and read English or Arabic. Surveyors had to introduce themselves, state the purpose of the study, and the approximate time needed to complete the questionnaire (around 10-15 minutes).

6.2.5. Data analysis

The data from the questionnaires were analysed using Triple One, Version 2 (Matrix, 2015) an automated statistical reporting tool. Descriptive analysis was also performed for this questionnaire where frequencies and percentages were reported for all categorical variables, bivariate analyses were performed and included the use of the Chi-Square test. For the Likert-type responses, all responses with any degree of agreement were grouped together as positive responses, and all responses with any degree of disagreement were grouped together as negative responses. Content analysis was also used to analyse the open-ended responses. Cronbach- α test was used to determine the reliability of respondents' responses to the questionnaire.

6.3. Results

Out of the 240 pharmacies visited, there were 17 pharmacists (7%) that refused to participate in the study. The distribution of non-responders according to regions was as follows; (5 Beirut, 1 ML, 5 Bekaa, 3 North, and 3 South). There were informal comments that came out of the pilot study which will be considered in the discussion of this chapter.

6.3.1. Demographic data

The study sample included 223 respondents. A descriptive analysis showed that 42.5% of respondents were female (n=90). The largest number of respondents was for the age group 31-40 years (39.2%), followed by the 21-30 years (28%). The majority of respondents' pharmacy locations were in the ML region (46%). Almost 50% of pharmacists had 10 years of experience or more, and 80% had obtained their degrees from Lebanon. The socioeconomic status of patients, as reported by majority of responding pharmacists was middle class (78.9%) (**Table 6.1**).

Demographics	Total (N=223)
	N (%)
Age	(N=222)
21-30	62 (27.9)
31-40	87 (39.2)
41-50	51 (23.0)
50 and above	22 (9.9)
Gender	(N=212)
Male	122 (57.5)
Female	90 (42.5)
Location of the Pharmacy	(N=215)
Mount Lebanon	99 (46.0)
Beirut	66 (30.7)
North	37 (17.2)
South / Nabatiyeh	10 (4.7)
Bekaa	3 (1.4)
Years practicing pharmacy	
Less than 5 years	70 (31.4)
5-10 years	45 (20.2)
Greater than 10 years	108 (48.4)
Socioeconomic Status of patients*	
Upper Class	49 (21.9)
Middle Class	176 (78.9)
Lower Class	43 (19.3)
Country of diploma	
Lebanon	179 (80.3)
Others	44 (19.7)

*N=268, respondents checked more than one answer

Table 6.1. Demographics of respondents

6.3.2. Professional responsibility

The analysis of the open ended question on defining CFM, showed that 57.5% of pharmacists reported to believe that the definition of CFM; was from an unknown source or was a bad quality product, 12.3% reported it did not have an FDA approval/unsafe and 11.8% reported it contained the wrong ingredients (**Table 6.2**). No statistically significant relationships were observed between respondents' responses and their demographics.

Definition of CFM* (N=204)	N (%)
• Unknown / Bad quality	117 (57.5)
• No FDA approval / Unsafe	25 (12.3)
• Wrong ingredient	24 (11.8)
• Placebo	20 (9.8)
• Identical to original effect	18(8.8)

*Counterfeit medicine

Table 6.2. Respondents' definition of counterfeit medicine

The analysis of the open-ended question on the source of CFM showed that almost 39% of respondents believed that the main source of CFM was China, 24.1% did not know, and 23.6% reported India (**Table 6.3**). No statistically significant relationships were observed between respondents' responses and their demographics.

Country of Origin	N (%)
China	82 (38.7)
Do not know	51 (24.1)
India	50 (23.6)
Arab Countries	38 (17.9)
Rest of the World (Africa and Latin America)	28 (13.2)
Far East Asia	23 (10.8)
Lebanon	19 (9.0)
Europe / USA	18 (8.5)

Table 6.3. The source of counterfeit product according to respondents

The open-ended question on how respondents became aware of CFM, showed that almost 40% of respondents became aware of CFM through the TV and 36% through the MoPH, OPL and WHO. Only 4% reported the CFM campaign, and 21% of respondents reported becoming aware of CFM through their experience/practice/education. No statistically significant relationships were observed between responses and respondents' demographics.

Respondents were also asked if they were aware of any campaign regarding CFM; 55% of respondents reported being aware of the campaign and 29.6% reported not being aware, 14.8% reported not sure, and 1.9% did not answer. There was no significant relationship response and demographics.

The majority of responding pharmacists reported differentiating CFM from their originals by the medicine's effect (67.7%), followed closely by cost (66.8%), then hologram (65.9%), and suppliers (64.1%) (**Table 6.4**).

Item	N (%)*
Product effect (N=223)	151 (67.7)
Cost (N=223)	149 (66.8)
Hologram (N=223)	147 (65.9)
Suppliers (N=223)	143 (64.1)
Packaging (N=223)	133 (59.6)
Package insert Information (N=223)	67 (30.0)
Other (N=223)	34 (15.2)

*Total >100% because respondents chose more than one answer,

**Counterfeit medicine,

Table 6.4. How respondents reported differentiating CFM** from their original

Using the Chi Square test, a statistically significant difference was only observed with gender with 77% of female pharmacists reporting that they believed that they could identify CFM from the original by the effect of the product, $X^2=5.79$ (df=1), $p<0.05$, and 37 (41.1%) of females versus 27 (22.1%) of males could distinguish a CFM from the package insert information, with $X^2=8.85$ (df=1), $p<0.05$.

As for knowing other pharmacists that dispensed CFM, 43% of respondents reported knowing other pharmacists that dispensed CFM, and 63.5% believed that the pharmacists were aware that they were dispensing CFM. Additionally, 85% of respondents reported believing that pharmacists who knowingly dispensed CFM should face consequences. The majority of respondents reported that such pharmacists should be punished with either a fine or prison sentence. Almost one third of respondents believed that pharmacists dealing with CFM should have their license withdrawn or their pharmacy closed (**Table 6.5**).

Questions	N (%)
Do you know of pharmacists that dispense CFM*? (N=212)	
Yes	91 (42.9)
No	121(57.1)
Was the pharmacist aware of dispensing CFM? (N=96)	
Yes	61 (63.5)
No	35 (36.5)
Should there be any consequences to dispensing CFM? (N=212)	
Yes	181 (85.4)
No	31 (14.6)
Actions to be taken against pharmacists dispensing CFM (N=92)	
Punishment /Pay penalty / Jail	47 (51.1)
Withdraw license / Close pharmacy	25 (27.2)
Inform MoPH / OPL	20 (21.7)

*Counterfeit medicine

Table 6.5. Respondents' awareness of other pharmacists that dispensed CFM, and the actions to be taken against them

Respondents who were among the age group 51-60 years, were less likely to report knowing about pharmacists dispensing CFM (11.7%) than those in the prevalent age group 31-40 years (35.1%), $X^2=5.43$ (df=4), $p<0.05$. For pharmacy location, statistical significance was observed with respondents from the Bekaa, being the least likely to report knowing about pharmacists dispensing CFM (2.2%) with the most to report from the Mount Lebanon region (43.3%), $X^2 = 13.52$ (df=5), $p<0.05$. No statistical significance was observed for the other questions listed in Table 6.5.

The statements describing pharmacists who deal or dispense CFM were analysed and summarized in **Table 6.6**, after dichotomizing the answers to strongly agree/agree and strongly disagree/disagree. The results showed that the majority of respondents (81.2%) disagreed that pharmacists who dispensed CFM were very clever, or were good businessmen/women (70.9%) and agreed that dispensing CFM was unprofessional (89.2%) and unethical (86.5%). Respondents also agreed that pharmacists who dispensed CFM did it for the easy money (87.9%), and big profit (86.5%). In addition, 26% agreed that pharmacists carried CFM in their pharmacies for their acceptable quality (**Table 6.6**). No statistically significant differences were observed in respondents' responses and their demographics.

Statement	Strongly Agree/Agree N(%)	Strongly disagree/disagree N(%)
Pharmacists that knowingly dispense CFM* are very clever	42 (18.8)	181 (81.2)
Pharmacists that knowingly dispense CFM are good businessmen/women	65 (29.1)	158 (70.9)
Pharmacists that knowingly dispense CFM are unprofessional	199 (89.2)	24 (10.8)
Pharmacist that knowingly dispense CFM are unethical	193 (86.5)	30 (13.5)
Pharmacists carry CFM in their pharmacy because it is easy money	196 (87.9)	27 (12.1)
Pharmacists carry CFM in their pharmacy for the big profit	193 (86.5)	30 (13.5)
Pharmacists carry CFM in their pharmacy because the quality is acceptable	58 (26.0)	165 (74.0)

*Counterfeit medicine

Table 6.6. Respondents' responses to statements describing pharmacists who deal with CFM

In order to determine respondents' attitude towards the law and risks related to CFM, three related statements were used to determine respondents' opinion. Respondents agreed that the law against CFM, and for those who sell/deal with CFM must be strengthened by 207/223 (92.8%) and 207/222 (93.2%) respectively. No statistically significant differences were observed in respondents' responses and their demographics.

Regarding respondents' opinion of the percentage of pharmacists aware of CFM in Lebanon, the analysis showed that 80.7% of respondents answered this question, and more than half reported the percentage to be between 80-100% (**Table 6.7**).

Percentage	N (%)
< 20	16 (8.9)
20-39	10 (5.6)
40-59	16 (8.9)
60-79	20 (11.1)
80-100	118 (65.6)
Total	180 (100)

Table 6.7. Percentage of pharmacists aware of counterfeit medicine in Lebanon, as reported by respondents

There was a statistically significant difference with pharmacists in ML (46%) and Beirut (32.2%), who believed that pharmacists had a greater awareness of CFM compared with pharmacists in the South (3.4%) and Bekaa (2.3%), with $X^2=45.49$ (df=20) and $p < 0.05$.

Regarding respondents' opinion of the percentage of CFM available in Lebanon, almost 40% of respondents reported the percentage to be between 20-39% (**Table 6.8**), however almost one third did not answer this question. No statistically significant differences were observed in respondents' responses and their demographics.

Percentage	N* (%)
< 20	52 (36.6)
20-39	56 (39.4)
40-59	20 (14.1)
60-100	14 (9.9)

*N=142

Table 6.8. Percentage of counterfeit medicine in Lebanon, as reported by respondents

As for checking the integrity of medicine suppliers, around 35% of pharmacists reported that they check it on daily bases, whereas, 20% of them reported to check it on yearly bases (**Table 6.9**). No statistically significant differences were observed between different demographic groups.

Frequency of checking integrity of product suppliers / wholesalers	N* (%)
Daily	69 (34.5)
Weekly	27 (13.5)
Monthly	36 (18.0)
Yearly	40 (20.0)
Do not check	28 (14.0)

***N=200**

Table 6.9. The frequency of checking the integrity of suppliers/wholesalers by responding pharmacists.

Almost 80% of respondents reported that no medicine were found to be counterfeit in their pharmacies, and only 11.8% reported to having medicine confirmed as counterfeit. No statistically significant differences were observed between different demographic groups.

Regarding being offered CFM, around 48% reported that they have been offered CFM. No statistically significant differences were observed in respondents' responses and their demographics.

With respect to which products were most likely to be counterfeited according to respondents, the results showed that high volume/chronic medicines (48%) were most likely to be counterfeited, followed by lifestyle/expensive medicines (32.3%). No statistical significance was observed in respondents' responses and their demographics.

6.3.3. Counterfeit products

When respondents were asked if they were willing to buy CFP, provided they were of good price and quality, 18% reported to be willing to buy CFP, however, choosing from a list of products, around 55% and 37% of responding pharmacists reported to be more willing to buy CDs, and pens respectively, than the other products on the list (**Figure 6.1**).

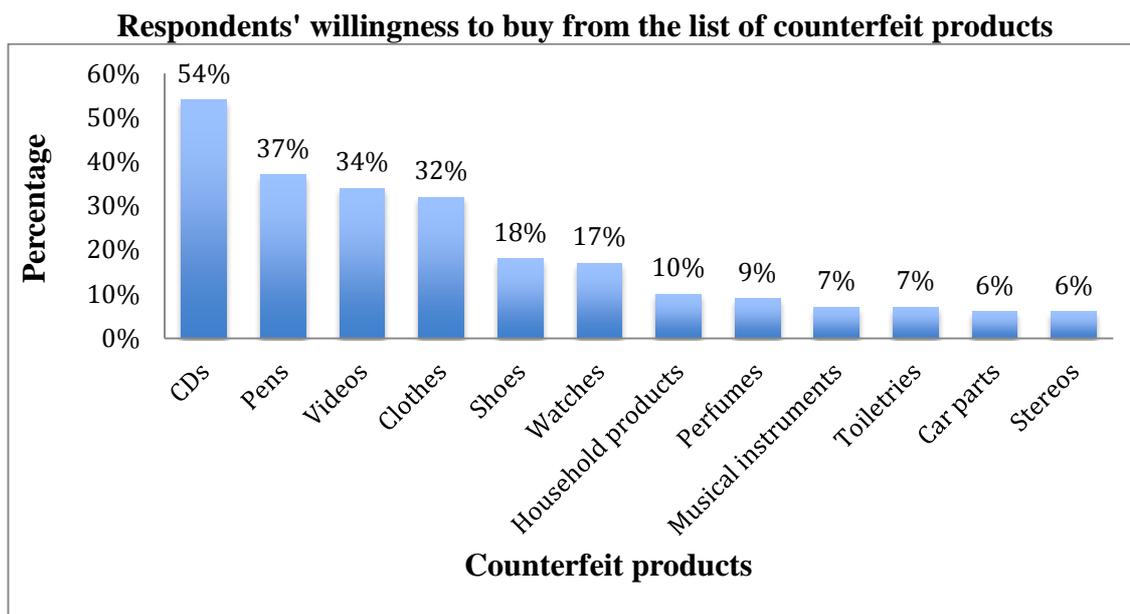


Figure 6.1. Respondents' reported willingness to buying specific counterfeit products.

The pharmacists' attitude towards CFP was assessed using statements describing the quality, value, risk and experience with CFP. The data from the questionnaire were analysed and summarized in **Table 6.10**, after dichotomizing the answers to strongly agree/agree and strongly disagree/disagree. The results showed that only 12% of respondents reported believing that CFP were as good as the originals, and about 52% reported that many branded products were overpriced. Furthermore, 90% were aware of the risks of CFP, and 65% of the respondents believed they could easily spot CFP by their quality and price. No statistically significant differences were observed. Almost 30% of responding pharmacists reported knowingly buying CFP in the past.

Statement	Strongly Agree/Agree N(%)	Strongly disagree/disagree N(%)
Most counterfeit products are as good as the originals	27 (12.1)	196 (87.9)
Many branded (original) products are highly priced; while counterfeit products are of better value	115 (51.6)	108 (48.4)
Counterfeit products can be very dangerous	201 (90.1)	22 (9.9)
It is easy to spot counterfeit products by their quality and price	145 (65)	78 (35)

Table 6.10. Respondents' perception regarding counterfeit products

For internal consistency, the reliability of respondents' responses was examined for this study using Cronbach's alpha coefficient. The acceptable value of alpha coefficient according to the literature; has ranged from 0.9 down to 0.6 (Nunnally et al, 1967; Bland and Altman, 1997; Clark and Watson, 1995; Tavakol and Dennick, 2011; DeVellis, 2012). The following questions were used to check for consistency (10, 13, and 14); "Pharmacists that knowingly dispense CFM are good businessmen/women", "Pharmacists decide to carry CFM in their pharmacy for the easy money", and "Pharmacists decide to carry CFM in their pharmacy for the big profit" respectively. The alpha coefficient value for all the items was 0.66, although the value was < 0.7 , the results of the survey would be considered reliable and consistent, since the test used only 3 items; therefore, would be considered reliable and respondents were consistent in their responses.

6.4. Discussion

This study was based on a questionnaire administered to pharmacists in various areas in Lebanon. The aim to determine pharmacists' awareness and attitude towards CFM was met, and the hypothesis that pharmacists were aware of CFM was true. The results revealed that majority of respondents defined CFM as a bad quality medicine, from an unknown source. Additionally, the majority identified CFM by the medicine's effect, followed by cost. Less than half of respondents reported knowing of pharmacists who dispensed CFM, and reported that offenders should pay a penalty, or be imprisoned. Moreover, the majority reported that pharmacists who dealt with CFM were unprofessional, unethical, and they did it for the easy money and big profit. Furthermore, most of respondents reported in believing CFM to be very dangerous, and the law against CFM and counterfeit salespeople should be strengthened. Moreover, slightly more than half of respondents reported that many branded products were overpriced, yet the majority reported being aware of the risks of CFP, and that they could easily spot CFP by their quality and price.

The convenience / opportunistic approach of this study could be considered biased, since it only included respondents who were approached and willing to participate, and this would be considered a limitation. Additionally, including more practicing pharmacists from the North, South and the Bekaa, might have given different results, for according to the results of Chapter Three, the extent of CFM in households was higher in the Bekaa and South than in ML and Beirut. These could be further addressed in future studies. Furthermore, with almost half of respondents reporting being offered CFM, not including questions to describe how they were approached, what they were offered, and how the encounter ended, were additional limitations to the study. As a result these questions were used for the pharmacist focus groups in Chapter Eight, to better understand the methods used by counterfeiters, to warn other pharmacists, and for authorities to monitor such acts in order to take adequate measures against such offenders.

The majority of pharmacists approached commented on the need to shed light on this topic and to understand what pharmacists know about CFM. However, pharmacists reported being cautious and conservative in their responses to the questions, to avoid any trouble, even after assurance of confidentiality. The 17 pharmacists that refused to participate in the study were abrupt, not welcoming, and their refusals were not due to lack of time. The pharmacists were not asked why they refused in order to avoid any conflict. Moreover, the

administration of the questionnaire at pharmacies might have affected the quality of the provided information, rather than if respondents were answering at their own leisure with more time to think about their answers, and returned in a day or two to pick it up.

The community pharmacies of responding pharmacists were mostly located in the ML area, and the majority of respondents were males. The largest group of respondents belonged to the age group (31-40) and almost half of respondents indicated that they have been practicing pharmacy for a minimum of ten years. According to the OPL website, ML has the largest number of pharmacies (44%), followed by the South (17.9%), Bekaa (15.2%), the North (14.7%), and the least in Beirut (8.2%) (Lebanese Order of Pharmacists, 2015). The National Health Statistics Report, showed that the ratio of M:F pharmacists in Lebanon was 2:5, and according to the OPL 2:1, however, in this study the male pharmacists were over represented (National health statistics report in Lebanon, 2012; Lebanese Order of Pharmacists, 2015). The study represented a convenience sample of pharmacies from different regions in Lebanon; however, the pharmacists in the North, South and the Bekaa were underrepresented. Future studies could address these areas for better assessment. Male pharmacists in this study were over represented, as they may have been more interested to share their views about CFM. Future studies may further investigate pharmacists' awareness among those who are older than 50, to determine if age would have an influence.

The study showed that there were differences among pharmacists in their reported definitions of CFM. Respondents' answers were more focused on the violation of IP rights, since the majority defined CFM as a medicine from an unknown source (not made by original company) or being of bad quality. The reason could be that there is no official consensus declared by the MoPH on the definition of CFM in Lebanon. Counterfeiting violates IP rights and would be considered illegal and unethical, however, IP violation is one negative aspect among many problems related with counterfeiting. A publicised agreement between MoPH and regulatory authorities on a CFM definition would be essential to distinguish between the different types of counterfeiting, to help avoid any confusion among regulatory authorities and any party involved in detecting the availability of CFM.

As for respondents' source of awareness about CFM, less than half reported becoming aware of CFM through the TV. Slightly more than half reported being aware of the CFM campaign that took place in Lebanon, however, only 4% reported it as a source of

awareness. The reason could be that they did not see it, or the campaign did not add to respondents' knowledge, therefore, future campaigns may need to consider different methods of education to reach a wider range of pharmacists. According to the General Pharmaceutical Council's Code of ethics for pharmacists; pharmacists must develop their professional knowledge and competence (General Pharmaceutical Council, 2015), and this could be accomplished through continuing education, workshops or seminars on CFM. Furthermore, a small percentage of pharmacists reported becoming aware of CFM through their experience/practice, or education. Addressing CFM in academia, such as schools of pharmacy, would be a better introduction of counterfeiting as a public health risk and would prepare future pharmacists to better understand the consequences regarding CFM and counterfeiting. In support, the study in California suggested that academic institutions could play a key role in educating HCP about CFM, on how to identify them, and the procedures for reporting suspicious products, in order to build better relationships with patients and to gain their trust (Binkowska-Bury et al, 2013).

With respect to identifying CFM from their originals, the majority reported identifying them by the medicine's effect. More female respondents considered the medicine effect, in addition to the package insert. The possible explanation could be that female pharmacists may be more aware, and may refer more to the package insert for more information, therefore, rely on them to differentiate between original and CFM. However, there is no evidence to support this as a possibility, moreover, studies show that males and females do have different views and beliefs (Goldberg, 1968). Moreover, a pharmacist from the pilot study highlighted after filling the survey that "... it is very hard to differentiate the fake from the original medicine since counterfeiters are being very careful in their job." In support, Chapter Two of this study found the package inserts for all the identified CFM to be different than those for the originals. Although cost was considered next after the medicine effect, the hologram, as reported by respondents, was the third item they considered when identifying CFM from originals.

After the 2010 scandal, when counterfeit Plavix[®] was withdrawn from the market, the head of regulatory department at Sanofi-Aventis Near East; said that the official hologram, and the security label of the manufacturer on the Plavix[®] box were forged (Ghosn, 2010). The head of regulatory department also added that it was even difficult for experts to differentiate between the counterfeit and original (Ghosn, 2010). This might explain why the hologram was not considered first by respondents, and why responding pharmacists relied more on the effect of medicine, when it is becoming difficult to detect a CFM. This

was also evident in Chapter Two, and Chapter Three of this study that demonstrated the difficulty in distinguishing CFM from original medicines, when using the visual examination.

One pharmacist from the pilot study hesitated before answering the question, and explained that even though a hologram is supposed to be the patient's reference for safety, he has reported seeing CFM with the original hologram. The pharmacists gave an example of counterfeit Fosamax[®] (Alendronate sodium; used to treat or prevent postmenopausal osteoporosis) (from a well known wholesaler), that had the same wholesaler's hologram, however, the colour of, and the writing on the box were different. Chapter Two of this study reported the same findings with counterfeit Plavix[®]; the package was different than the original, but the hologram was identified as genuine when compared to the original, as the spectra of the hologram on the two packages were the same.

This study showed that less than half of pharmacists reported being aware of other pharmacists who dispensed CFM, and of those that responded to the question, more than half reported believing that pharmacists were aware they were dispensing CFM. Respondents who were among the age group 51-60 years, and those practising in the Bekaa region, were the least to report knowing about pharmacists dispensing CFM. This could be due to lack of awareness about CFM, in addition to the higher incidences of organized crime in the Bekaa, and the reported unauthorised sites producing CFM that were sold across Lebanon (Cilluffo, 2000; Stewart, 2010; IRACM, 2014; Naharnet, 2014). Moreover, more than half of respondents reported that pharmacists should be punished either by paying a penalty or being imprisoned. When a pharmacist becomes aware of another pharmacist or HCP whose actions would cause harm to patients and society at large, the pharmacist would have an obligation and duty to apply the Code of Ethics "Use your professional judgement in the interests of patients and the public" and inform the authorities (General Pharmaceutical Council, 2015). When a pharmacist, in good faith and in the public's best interest, discloses and resolves a significant deficiency in the quality or safety of healthcare, would be referred to as a "whistleblower" (Bolsin et al, 2005). This would be considered a new culture for the Lebanese pharmacists, however, it would encourage them to take actions against pharmacists who are not abiding by the ethical standards of this profession. However, this would best be supported if the OPL would acknowledge or adopt a Code of Ethics to use as a guide for pharmacists' professional practice. Studies have reported that pharmacists with limited experience or awareness towards CFM, have consequently exposed their patients to the risks of using CFM

(Binkowska-Bury et al, 2013; Law and Youmans, 2011; Shahverdi et al, 2012). Whistleblowers would need to act and inform regulatory authorities to take appropriate measures against such pharmacists, to protect the patients, the public, and the society from the harm of CFM use.

A pharmacist from the pilot study said, “even if I know I won’t expose the pharmacist because I don’t want to get into trouble”, indicating the reluctance to whistleblowing, and this could be further investigated to determine the reasons behind pharmacists’ reluctance. The majority of responding pharmacists reported that they as pharmacists cannot do anything, and also the government and the MoPH are responsible for the availability of CFM. In addition, the OPL has a limited role, and pharmacists should do their own control in their pharmacies.

A study in Iran, a developing country, used a questionnaire to address pharmacists’ knowledge, attitude and practice regarding CFM, showed that more than one third of participating pharmacists reported that over 50% of community pharmacies supplied CFM (Shahverdi, et al, 2012). Additionally, more than half of respondents reported believing that other pharmacists exchanged CFM with suppliers and did not inform authorities about this practice (Shahverdi, et al, 2012). Also the study in Jordan showed that more than half of respondents reported not encountering any CFM themselves, however, more than a third reported encountering CFM cases (Taleb & Madadha, 2013). This would suggest that there are pharmacists that are involved and dealing with CFM, and regulatory authorities would have to take the adequate measures to stop them. Since Jordan and Iran, are also considered developing, or upper middle-income countries like Lebanon, it would be likely to have similar cases in Lebanon as well (The World Bank, 2015).

Moreover, the majority of respondents in this study believed that selling CFM was unprofessional and unethical, and pharmacists did it for profit considering it to be easy money, and almost one third of respondents considered pharmacists who dispensed CFM were good businessmen/women. A former Member of Parliament, long time anti-counterfeiting advocate and lawmaker in Lebanon, commented that “pharmacies sometimes prefer to sell fake products because the profit margin is higher” (Kircher, 2008). The decrease in pharmacists’ minimum wages to USD1350/month (Lebanese Order of Pharmacists, 2014b) could be one of the reasons why some pharmacists chose to deal with or sell CFM.

Additionally, according to this study's pilot results, a pharmacist reported " ... the competition among colleagues made some pharmacist commit this crime, and get carried away by easy money and big profit making." Another reported the same idea, however, was more "understanding" and said "owners of smaller pharmacies feel pressured by their competitors to achieve the same margin of profit, consequently carry CFM to remain in the realm of competition". They are small fish in big ponds." The majority of respondents agreed that the law should be strengthened and enforced against those that "sell or deal" with CFM. The Lebanese authority strengthened its regulation and considered the import, distribution or sale of CFM a crime.

When asked about the percentage of pharmacists' who are aware of CFM in Lebanon, slightly more than half of responding pharmacists believed that 80-100% of pharmacists were aware of CFM. Respondents in the ML believed that pharmacists had higher levels of awareness of CFM to respondents in the South and the Bekaa. This could also be explained by the higher incidences of organized crime in the Bekaa, (Cilluffo, 2000; Stewart, 2010; IRACM, 2014; Naharnet, 2014) and for the weak law enforcement, where the authority of law enforcement officials is weak (PricewaterhouseCoopers, 2003). In support, Chapter Three of this thesis showed that households in the Bekaa and South regions were more prone to having CFM than others, showing the extent at 5.8% in the South, 12.1% in the Bekaa, and 4% for the country.

In fact, less than half of the respondents estimated that 20-39% of medicines in Lebanon were counterfeit. This could be due to hearsay, from other pharmacists, the media, their own experience, or a random estimation of the availability of CFM in Lebanon. According to Chapter Three (Counterfeit medicine in domiciles), the extent of CFM ranged from (3-12%), therefore, the results would highlight the need for pharmacists to be more aware of the extent of CFM, and the positive impact pharmacists may have on controlling the use of CFM by the public. However, irrespective of the range, knowing that CFM are available would require pharmacists to be knowledgeable about CFM and always on the alert, therefore, educational seminars or workshops for pharmacists would be essential.

Moreover, when asked if respondents were offered CFM, the answers were almost divided in half but were more towards "yes". Additionally, two pharmacists from the pilot study reported being offered CFM, one was offered CFM Plavix® from the supplier, ... "a very expensive medicine, for only USD 8." The second pharmacist reported being offered to purchase CFM Plavix®, Lipitor®, etc. "Lipitor" which was offered to him for only USD 20

and he stated that he could not differentiate it from the original one.

Slightly more than one third of pharmacists checked the integrity of the medicine suppliers on daily basis, whereas less than one third checked on a yearly basis. Once a year or not checking at all puts the pharmacist in a vulnerable situation, besides being an easy target for counterfeiters. According to the pilot study, one pharmacist reported that a well-known agent requested to remove their medicines from use, as they were suspected of being CFM. The medicines were later confirmed as CFM, and the pharmacist could not differentiate between the CFM and their originals.

A senior director at Pfizer; stated “know who your supplier is, and be familiar with the packaging”, advising USA pharmacy buyers to be selective of the source of product and to go directly to the authorised distributor of a manufacturer, if possible, to guarantee getting the original product (Frederick, 2011). Rarely do incidences occur through the legitimate supply (Frederick, 2011), nevertheless, regular checking would be a good practice. The two scandals that took place in Lebanon, in 2010 and 2012, were through the supply chain. Therefore, reactivating the National Laboratory would allow the MoPH and regulatory authorities to regularly and randomly check the medicine available at different suppliers (wholesalers, warehouses, dispensaries), for better control. As a result, the findings illustrated the need for the laws to be strengthened, implemented and enforced.

As for CFP, the respondents of this study did not show favourable responses towards CFP, as more than half of respondents reported that they did not buy CFP in the past, however, acknowledged that CFP were of better value than their originals, yet they were potentially more dangerous. The results of Chapter Five on the public attitude towards CFP showed similar findings, where the majority of respondents also showed unfavourable responses towards CFP, yet more of the public respondents reported to believe that branded products were highly priced and CFP were of better value. Research suggests that individuals, who are more lawfully minded, tended to have less favourable opinion of counterfeiting and were therefore less likely to buy them (Cordell et al, 1996). Other studies found that respecting the law was not a reliable predictor of buying intentions (Cordell et al, 1996; Casola et al, 2009). Individuals’ opinion as a result may be based on previous experiences that develop a specific attitude towards a product. The same may be extrapolated to medicines however; the risks and consequences of using CFM would be higher.

As a follow up to the public awareness and attitude towards CFM in Chapters Four and Five, this chapter described the pharmacists' awareness and attitude towards CFM. The questionnaires used did not allow the author to explore the views and beliefs that people had towards CFM, nor how much they knew about CFM. Therefore, the following Chapter (Seven) will attempt to explore further, the public and pharmacists' experience, views and beliefs towards CFM using focus groups.

6.5. Conclusion

According to the author's knowledge, this study was the first to assess pharmacists' awareness and attitude towards CFM in Lebanon. The study highlighted the need for a CFM definition to distinguish between the different types of counterfeiting, to better identify CFM, and to minimize confusion with other categories or types. The findings established the need for additional awareness campaigns, with emphasis on the role that pharmacists have in protecting patients from using CFM. Furthermore, the role that the MoPH and regulatory authorities should play in controlling and securing the supply chain of medicine, with emphasis on implementing and enforcing the law against such offenders. Finally, the study demonstrated the need for the OPL to adopt a Code of Ethics for pharmacists to guide them in their professional practice, and to introduce whistleblowing against offenders to protect the patients, the public, and society from harm, especially when related to CFM use.

Chapter Seven

Public and Pharmacist Views on Counterfeit Medicine in Lebanon

7.1. Introduction

Chapters, Four, Five and Six assessed the public and pharmacists' awareness of and attitude towards CFM, and showed that the majority of respondents were aware of the term CFM. When assessing their ability to differentiate between original and CFM, however, almost half of the respondents either did not answer or indicated they did not know. The public attitude results showed that respondents reported agreeing that the original medicines were highly priced, and CFM were of better value, and that CFM are of risk. In addition, the majority of respondents believed that pharmacists who knowingly dispensed CFM were unethical and unprofessional. The pharmacists' attitude showed that the majority of respondents reported that pharmacists who dealt with CFM were unprofessional, unethical, and they did it for the easy money and big profit. Furthermore, most of the respondents reported in believing CFM to be very dangerous, and in addition, the law against CFM and counterfeit salespeople should be strengthened.

While the questionnaire allowed us to get information from a large sample of people, it did not allow us to explore the views and beliefs that people had towards CFM, nor how much they knew about CFM. Therefore, this chapter will attempt to explore further the general public and pharmacists' experience, views and beliefs towards CFM using focus groups.

Focus groups offer a useful method to explore participants' experience, views and beliefs towards CFM, and provide insight on how participants think and why they think a specific way (Kitzinger, 1995; Gibbs, 1997). Focus groups are a qualitative method that involves interactive discussions among a small group of participants, to gather their perspective on a specific topic (Morgan, 1996). Typically group size ranges from 6-10 (Morgan, 1996; MacIntosh 1993), but some studies use up to 15 (Goss and Leinbach 1996) and as few as 4 (Kitzinger 1995). A focus group is a method that yields a large amount of data in a short period of time, 1-2 hours (Mack et al, 2005; Stewart and Shamdasani, 2014). Focus groups are used for assessing health education messages, and to examine the health behaviour and public understandings of certain diseases, and health related matters (Bash, 1987; Khan and Manderson, 1992; Kitzinger, 1993; Duke et al, 1994; Murray et al, 1994; Ritchie et al, 1994).

There have been a few studies that have used focus groups to probe the area of counterfeit products with the public (Bian and Veloutsou, 2007; Bian and Moutinho, 2011). One study however, explored the knowledge and perceptions of drug (medicine) quality among drug

sellers, and consumers in Lao People's Democratic Republic (PDR) (Syhakhang et al, 2004a). The study in Lao PDR did not specifically focus on CFM; it was focussed on low quality medicines that may be considered counterfeit if the intention was to deceive. The PDR study used structured interviews and 8 focus group discussions with drug sellers (at pharmacies) and community members (who bought medicines at a pharmacy during the research team's visit to the pharmacies). Six focus groups were conducted with consumers and two focus groups with drug sellers, with 7-12 participants in each group, aged (30-50). The drug sellers' focus groups were with owners or licensees of a pharmacy (no qualified pharmacists). The results indicated that perceived efficacy of the medicine, and the cost of the medicine was important when consumers were assessing medicine quality. Consumers living in the urban area were more knowledgeable than more rural areas, maybe due to better educational level, and better opportunity to receive information on their medicine. Additionally, consumers trusted that doctors, pharmacists, and pharmaceutical companies, would give them good quality medicine, and their main worry was the financial constraints, that caused them to buy cheap medicine. For drug sellers, only one had a fully correct knowledge of the definition of medicine quality, and about half had a partial knowledge of it. Also, drug sellers had limited knowledge of medicine quality indicators such as labels, expiry dates, active ingredients and storage conditions. The study recommended for the government to focus on educating drug sellers, healthcare professionals, and the public regarding CFM; in addition to, strengthening the enforcement of pharmacy regulations (Syhakhang et al, 2004a). Including pharmacists in their study would have provided a better insight of their awareness regarding CFM since they would have better scientific background than drug sellers.

Counterfeit studies in the literature have been more focused on the supply of counterfeit products (CFP) and less on the demand for counterfeits (Albers-Millers, 1999; Penz and Stottinger, 2005), when consumers intentionally buy CFP, and are aware that these products are not the originals (Penz and Stottinger, 2005). Studies also added that counterfeits are available due to the availability of brands and what they promise consumers (Bloch et al, 1993; Cordell et al, 1996; Ang et al, 2001; Prendergast et al, 2002; Penz and Stottinger, 2005). Studies found that consumers buy CFP due to the perceived price benefit of such products (Albers-Millers, 1999). Furthermore, studies found that the physical product attributes and the intangible brand image, the prestige that is connected to a specific product, especially with luxury products, enhances their self-image and improves their self-concept (Dornoff and Tatham, 1972; Onkvisit and Shaw, 1987; Dubois and Paternault, 1995; Nia and Lynne Zaichkowsky, 2000). A study found that consumer'

intentions to buying luxury products were not affected by the availability of CFP (Nia and Lynne Zaichkowsky, 2000). Therefore, when counterfeits can supply the demand for CFP at a cheaper price, consumers end up getting the prestige without having to pay for it (Cordell et al, 1996; Grossman and Shapiro, 1988).

There are no focus group studies on CFM, and to date, public and pharmacists' views towards CFM have not been investigated or discussed in focus groups. Therefore, in addition to the concerns raised by the availability of counterfeits, and the present risks of CFM use, exploring the public and pharmacists' experiences, views and beliefs on this topic, would help get a better understanding of how the public and pharmacists think about CFM and their supply. Four focus groups (FG) were used for this study with the aim to explore participants' experiences, views and beliefs regarding CFM, and who they believe to be responsible for the availability of CFM. Due to the qualitative nature of the FG, it would not allow for generalization, however, it would reflect participants' experiences, views and beliefs regarding CFM, that could be further investigated in future studies. In addition, the findings may be informative for future planning of educational programs on CFM.

7.2. Methods

The study is descriptive, and based on the FG discussions of CFM availability and use in Lebanon. The author used small focus groups for the opportunity it creates in allowing participants to listen to the opinion of others, to gather views of several people simultaneously and to understand the issues that would not be possible to generate without the interaction produced from group discussions (Taylor and Bogdan, 1984; Rubin and Rubin, 2011; Boyatzis, 1998; Ryan and Bernard, 2000; Krueger et al, 2001; Rabiee, 2004; Mack et al, 2005; Braun and Clarke, 2006; Krueger and Casey, 2009; Stewart and Shamdasani, 2014).

7.2.1. Setting and study population

The study was based in Lebanon, and the goal was to run two public FG with participants from different backgrounds, and two pharmacists FG with participants from different pharmacy settings. The Arabic language was used with the public since it is the common language used by all participants and English was the preferred language to use by participating pharmacists. The inclusion criteria for the public included any volunteer who was; a) 18 years old and above, and b) spoke English or Arabic fluently. For pharmacists the inclusion criterion was any pharmacist who is currently practicing in Lebanon (Lebanese Order of Pharmacists, 2014a). Participants were informed before the focus group meetings that the meetings would be audiotaped.

7.2.2. Procedure

7.2.2.1. Public recruitment

The author contacted the principals of two schools in Mount Lebanon, and requested a meeting. Before the meeting with the principals, the author sent an email providing a brief introduction on the topic and the reason behind the visit. The author met the principals, and emphasised at the end of the meeting the need to inform participants (parents, staff members, or teachers) that each would be required to sign a consent form, and that the meeting would be audiotaped. Furthermore, upon approval to use their sites, they were provided with the following exclusion criteria; any individual who; 1) was younger than 18 years old, 2) was not living in Lebanon, 3) does not approve of using the audiotape during the meeting, and 4) does not consent to participate in the FG. Schools were considered a

convenience sampling method (Gehart et al, 2001), since it offered easy access to members of the public.

The principals at both schools asked the parents/staff members and teachers that randomly visited their offices if they would be willing to participate. For one of the schools, those willing to participate were asked to register their names on the list with the assistant. Once the date was set, the assistant contacted them and informed them of the set times, and 13 were willing and able to participate on the set date. The other school had only teachers and staff members interested, and due to the time limitation, did not invite parents. Of those asked, 11 were willing to participate.

All participants were present by the set time. The moderator welcomed the participants, explained the purpose of the meeting for each group, and encouraged participants to speak freely about their knowledge and experience of CFM. The process was facilitated by the set of questions that were prepared and used as a guide (**Appendix 7. I**).

The FG were held over a period of 8 weeks with a total of 24 participants for the public FG divided into two groups.

7.2.2.2. Pharmacists recruitment

The recruitment of pharmacists was by the snowball approach. The snowball approach is used when a population is hard to reach, or recruit (Sadler et al, 2010). Due to the sensitivity of the topic, not all pharmacists were enthusiastic or willing to participate. The process of arranging for the FG meetings took around 3 months. The aim was to have two groups of 6-8 participants each.

In order to avoid embarrassing or coercing any pharmacist not willing to participate, a colleague of the author asked potential participants. This colleague who is a member of the OPL contacted pharmacists and asked them if they would be willing to participate in a FG on CFM. Once the author received from the colleague, the names and contact information of pharmacists willing to participate, the author called each pharmacist to explain the purpose behind the FG meetings. The call was followed by an email, reiterating what was discussed over the phone. The FG meetings were set for two weeks after the contact with pharmacists. The FG meetings followed the same procedure as the public FG, and a set of questions was used as a guide during the FG meetings (**Appendix 7.II**).

Once the meeting dates were set, two pharmacists declined, one because the meeting place was too far (1 hour away). The other pharmacist was reluctant to attend the FG being concerned and worried about the audiotape.

The FG were held over a period of 2 weeks, with a total of 13 participants divided into two groups (6 and 7).

The moderator reviewed the consent form with participants before the meetings started and participants were encouraged to ask questions if anything was not clear before signing the form. Participants took home a sheet with the author's contact information in case they had any question after they left.

Both the public and pharmacists' groups preferred not to take a break midway through the meetings, for it would interrupt the flow of the discussion. Refreshments were offered in each meeting.

7.2.3. Data collection

Participants were given a demographic questionnaire to complete (**Appendices 7.III and 7.IV**). This questionnaire contained closed-ended questions and was designed to record for the public participants' age, gender, years of living in Lebanon, language spoken at home, areal of living, level of education, occupation, and if currently using any medicine. For pharmacists, age, gender, years of living in Lebanon, area of living, where is the pharmacy degree from, area of practice, practice setting, years of practicing in Lebanon, and comments for participants if they needed to add anything.

There were 7 and 8 open-ended questions for the public (**Appendix 7.I**) and pharmacist FG (**Appendix 7.II**) respectively. Follow-up questions were asked to learn more, and probe about topics that participants brought up. The author used the WHO definition, as a reference when pharmacists defined CFM (World Health Organization, 2012b). The public participants on the other hand were considered aware of the meaning of CFM, if they said it was not the original, fake, or anything related.

The author acted as the moderator for all FG and the note-taker was also the same for all meetings. The moderator and note taker debriefed after each meeting, discussing the

observations noticed and the major ideas that highlighted each meeting. The discussions for the four meetings lasted around 120 minutes for each.

7.2.4. Ethical requirements

The study proposal was submitted and approved by the School of Pharmacy and Biomolecular Sciences Research Ethics Committee at University of Brighton (**Appendices 7.V and 7.VI**).

7.2.5. Data analysis

The discussions of the public and pharmacists' FG were transcribed from the audiotapes and the notes taken during the meetings. The transcriptions of each group were reviewed and analysed using the qualitative method, followed by a structured process combining description and interpretation of the data. The analytical method used was thematic/category analysis as described by Kitzinger and Barbour (Kitzinger and Barbour, 1999). With this method a theme is developed based on capturing something important in relation to the researched topic, irrespective of the number of persons who referred to it. From the transcripts, meanings were interpreted and analysed into categories then grouped and labelled with a code and then themes were formed that developed into subthemes. Each focus group was analysed separately and then together (Carey, 1995; Björkman et al, 2008; Denzin and Lincoln, 2011). Data were initially organized by each question and then responses were reviewed to identify themes and sub-subthemes. The relevant discussions were used as quotes to support an observation. The results and discussions parts for both the public and pharmacist FG are reported separately.

7.3. Results and Discussion

The findings of this study were used to explain the findings of Chapters Four, Five and Six of this thesis. The qualitative nature of the study does not allow for generalization, however, the reflected experiences, views and beliefs regarding CFM were common to all participants, and may be the same for other members of the public or practicing pharmacists in Lebanon that did not participate in the FG discussions. Therefore, future studies could further investigate the findings of this study.

The study sample for the public and pharmacist FG had an over-representation of females, and this might have skewed the results either way, since males may have provided different opinions and beliefs towards CFM. Studies show that males and females do have different views and beliefs (Goldberg, 1968). In addition, the majority of public FG participants were educated and this could also be a limitation since different educational backgrounds might lead to differences in their experiences, views and beliefs towards CFM.

Based on the analysis, themes and subthemes were developed from the discussions, and the relevant quotes are used in support. The full transcripts for all 4 focus groups are found in **Appendices (7.VII-7.VIII)**.

7.3.1. Public

The samples chosen from the two schools could be considered random; since participants were asked based on their random visits to the principals' or the assistants' offices. Nevertheless, had there been more time, an official email to all parents, staff and teachers might have been a better approach for both schools, to be followed by accepting the first 12 that replied to the email, to have a better random representation of the public.

The total number of public participants was 23, and 21 of them were women. Slightly more than one third of participants were between 31-40 years old. The majority had a university degree, and lived in the Mount Lebanon area. More than one third of the participants reported to be currently taking medicine for treatment (**Table 7.1**). Future studies may consider using FG with equal participation of genders, and lower educational backgrounds, to determine if their results would be different or the concerns would remain the same for all.

	Focus Group 1	Focus Group 2
Number of participants	10*	13*
Age		
<30	1	
31-40	5	7
41-50	2	6
51-60	1	
Gender		
Male	2	
Female	8	13
Spoken Language		
Arabic	3	2
Arabic & English		1
Arabic & French	4	10
Arabic, French & English	2	
Years living in Lebanon		
<10		1
20-30	1	1
31-40	3	5
41-50	2	3
51-60	1	
Area of living		
Beirut	2	1
Mount Lebanon	8	12

Table 7.1. Demographic information for public focus group participants

Five main themes emerged from the two public FG discussions. These were: 1) Awareness, 2) Trust, 3) Corruption, 4) Locus of control, and 5) Overcoming counterfeit medicine (**Table 7.2**).

The main themes and subthemes developed from public focus groups

1. Awareness

- Defining counterfeit medicine
- Identifying counterfeit medicine
- Counterfeit medicine reporting System

2. Trust

- Pharmacists
- The system

3. Corruption

4. Locus of control

- Internal
 - Lack of knowledge
- External
 - Worries
 - Financial concern
 - Political instability

5. Overcoming counterfeit medicine

- Education
- Responsibility and accountability
- Laws and regulations

Table 7.2. The 5 main themes and subthemes developed from the public focus groups

7.3.1.1. Awareness

The focus group discussions demonstrated a gap in participants' awareness towards CFM and were divided into three subthemes.

• Defining counterfeit medicine

The majority of participants were not able to define or provide a meaning to CFM, and either gave false definitions, or did not know the meaning of CFM. Only 3 participants from both groups were considered aware of CFM, and the following statements capture the subtheme.

“I don't really know....”

“I would say the one with the different name is fake and the different composition is copy”

And for the 3 participants that knew the meaning of CFM provided the below definitions:

“... CFM has exact same name ... There’s an intent to cheat, to deceive.”

“Is expired medicine whose expiry date has been changed.”

- **Identifying counterfeit medicine**

With respect to identifying CFM, the majority said they did not know how to, however a few were slightly more knowledgeable. Few referred to the hologram as a mean that can be used, according to the media reports that they have seen recently. The following are examples of what was said in relation to this theme.

“I’m not sure how to tell the difference, honestly.”

“don’t know how to differentiate, as we don’t think we have the necessary knowledge/information.”

“The logo of the importers which the ministry has advertised ... so it is only recently that we started paying attention. Before that we used to examine the box, the shape, the colours, etc. A guesswork, basically.”

- **Counterfeit medicine reporting System**

None of the participants knew how to report a CFM, and were guessing and speculating what could be the answer.

“There’s no point of reference or particular authority to file complaints to.”

“...we also aren’t in the habit of reporting abuse or incidents of being deceived by pharmaceutical companies and their products...”

“...We basically have no one to turn to. If I turn to the authorities to complain, I will most likely be given a pat on the back and asked to be thankful that I’m still alive...”

Participants’ discussions reflected lack of experience and limited awareness towards CFM. The results of Chapter Five on public attitude towards CFM, showed that the respondents of the questionnaire agreed to how difficult it is becoming to differentiate between counterfeits and originals. However, FG participants were aware of their limitations and explained that they did not have the necessary knowledge and information, to the extent that those who knew about CFM had to guess if a medicine was counterfeit or not. Additionally, participants described how they were not in the habit of reporting anything, and that could also be related to lack of awareness towards CFM. The FG findings

supported the results of Chapter Four as the majority did not know what CFM meant, and were unable to differentiate between CFM and the original. Although the respondents of the public awareness questionnaire in Chapter Four, reported relying on the hologram, the FG participants did not, and this might explain that respondents of the questionnaire might have chosen the hologram as an educated guess considering they were an educated sample of the population. The FG participants were not aware of any CFM reporting system, therefore considered going to the pharmacy when suspecting a CFM, since it was the source of their medicine. This could explain why respondents of the questionnaire in Chapter Four chose pharmacists among the listed choices, when asked what they would do if suspected a CFM.

7.3.1.2. Trust

Participants expressed no faith in pharmacists and in the system in general and specifically with CFM, and did not consider their acts were for the public's benefit, therefore, did not trust them.

• Pharmacists

As participants were indicating that they did not know how to avoid buying CFM, few believed that their trusted pharmacist would be a way to avoid buying CFM. There were statements made by few that clearly described the mistrust and views towards some pharmacists.

“I would say the first person to blame is the pharmacist. I think pharmacists are always aware that a medicine is counterfeit when they are selling it to people.”

“I trust my pharmacist blindly. I travel distances to get my medicine. I don't steer away from this pharmacy. They've been great to me and my family.”

“I don't think enough effective measures have been taken, to be honest. They stopped one pharmacy, but they didn't put together a plan to punish others.”

The mistrust towards pharmacists and the system emerged from participants' discussions, as they might have expected more of a professional conduct from healthcare professionals and the government. According to the UK code of ethics, the public need to trust that they are the pharmacists' first concern, and that pharmacists are honest, trustworthy, and protective of patients from any harm by providing safe and effective medicines (General Pharmaceutical Council, 2015). Although, there is no known or published Lebanese code of ethics, yet there are pharmacists who should be aware of the code, as it was part of the curriculum as evident on the official websites of two Schools of Pharmacy (Lebanese

American University, 2015; Lebanese International University, 2015). Therefore, pharmacists would be expected to share the same concerns and duty as healthcare professionals towards their patients. The trust among the FG participants was between the few who trusted their pharmacists blindly and the majority that did not. Some even blamed pharmacists for the availability of CFM, and expected them to be aware at all times when a medicine is counterfeit. The results of Chapter Five showed that respondents had a negative attitude towards pharmacists who dealt with CFM, as the majority reported to disagree that pharmacists who dispensed CFM were clever, or good businessmen/women, and also agreed that those pharmacists were unprofessional and unethical, and were dealing with CFM for the profit and easy money. The mistrust expressed by FG participants was most probably based on personal or others' experiences, therefore, future studies may need to consider investigating the trust between pharmacists and patients to determine how to best address it. Future studies could determine the role of ethics and the ethical problems in pharmacy practice especially with the availability of CFM and their duty towards their patients and society.

- **The system**

Participants believed that the MoPH and the OPL were not carrying out their duties as should be. The majority accused pharmaceutical companies of taking part in counterfeiting.

“... Now it is the responsibility of the MoPH and the OPL to send medicine to laboratories to test it and make sure it is the original product and is not harmful...”

“... I shouldn't be the one discovering that I have fallen victim to CFM. Just like in any other country, someone else's full-time job (MoPH)...”

“... I believe it's not out of question that pharmaceutical companies themselves are counterfeiting medicine to get rid of their stock. Parties that engage in counterfeiting are profit-oriented people who don't give much thought to the good health and wellbeing of the community, but care about realizing profits and dodging losses.”

Participants stated expecting better services, and protection from the government. They indicated that the MoPH and OPL did not appear to be doing their work to protect the public from using CFM, highlighting their responsibilities in testing the medicines in laboratories to guarantee the safety and efficacy of medicines. They even expressed their mistrust in pharmaceutical companies, as they believed them to be involved in counterfeiting medicine through recirculating their expired medicines. In support, according to the WHO, counterfeiting is contributing to damages in the reputation of

pharmaceutical companies, by destroying public confidence in medicines, which causes the reluctance of some companies in publicizing incidents of counterfeiting their products (World Health Organization, 2006c; Swaminath, 2008).

7.3.1.3. Corruption

Participants expressed their dissatisfaction with the services provided by the government in delivering key services, such as safe and effective medicines, and believed they were manipulating the affairs for private gains. The majority of participants stressed how corruption is affecting everything in the country, and considered it a contributing factor for the availability of CFM.

“It turned out it was the minister’s brother who was involved in counterfeiting medicine. Nothing much was done.”

“... Fighting corruption is an immense, large-scale project, actually. There is a lot of corruption and “freedom” at the port, there are groups who don’t adhere to standards and do whatever they want over there.”

“Because this is Lebanon. There is a lot of corruption. The government is corrupt. There are many loopholes and some people have immunity. They can do whatever they want.”

Dissatisfaction was expressed by participants towards the government, for being corrupted and not adhering to any standards, and for using the system for their private gains. Participants also highlighted that the lack of inspection, and the use of bribes, were contributing to the availability of CFM. Participants expected equality before the law but found discrimination with how offenders were penalised, and their discussions revealed the powerlessness they expressed towards the actions and decisions of the government and MoPH. The results in Chapter Three showed that respondents reported to believe wholesalers and customs being responsible for the availability of CFM, followed by manufacturers, and then pharmacists. The reasons given by FG participants were the lack of control, implementation and enforcement of laws by MoPH and regulatory authorities. According to a study that measured the degree of trust in societies around the world (Wike and Holzwart, 2008), reported that it varied considerably, and trust was strongly correlated with views about crime and corruption. Furthermore, in countries where people reported to trust each other, there were less worries about crime or corrupt political leaders.

The above study also reported that 67% of the Lebanese respondents disagreed that most people in society are trustworthy, compared to Egypt (40%), Jordan (45%) and Kuwait

(71%) (Wike and Holzwart, 2008). In addition, the study reported that Lebanese and Nigerian's trust was rare due to respondents' reported concern towards the widespread of political corruption (Wike and Holzwart, 2008). This study's findings would suggest that when the law is not respected, not implemented and enforced, corruption would be encouraged, thereby encouraging counterfeiters to prosper. Future studies could investigate the impact of trust and corruption on implementing and enforcing the law on problems that affect the public such as CFM. Additionally the mistrust towards pharmacists needs to be further studied and addressed to determine the methods that could be used to change the mistrust back to trust.

7.3.1.4. Locus of control

When participants were describing the CFM situation in the country, they were referring to the extent to which they believed they had the power to control the events around them and over the use of CFM.

- **Internal**

The internal controls describe when participants' believed they had the power to control the event and the outcome themselves. The outcome would be directly related to the individual making the decision.

- **Lack of knowledge**

The majority of participants highlighted that people in general lack enough knowledge about medicine, and do not know what to do. In addition, the majority indicated that pharmacists would be the ones responsible for the availability of CFM, with few who did not believe it was the case.

“And a lot of people lack the necessary knowledge ... to know what they're taking.”

“They either don't know about the availability of CFM, or they do but neglect it, since CFM is usually cheaper.”

“If we took CFM, we thank God we didn't die or go to the hospital. We will also stop going to the pharmacy where we bought counterfeit medicine from.”

The internal control was reflected by what participants described as lack of knowledge about CFM and the related risks and consequences. With knowledge people would be controlling their choices, and would know what to look for and how to avoid buying CFM.

Otherwise, lack of knowledge would make them more vulnerable and exposed to using CFM.

- **External**

The external controls describe when participants' believed they did not have the power to control the events but would rely on outside influences or external factors beyond themselves. The outcome would be related to external factors such as other people, timing, or fate.

- **Worries**

Participants' expressed their worries and concerns related to the outcomes of these medicines.

“Two indicators can help one know whether a medicine (CFM) is good or bad: we either don't get better at all, or suffer from side effects: getting poisoned or even dying.”

“We take the medicine and pray to God we wouldn't die.”

“I worry and I am bothered and uncomfortable thinking that such a thing might come out of medicine, a product that is supposed to help me feel better.”

- **Financial concern**

The first reason according to participants behind the availability of CFM, was the high cost of medicines for the patients, and the big profits for counterfeiters. Patients would unknowingly go for a cheaper medicine if given a choice.

“Financial reasons have a role, too. The price of original medicine determines the decision to buy CFM.”

“There is a market because people can't afford the real thing...”

“Some people need to think about money nowadays, though. Not everyone can afford the luxury of expensive medical services, especially if they have 6 or 7 children.”

“People get into the counterfeit medicine business for money, to make profits, to become rich fast...”

○ **Political instability**

The majority of participants seemed overwhelmed with the country's lack of political stability, and did not consider CFM a priority for the politicians or the government. They considered themselves unworthy of “good” medicine.

“We have a lot of other things on our plate and barely have time to even think about this.”

“... undo all political ties this might have to any political party. Politics and health should be separated.”

The external control as reflected by participants was related to three issues that they could not control. Firstly, worries about the outcome of using a medicine and not knowing whether it would be poisonous or beneficial, to the extent that they would have to pray that it would not lead to their death. Secondly, financial concerns and how the high prices of medicine could force people to choose cheaper medicine (CFM) because they cannot afford the original. The financial concerns of the FG participants could be shared by the findings of a study in Poland, that reported people consciously buying CFM, due to their availability and low cost, therefore, increasing the demand for CFM (Binkowska-Bury et al, 2013). Additionally, people who had low monthly income, found the low cost of CFM attractive, and as a result were more prone to buying them (Binkowska-Bury et al, 2013). Finally, political instability according to participants caused politicians not to make the subject of CFM a political priority. The external control subthemes reflected that participants appeared having no choice but to accept what was provided, and to deal with the situation the best way they could.

7.3.1.5. Overcoming counterfeit medicine

The more participants discussed their ideas and experiences about CFM, the more it became apparent the need to learn more about CFM and the need for authorities to be more transparent. Participants also suggested that responsible parties or authorities should use different methods to discourage and stop counterfeiters, and their suggestions included the public as well.

● **Education**

“To limit counterfeiting, awareness is key. It would be creating a barrier for people who are counterfeiting or looking to get into the business...”

“Media ... conferences ... This focus group has helped us a lot...word of mouth, we talk, we discuss, we get more information, we become aware.”

Participants considered education as the key in limiting counterfeiting, suggesting for officials to use campaigns that would explain the risks and consequence of CFM, and the best means to avoid using them. Education according to participants could be through the media, conferences and even focus groups such as the one they participated in. This was in agreement with the results of chapters Four and Five, as respondents of the questionnaire reported education being part of the solution to control the availability of CFM.

- **Responsibility and accountability**

Participants believed that naturally the MoPH, needs to be responsible for guaranteeing that safe and effective medicines reach pharmacies and patients.

*“... If **importers are held accountable** and are asked to acquire all the necessary forms and signatures, that would reduce the possibility of the presence of counterfeit medicine drastically.”*

*“There should be forms and certificates and sustainable supervision that doesn’t only hold people accountable once a year, **but consistently checks for quality and adherence** to international standards and local regulations.”*

Participants also suggested for the MoPH and OPL to use the national laboratory to test medicines’ safety and efficacy, in addition to regulating the medicines in the country, and continuous checking of importers’ credentials and supply chain.

- **Laws and regulations**

Participants emphasized the need to implement and enforce the law to set a precedent for offenders.

“There should be clear laws—which many of them are present—but lack an organized mechanism to be applied.”

“There should be penalties and organized measures to penalize the ones who counterfeit medicine or those willingly involved in the process.”

“I believe the person should be tried publicly for everyone to see and so that a precedent is set. It doesn’t help to drag someone through months of litigation and not let all the others who are doing the same thing know what the consequences of getting caught are.”

Participants stated the need to have clear laws that should be implemented and enforced, suggesting for offenders to be tried publicly. Participants, on the other hand did not believe their suggestions would be implemented or would change anything, since corruption could also be so deeply rooted in the culture that people may believe it being a necessary tool

even when what they are asking for would be rightfully theirs (Uslaner, 2004; Stanley, 2001). Cultures of corruptions will not fade away (Tanzi, 1998), and according to the focus group participants, this is the case in Lebanon.

7.3.2. Pharmacists

The author used the snowball approach for the pharmacists' FG since it was hard to reach or recruit pharmacists. As a result, the author did not approach pharmacists in person, in order for them not to feel coerced or pressured to participate, allowing pharmacists the chance to accept or reject without feeling any embarrassment. Therefore, the limitation of the study was the availability of the contacted pharmacists and their willingness to participate. Future studies may consider FG with an equal gender representation of pharmacists, to determine if their experiences, views, opinions and belief would be the same for both. Additionally future studies may be useful to determine the generalizability of the public and pharmacists' shared views, by assessing a larger group of the population with different backgrounds.

The total number of pharmacists who volunteered to participate was 13, and were mostly from Mount Lebanon and Beirut. Participants were divided into two focus groups, according to their availability. The demographics of pharmacists that participated in the focus group meetings are described in **Table 7.3**.

Parameters	Focus Group 1	Focus Group 2
Number of participants	7	6
Age		
26-30	6	3
31-40	1	2
41-50		
51-60		1
Gender		
Male	2	
Female	5	6
Years living in Lebanon		
20-30	6	3
31-40	1	3
41-50		
51-60		
Area of living		
Beirut	4	2
Mount Lebanon	3	4
Pharmacy Degree from		
Lebanon	7	6
Abroad		
Area of Practice		
Beirut	1	2
Mount Lebanon	4	4
Middle East Region	2	
Practice setting		
Pharmaceutical Industry	3	2
Community	3	2
Hospital	1	1
Community & Academia		1
Number of years practicing in Lebanon:		
Range	(4-14)	(1.5-20)
Average	4.7	9.6

Table 7.3. Demographic information for pharmacist focus group participants

The following five themes emerged and each theme had the related quotes that reflected the views shared by participants. The themes were; 1) Awareness, 2) Reasons for availability of counterfeit medicine, 3) Trust, 4) Corruption, and 5) Overcoming counterfeit medicine (**Table 7.4**). For clarification, during the focus group discussions, participants were referring to medicines as “drugs”.

The main themes and subthemes developed from pharmacists' focus groups

1. Awareness

- Prevalence and extent
- Identifying counterfeit medicine
- Counterfeit medicine reporting system

2. Reasons for availability of counterfeit medicine

- Pharmacists
 - Profits
 - Professional experience
- Medicine shortages
- Demand
- Control

3. Trust

- The system
- Pharmacists

4. Corruption

5. Overcoming counterfeit medicine

- Central Laboratory
- Dedicated pharmacists
- Education
- Laws and regulations

Table 7.4. The 5 main themes and subthemes developed from the pharmacists' focus groups

7.3.2.1. Awareness

A few participants believed that there are pharmacists in Lebanon, who do not know what CFM is or have any background regarding CFM.

“They might be all aware that there are counterfeit drugs, but many, especially those who don’t deal with them, know nothing about counterfeit drugs, because I’ve asked some and they all said they knew nothing about counterfeit drugs. They know “of” them, but as they had never been visited by anyone nor been in a situation, they knew very little.”

“No one can work in the field and not know. Because if one doesn’t know and suddenly have the counterfeit drugs in their pharmacies, how will they be able to stop it?”

• Prevalence and extent

According to participants CFM were mostly prevalent in the northern and southern parts of the country and close to the borders, since there is almost no enforcement of the law there and the borders are wide open, and the current political situation makes it worse.

“... depends on the location of the pharmacy and this is really important. When a pharmacy is in Tripoli or in Bekaa, which is the north and the south and on the border with Syria, you have medications in Lebanon that you have never heard of.”

“These drugs are mainly available where the borders are more open, for example in the North and in the South. But they are also present and active in Mount Lebanon. I don't know about Beirut, though.”

“I have asked multiple pharmacists, from Mount Lebanon, and they all agreed that the more you go to the periphery, the higher the percentage of counterfeit medicine, but they don't know the exact percentage because you need to have a very close relationship with the pharmacist who is dealing with counterfeit drugs to be able to know the percentage, otherwise it's impossible.”

All participants were aware of CFM, however, the level of expertise was relevant to the years of practice. Participants indicated that CFM is more prevalent in the North, South, and Bekaa as these areas are close to the borders where there are less control and regulations. Participants were not sure of the extent of CFM and a couple guessed it to be 20%. According to the pharmacist awareness and attitude questionnaire of Chapter Six, more than a third considered the extent of CFM between 20-39%, as few of the FG participants were in that range as well.

- **Identifying counterfeit medicine**

The majority had concerns in the difficulty identifying CFM, and shared how they try to minimize their risks, understanding the limitations they have.

“It's usually through the patient's response.”

“It's becoming difficult.”

“They asked us how come you bought counterfeit medicine. We said how were we supposed to know it's counterfeit? We got it from a legal source.”

Participants believed that it was becoming difficult to identify CFM, and had to rely on patients' response to medicines. Additionally, participants were in agreement with the Chapter Six results, were responding pharmacists relied on the medicine effect as well, however, unlike the questionnaire results, FG participants did not rely on the hologram and did not give it the weight given by respondents of the questionnaire. In support, many studies have documented that even the high-quality holograms are becoming easy to replicate or counterfeit (Benbasat, 1999; Deisingh, 2005; Newton et al, 2006a; Newton et al, 2006b; Lancaster, 2009), and probably participants experiences might have lead them to the same conclusion.

- **Counterfeit medicine reporting system**

Participants showed concern, as they were not aware of any process or reporting system for suspected CFM, and were not sure who to report to.

“...There is no official reporting system ... There is no regulatory agency that takes feedback from the market.”

“... When we have counterfeit products (medicine) and we discover they are counterfeit because we bought them. What do we do? Who do we call? ...”

Participants expressed the need to have an official reporting system for CFM cases or suspected medicines. Pharmacists need to report any case of CFM they encounter to the regulatory body and to counsel patients about them (Jackson et al, 2012), and the FG participants believed this as well.

7.3.2.2. Reasons for availability of counterfeit medicine

Participants described what they believed to be the different reasons behind the availability of CFM.

- **Pharmacists**

Participants reported that pharmacists could be considered one of the reasons for the availability of CFM, and these reasons in their opinion, are mostly related to business and profit, and the pharmacist's professional experience.

- **Business and profit**

When asked if participants were approached and offered CFM, most said, counterfeit dealers are always checking who may be interested. According to the majority of participants, there are some pharmacists out there who do not care. The majority reported that each community has pharmacists that deal with CFM, and they are most probably contributing to the bad reputation and the mistrust towards some pharmacists.

*“.... It's a **business**.”*

“...So some pharmacists may look at this from a profit perspective and may want to have their hands on such products because let's face it ... It may be a form of profit for the pharmacists dealing with it.”

As a result, participants were disturbed that some pharmacists give discounts to patients on the already priced medicines by MoPH, because patients perceive those pharmacists as more caring and “doing good” to them.

“And this is very common in Lebanon. The pharmacist who does discounts is known to be doing good to patients.”

- **Professional experience**

Participants shared their experiences on how some of them were approached and offered CFM, and the majority of pharmacists went on explaining that counterfeiters would tend to target new pharmacies, young graduates or the inexperienced.

“Really a target. Once I opened, you cannot believe how many used to come and sell me these things and as you have been saying, you are not that much aware, even whether it’s legal or not. At first you’re not aware but when you are older and more mature and these people know that you’re not buying they wouldn’t come anymore.”

In support, the older participants stated that in the past, they were also approached when they opened their pharmacies, and due to the pharmacists’ continuous rejections of buying CFM, they stopped seeing the people with the offers.

“... I have asked multiple pharmacists, they all agreed that they have been visited 10 or 15 years ago by people selling counterfeit medicine and they have had to refuse more than once.”

According to participants, pharmacists end up selling or dealing with CFM, either for the business and profit that comes with it, or the lack of experience with CFM that makes some pharmacists more vulnerable than others into buying CFM. The reasons could have been due to the continuous increase in the number of pharmacists every year that resulted in the decrease in pharmacists’ minimum wages to \$1350/month (Lebanese Order of Pharmacists, 2014b). In addition, participants were in support with the results of Chapters Five and Six; that pharmacists deal with CFM for the easy money and big profit.

- **Medicine shortages**

In addition, the majority of participants believed that counterfeiters do take advantage of medicine shortages for serious diseases, and walk into pharmacies that they suspect may be willing to buy the new alternatives.

“This is what they’re taking advantage of...drugs in shortage ... and drugs that are really expensive. If you’re a patient and your medicine costs more than Lebanese liras (L.L) 100.000, (around USD 66) and someone pops up saying they

have the same product for 5 dollars. What would you do?...You buy the 5 dollars product and you sell it for 50 dollars. Plenty of people, pharmacists do it, unfortunately.”

“Someone came to the pharmacy where I worked ... offered us Phenytoin when that was not available on the market and when patients were panicking. The guy offered Phenytoin from India. Yes, and he showed me documents but I didn’t know whether they were illegal or not. It was for 1.5 dollars a box containing 100 tablets.”

Medicine shortage is considered a global concern that is according to participants a problem in Lebanon as well, and these are situations that counterfeiters take advantage of (Newton et al, 2002). Moreover, participants explained how counterfeiters would approach some pharmacists, as a casual customer asking for a medicine followed by offering a CFM as a cheaper medicine or an alternative to a medicine in shortage, or by walking in as a salesperson with attractive offers for medicine that can only be counterfeit.

• Demand

The majority of pharmacists highlighted that patients end up buying or using CFM, due to the financial situation that is affecting a lot of people in the country, and the cost of medicine, in addition to the lack of awareness towards CFM.

*“This is the problem... the rest of the population who are looking to get medication for cheaper prices, which is their right knowing **the financial situation** in the country...”*

*“Sometimes the level of understanding of people is different. Sometimes if you tell people that a product is counterfeit or bad, they wouldn’t take it well and not believe you. They would ignore. They would say this person is giving the medicine for 20% less of the original price. They don’t see the difference and the harm the **cheaper medicine** might cause...”*

*“No, not all are **aware**. Some are not, some don’t care.”*

*“There is no way they don’t know, but sometimes when there are so many **financial** problems, they try to ignore. They say no it won’t happen to me.”*

According to participants, the public demand to have cheaper medicines is probably due to the financial situation in the country as a result of the political instability. Participants believed that some members of the public may be aware but do not care, or choose the cheaper medicine (CFM) because of the high cost of original medicine, and some do not know. The drivers to buy CFM, for the public was lack of awareness and the financial situation in the country, and these are situations that would cause patients to look for cheaper medicine (Cordina, 2010), as was supported by the FG participants.

- **Control**

A major concern among all participating pharmacists was the MoPH's lack of control on the medicines that enter the country; therefore, more pressure is placed on pharmacists when they have limited control themselves.

“Ministry should be responsible for screening counterfeit medicine, but that’s non-existent.”

“... Also there isn’t so much tight regulations or follow-up at the borders. But I also believe there might be people working in the country and producing drugs here.”

“A pharmacist is not supposed to check for CFM after having received a shipment of products from a supposedly respectable, trustworthy pharmaceutical company.”

According to the majority of participants, in addition to pharmacies, CFM could be found in other places, that pharmacists have no access to or control over, and that caused pharmacists to question the role of the MoPH, OPL, authorities and regulatory agencies on this issue.

“...not all counterfeit meds are only sold in pharmacies, there are many other places, such as dispensaries ..., gyms where they sell proteins, hormones that are banned.”

“On the streets, nightclubs, etc.... so it’s not only found in the pharmacy.”

The MoPH is considered responsible for screening CFM, and for the lack of regulations at the borders. As a result, participants stated that pharmacists end up doing their own control, as they feel unsupported. Participants highlighted that CFM can be found in places other than pharmacies such as gyms, nightclubs, and streets, and these sites are considered against the law, yet participants believed that there is no control on the spread of CFM in the country. The two major CFM scandals that took place in January 2010 and November 2012 (Chakrani 2012); were related to the same person, indicating the need for strict control and implementation of the laws, to deter counterfeiters from bringing more CFM into the country.

7.3.2.3. Trust

Participants expressed the mistrust towards the MoPH, and believed that they were doing the work of the MoPH, and the MoPH's actions were not for the public's benefit.

- **The system**

The majority of pharmacists expressed frustration on the difficulty continuing to work without the adequate control from the MoPH and responsible authorities, when no measures are taken against these offenders, in addition to the mistrust towards the legislative system.

“Unfortunately, in this country, those who have influence and those in the political regime, current or previous have financial interests in these products, especially in a country where nothing is well documented.”

“...The Ministry of Health. I’m not supposed to be doing their work. I should be feeling a little safe that this product has been checked and is safe because it’s been through a safety check process in the country.”

“OPL never checked for CFM at pharmacies ... They will not go somewhere they are sure they will find something fishy, ... they just cannot do it... cause these people are protected... those in the political regime have a financial interest ...”

“... there is no trust in our legislative system ...”

Additionally, the majority of participants expressed their concern about the distribution channel, as they referred to an incident, when a CFM was available in pharmacies through legal channels. Therefore, they would have to always be cautious with all received orders.

“.... One of the medications has been distributed through legal channels and then discovered as being counterfeit medicine ... Plavix is one of them.”

“Pharmacists are afraid that wholesalers might be dealing with counterfeit drugs... heard from pharmacists that they can’t recognize the difference between original product and counterfeit. However, when they buy directly from the agent it’s different. When they need something from the wholesalers is when they cannot be sure anymore.”

As the majority of participants started to define CFM they stressed the risk they would be taking if not sure of their source of medicine, and according to them the supply chain would be an important factor that would make a big difference.

“ We can only trust the agent... ”

“We can prevent that from happening by ordering from the agent.”

“Know the source well; they should only buy from one of the world-renowned companies; those are licensed.”

Participants mistrusted the MoPH, OPL and responsible authorities, due to the lack of control, and for not carrying out their duties in providing safe and effective medicines to patients. Participants also stated the lack of control of the distribution channel, describing

the incident of Plavix in the Lebanese market in 2010, expressing their mistrust in wholesalers as well. The agents according to participants were trustworthy, as they had more to lose, therefore, would be expected to be more cautious.

- **Pharmacists**

The majority of participants emphasized how their image is affected but the few pharmacists that were involved in past CFM incidents, and indicated that they would have to work hard to improve that image and regain the respect and trust of people.

“The scandals are destroying the image of pharmacists. The problem is it does not highlight the source of CFM, or drug supply chain, but only accuses pharmacists ...”

“... it’s the pharmacists’ mistake to begin with. If we are seen badly by the community today, it’s because of mistakes that have been made in the past.”

“...I think we are at risk of losing our status...”

Some participants believed that the public trusted them as pharmacists, while others acknowledged that members of the public may not trust them and may consider them involved in the availability of CFM. Participants expressed their concern of losing their image with the public due to the involvement of pharmacists in the CFM scandals.

7.3.2.4. Corruption

Pharmacists expressed concern in their description about the lack of control due to the corruption that is taking place, and added that working in such conditions is becoming very difficult.

“... look at the people who are bringing this kind of medication. They are all backed up by a politician or somewhere higher up. It’s always like that. And by the way, without naming the company, the company that was bringing counterfeit medication is a money laundering company.”

“...some of the dealers might be pharmacists unfortunately and also I think that some of the dealers may be working as nurses or technicians in some health institutions so I think some of the people working in the health system they are corrupt and working illegally.”

“ ... Once during the night shift, a male in his early 30s came in asking for Cytotec® (misoprostol, used for abortion) without a legal and clear prescription. He took out his OPL identification card said I have big connections and I am a pharmacist from Tripoli, does that work? We said no. He joked about it and bought other OTC drugs... and left.”

Pharmacists went on to explain how CFM sneaks through the system to reach the market or pharmacies all over the country.

“It leaks through the system by certain people inside the MoPH with different political affiliations.”

“And pharmacists were the ones who paid the penalty, and they’re the ones who didn’t have any idea about it.”

Participants were in agreement with the public FG participants, and believed that corruption had a role in the availability of CFM, causing weak or lack of implementation and enforcement of the law, in addition to the almost diminished border and customs control. Moreover, participants referred to corruption within the government, the MoPH and high officials, indicating how pharmacists end up paying the penalty instead of the actual offenders. Corruption among wholesalers and illegal supply chains in the USA and UK, allowed CFM to enter their legal chain system, as they were manufactured and distributed by well-organized criminal networks (Clark, 2003). According to FG pharmacists, corruption in Lebanon is at a bigger scale, due to lack of control and political instability. Participants went on to describe the selective approach of punishment used by authorities, describing the negligence and minimum control that were obvious by the very few offenders who were prosecuted (Chakrani 2012).

7.3.2.5. Overcoming counterfeit medicine

- **Central laboratory**

All participating pharmacists stressed the need for the MoPH to reactivate the national laboratory, to randomly test samples of the medicines that enter the country, and any area that has medicine to be used by the public.

“... It’s unfortunate because we don’t have a national lab, The MoPH needs to make sure that the right quality of meds is entering the market.”

“I think also the Ministry of Public Health should have a central lab to test drugs. Our role lies in refusing to buy or get some drugs from wholesalers.”

“... I think also the MoPH should have a central lab to test drugs...”

- **Dedicated pharmacists**

The majority of participants believed that pharmacists could have a major role in controlling the availability of CFM. In addition, qualified pharmacists should be available

in every place that handles medicine, in order to check and monitor its use, a self-driven role.

“I can stop it in my pharmacy, that’s why people who understand the situation stick to their pharmacy.”

“So I guess as pharmacists, our role is very important on a day-to-day basis. We are solo workers. No one is backing us up.”

Pharmacists suggested the need to organize and control the pharmacy profession, to stop the outliers that do not belong to this profession, and highlighted the importance of pharmacists’ being part of the supply chain and the role they could play in controlling the availability of CFM.

“... those good pharmacists who work in their pharmacy decently have built up the status for us today. ... We need to organize this profession because today we are still important in the chain.”

“... we need pharmacists in all the processes and departments... Ministry of Health, Ministry of Defence, the airport, the Port of Beirut, or anywhere drugs can be acquired, on the boundaries, etc. ... we need pharmacists who are dedicated, with good conscience. There are pharmacists dealing with counterfeit medicine everywhere. We need people with conscience and real dedication to their profession and their patients.”

• **Education**

The majority of participants raised a concern that physicians also should be aware and educated regarding CFM, because due to their experiences, there seems to be a lack of awareness among physicians. Furthermore, all participants believed that they have a duty to communicate with their patients to educate, explain and give alternative options to help them avoid using CFM.

“I think an issue that should be dealt with is the level of awareness of the physician about the harm that these medications can do...”

“This is where I tell you our role is to make the patient aware...”

“... I think it is important that us pharmacists need to increase awareness for those people. It is one of our responsibilities which we need to also address at a certain point.”

Participants stressed on the importance of knowledge, however to know alone is not sufficient; the “know how” according to participants is a must but is always missing.

*“... We have big headlines like: Be aware of counterfeit drugs... **But how?** We don’t have the how? This is the issue with counterfeit drugs and other issues. We*

do campaigns: be aware of counterfeit drugs. That's great, but how would I as a patient or as a pharmacist know?..."

"They OPL have an educational role as well."

- **Laws and regulations**

Pharmacists agreed during their discussions on the need for a legal decision to tackle this issue with an appropriate action plan to implement it. In addition, developing a CFM reporting system and a point of reference where the MoPH and OPL can be available and involved.

"First, we need a well-established political system..."

"Also, we want a reference, someone to get back to if we face any problem, so now she's doing her own way in detecting the adverse drug reactions. We should have a well-defined, standardized system between all of us."

"Pharmacists have a limited role now; they can help in their own pharmacies. This should be a national effort."

"Inspectors should inspect all, not specific areas,... the approach should be standardized and with appropriate approach."

"We need to have not just laws, because we might have laws saying vague sentences like there should be a pharmacist in the Ministry of Health, but what is the role of the pharmacist in the Ministry of Health? We do not have an agreement on the roles. Who should be responsible? The OPL, the Ministry ... let's say who should be responsible. But how should each institution be responsible? In what way?..."

Participants believed the need for the MoPH to re-activate the national laboratory in order to test all the medicines available in the country. These pharmacists believed that dedicated pharmacists could have a key role in controlling the availability of CFM and stopping it from reaching patients, on daily basis, stressing on the need to have pharmacists present in any place that medicine is available. Participants believed in educating their patients, and all pharmacists about CFM, in addition to physicians and anyone that handles medicines, emphasising on the need for the government to develop legal frameworks and strong legislations regulating the market with severe penalties to deter counterfeiters. Local authorities would need to provide strong quality control over the manufacturing, distributing and importing of medicine, decreasing the chances for counterfeiters to infiltrate the system.

When comparing the four focus groups and the emerged themes, four themes were in common; awareness, trust, corruption and overcoming CFM, indicating that they had similar views and beliefs with CFM, each from their own perspectives and experiences.

The awareness for all FG participants demonstrated that education could be the turning point for controlling the use of CFM, and both the public and pharmacists would benefit from additional educational campaigns, seminars, workshops, or conferences that would focus more on what CFM represent, highlighting the risks and consequences related to their availability.

Participants' experiences, views and beliefs towards trust and corruption were powerful in the effect they had on their discussions and their disappointments in both the pharmacists and the system. According to participants' attitude towards the government and regulatory authorities; the reported CFM cases in 2012 (Chakrani 2012), demonstrated the casual attitude and negligent approach used by the government in protecting the public from the entry of CFM into the Lebanese market. The 2012 scandal indicated that some officials were aware of the scandal and called for the CFM to be withdrawn, but no action was taken to withdraw them from the market. When the media exposed the scandal, then they were asked to be withdrawn from the market (Kataeb, 2012). The exposed scandals by the media were the only means for the public to learn of what was happening in the country. This lack of transparency might have contributed to the mistrust towards the government officials, and the conduct that they could only interpret as corruption.

The public perception of pharmacists, after the scandals in 2010 and 2012, affected the image of pharmacists negatively, yet, according to participants, pharmacists are still respected by patients, but their status is deteriorating. Many studies documented the impact pharmacists can play in improving patient health outcome, and the role they have to decrease the chances of dispensing CFM (Pickard et al, 1999; Ziance, 2008; Law and Youmans, 2011; Jackson et al, 2012). However, the good or bad headlines do influence the course of pharmacy profession, therefore, more efforts would be required to improve the image and re-establish the trust that was lost (DiPiro, 2011).

Trust is a very important asset the public can give to healthcare professionals when their work is on behalf of the public for furthering social justice and the public's health (Kass, 2001). In order to improve the image of pharmacists, they must act in accordance to the trust placed on them by the public, maintaining the reputation of the pharmacy profession (General Pharmaceutical Council, 2015). Since there is not a code of ethics for pharmacists published on the OPL website, the OPL would need to consider agreeing on a pharmacist code of ethics that all registered pharmacists must follow, and once decided upon, to post it online for all to see. The majority of the public FG participants did not trust pharmacists,

unlike the majority of the pharmacist FG participants, as they believed that the public trusted them. The pharmacist FG participants acknowledged that some members of the public may not trust them due to the negative impact of the scandals that exposed the involvement of pharmacists with CFM. As a result, the trust relationship between patients and pharmacists should be addressed further, to describe the role that pharmacists have in protecting their patients and public health.

The last theme, overcoming CFM, demonstrated that all FG participants irrespective of their profession or position had similar thoughts and solutions towards this problem. Counterfeit medicines do not discriminate, therefore, participants believed that reactivating the national laboratory, education, strict control, implementation and enforcement of the laws should play a role in helping control the availability of CFM in the country.

7.4. Conclusion

This is the first study that explored the views, experiences, and beliefs of 24 members of the public and 13 practicing pharmacists, using focus groups. According to FG participants, healthcare in Lebanon, is not taken for granted, for the situation is serious, and requires more attention from the MoPH and OPL. The results of both the public and pharmacists FG helped explore how participants thought of CFM and their views towards pharmacists, the MoPH, OPL, pharmaceutical companies and wholesalers. Furthermore, the OPL would need to agree on a pharmacist Code of Ethics to be followed by all registered pharmacists in Lebanon, and to be posted online. The findings come in support with the previous chapters on the need for additional and continuous educational programs for the on going problem of CFM. Additionally, the need for the MoPH and regulatory authorities to establish strict controls on the medicine that get into the country, such as the supply chain, and the distribution system, in addition to reactivating the central laboratory, creating a CFM reporting system, and implementing and enforcing the law.

Chapter Eight

Final Discussion and Recommendations

8.1. Discussion

This study is the first to address counterfeit medicine in Lebanon using four different methodologies to determine the nature and extent of CFM, and awareness towards CFM among the public and pharmacists. The first methodology used the physical examination and chemical analysis to determine the nature of CFM in Lebanon. The second methodology, according to the literature search, was the first to use medication use evaluation, to determine the extent of CFM. The third methodology used questionnaires to determine the public and pharmacist awareness and attitudes towards CFM. The fourth methodology used focus groups to further explore the public and pharmacist experiences, views and beliefs towards CFM. The study took place at different regions in Lebanon, and only the chemical analysis took place at the University of Brighton – School of Pharmacy and Biomolecular Sciences. The work of this study adds to the available knowledge, the nature and extent of CFM in Lebanon, additionally the awareness and attitude of the public and pharmacists towards CFM in Lebanon, followed by the focus group meetings that provided a better understanding of the areas that could be further studied to help better control the availability of CFM, such as developing educational campaigns and better regulatory control.

8.2. Overview

The **nature** of CFM in Lebanon was determined with the five identified CFM from the MoPH (Panadol[®], Amoxil[®], Viagra[®], Cialis[®] and Plavix[®]), and showed that the identified CFM matched three of the six categories identified by the WHO. The three categories were; firstly, medicines with incorrect quantities of active ingredients that accounted for 20.2% of the CFM, and matched three of the identified CFM, Amoxil[®], Viagra[®], and Plavix[®], secondly, medicines with correct quantities of active ingredients with counterfeit packaging that accounted for 15.6% of the CFM, and matched one of the identified CFM; Panadol[®], and finally, medicines with high levels of impurities / contaminants that accounted for 8.5% of the CFM, and matched one of the identified CFM; Cialis[®]. The findings demonstrated that the CFM are not limited to a specific medicine class and ranged from life style medicines to life saving medicines, most probably depending on the urgency and need associated with their use.

The **extent** of the CFM in Lebanon was determined using the medication use evaluation, by the photos taken after evaluating each medicine. The study showed that the CFM were

available in 49 (32.7%) of the 150 households visited. The extent of CFM ranged from 3 - 12% and was least prevalent in Mount Lebanon, and most prevalent in the Bekaa. The findings demonstrated the reality of the situation and the consequences that CFM may have on public health and the risks associated with their use.

The **public awareness and attitude** towards CFM showed that respondents had heard of CFM, although the results demonstrated a gap in their knowledge regarding CFM. The respondents reported believing wholesalers being responsible for the availability of CFM, and that the best way to avoid getting CFM, would be getting it from a trustworthy pharmacist. The respondents disagreed that CFM were as good as the originals, and agreed that the original medicines were highly priced, and CFM were of better value, and could be very dangerous. The majority agreed that pharmacists who dealt with CFM were unprofessional, unethical, and did it for the easy money and big profit.

The **pharmacist awareness and attitude** towards CFM showed inconsistency in respondents' definition of CFM. Additionally respondents relied on patients' response in identifying CFM from their originals. Less than half of respondents reported knowing of pharmacists who dispensed CFM, and majority of respondents agreed that pharmacists who dealt or sold CFM were unprofessional, unethical, and did it for the easy money and big profit.

There were 4 **focus groups** (FG) in total, two for the public and two for the pharmacists. The public FG participants were 24, and 13 for the pharmacist FG. Common themes between the focus groups were; awareness, trust, corruption, and overcoming CFM, indicating common and similar experiences, views and beliefs towards CFM.

The most updated WHO definition refers to CFM as “Spurious/falsely-labelled/falsified/counterfeit (SFFC) medicine....” (Spring, 2006; Majid, 2008). Falsified, substandard, spurious, unwholesome, and fake medicines are common terminologies that are used interchangeably in the literature and elsewhere to describe CFM (World Health Organization, 2012b). Some reviewers argue that it is “not immediately obvious that a specific definition of ‘counterfeit medicine’ is a necessary tool to effectively combat the public health problem of unsafe medicines” (Delepierre et al, 2012). Henceforth, differentiating between other terms that are being used or confused with CFM is important, to allow regulatory authorities to determine appropriate counter-measures with respect to each situation (Newton et al, 2009; General Council of Official Colleges of Pharmacists,

2010; Newton et al, 2010; Delepierre et al, 2012; World Health Organization, 2012b). As an example, some of the terms found in the literature to describe CFM were; imitation brand (Lai and Zaichkowsky, 1999) custom made copies, commercial and corporate piracy (Budiman, 2012), and garage piracy (Van Wijk, 2002). Additional terms may also be misleading or confused with CFM, but do not necessarily mean CFM, as described in **(Appendix 8.I)**.

Thus, differentiation between counterfeit, generic, substandard, degraded, misbranded, pirated, adulterated, out-dated, parallel and smuggled medicines **(Appendix 8.I)** would be vital for regulatory authorities (Newton et al, 2009; General Council of Official Colleges of Pharmacists, 2010; Newton et al, 2010; World Health Organization, 2012b). To emphasize, a study considered a medicine counterfeit if the content of the active ingredient was 0% (Seear et al, 2011). The 0% could be misleading, for according to the WHO definition, this is one possibility of a medicine being counterfeit, hence, the chances of missing or not identifying a CFM would be high. Currently, many countries cannot agree upon what constitutes a CFM, creating a lot of confusion due to the different terms used, for this reason, a universal definition would be essential to be able to control and stop CFM from spreading globally (World Health Organization, 2011).

Consequently, the study demonstrated the need for an official consensus on a CFM definition in Lebanon, to be used as reference to distinguish between the different terms used for counterfeiting. This would allow all parties involved in handling medicine to better identify CFM; especially regulatory authorities to allow for taking appropriate measures against offenders.

Important to realize that the study highlighted the nature and gravity of the CFM problem and the risks related to the availability of CFM on public health. Furthermore, it demonstrated how vulnerable patients and pharmacists could be, the patients for using the CFM, and the pharmacists, for unknowingly dispensing it. In addition, the study suggested how greed, lack of awareness and corruption could be factors in the availability of CFM. Hence, pharmacists have a duty to buy from trustworthy sources, and the MoPH has a duty to control the quality and safety of the medicines that enter the country, by implementing and enforcing the law, and strict inspections and control of places that carry or handle medicine. Just as the above measures could be effective to control the availability of CFM, thus gaps in knowledge would also need to be filled (Jha, et al, 2010). As a result, the public and all stakeholders would need to become more aware and educated of the risks

related to CFM.

Moreover, despite all the efforts to control the availability of CFM, counterfeiting continues to be a serious problem. The study demonstrated how counterfeiters are catching up fast with the technology, and identifying CFM is becoming more difficult, as shown in Chapter Two by the physical examination and supported by the chemical analysis. Counterfeit medicines are often indistinguishable from the original and may contain the same amount of the active ingredient, but may have detrimental effect on patient's health due to the complete absence of quality control (Ham, 2003). Therefore, patients' lives and health are constantly at risk when they unknowingly consume CFM (Interpol, 2015). The threat of CFM use appears to be on the increase, and with it a rise in morbidity, and mortality (Newton, et al, 2006a; Nayyar et al, 2012), and according to the Interpol, it is impossible to quantify the extent of CFM (Interpol, 2015).

The impact of CFM varies from failure to treat minor and major diseases, to medicine resistance, due to absence of active ingredient or sub therapeutic doses of medicine (Nuhu et al, 2011). The severity of the health risks associated with CFM can vary from inconvenience to unwanted pregnancies to fatalities (Lybecker, 2007). Counterfeit medicines also violate the intellectual property rights, medicine legislations, and other aspects of criminal law (Parloff, 2006). Not to mention the effects counterfeiting has on governments and businesses that would affect the whole economy, when the global losses from counterfeiting are estimated in billions (Hardy, 2010). Moreover, the mistrust by the public towards pharmaceutical companies, as expressed by FG participants in Chapter Eight, is also an expected reaction (Cockburn et al, 2005). The mistrust due to availability of CFM could lead people to serious consequences such as; abstaining from treatment, leading to deterioration of health, health complications, and maybe death (Dondorp, et al, 2004; Deisingh, 2005; Newton et al, 2006a; Newton et al, 2006b).

Besides, patients may not realize they are using CFM, and this could be clarified by the fact that often, CFM do contain the active pharmaceutical ingredients, to avoid any detection or suspicions related to the medicine during therapy, to generate repeated businesses (Jain, 2006). In like manner, some may contain expired active ingredients to save cost or undergo poor, if any, quality control measures (Jain, 2006). The CFM may be ineffective and/or dangerous, as well as difficult to detect by HCP; as an example they may use active ingredients, from a similar/different class; by substituting a class of medicine for another class of a cheaper generic form (Jain, 2006). All could have an impact on the cost

of healthcare that may increase for patients, leading to hospitalization and complications that would require more care at a higher cost (Dondorp, et al, 2004; Cars and Nordberg, 2005; Deisingh, 2005; Kelesidis et al, 2007). The precise burden of CFM is not known (Jha, et al, 2010), as there are no figures in to describe the hospitalized cases related to CFM use, except for the reported cases of death (i.e., Appendix 1.III). Thus, future studies may consider reviewing hospital admissions that could be related to CFM use, and their related outcomes.

The extent of CFM in Lebanon was compared with what is reported for other developing countries, and the extent of 4% for Lebanon would be considered low, when about 1% of prescribed medicines in the developed world are considered CFM, versus about 10-30% in parts of the developing world (Cozzella et al, 2012; U.S. Food and Drug Administration, 2015). The findings also highlighted the factors that may be contributing to the availability of CFM in Lebanon, that were similar to other developing countries (Kaur et al, 2010), and the factors were:

1. The history of civil war, and the negative impact war has on people and society (i.e., poverty) (Ministry of finance, 2013).
2. Lack of awareness regarding CFM.
3. High cost for original (brand name) medicine.
4. Shortage of medicine supplies.
5. Minimum law implementation and enforcement of the laws and regulatory actions, prohibiting counterfeiting of medicines
6. Lack of customs and borders control.
7. Lack of transparency by the government and authorities towards the public on cases related to CFM.
8. Lack of a just and standard process for supervision or control by MoPH and OPL inspectors (World Health Organization, 1999; Gordon, 2002; Nassour, 2008).
9. Corruption (Government, MoPH, customs, wholesalers, agents, regulators, and pharmacists).

Consequently, the availability of CFM in Lebanon is a problem that would need to be acknowledged, recognized, and controlled by all stakeholders, primarily for the risks they pose on public health.

In general, producing CFM is considered an easy task and does not require large infrastructures or facilities, as some of the CFM producers carry out their activities in regular homes, backyards, and basements, and the requirements are; a tablet press, a printer, commonly found household materials and the intention to harm (Mehta, 2006; World Health Organization, 2008; Kaur et al, 2010). At the same time, the quality of CFM could vary based on the sophistication of counterfeiters, and the high technology used (Newton, et al, 2006a). Correspondingly, the global trade in CFM is huge and is growing, due to the amount of money generated, their low production costs, and the high demand for medicines at low costs (World Health Organization, 2012a). The thesis showed how pharmacists could no longer rely only on the physical appearance of the medicine or the presence of a hologram. Yet, the physical examination should continue, as it could still identify the low quality counterfeits that may continue to be found in the market. The pharmacists and public need to be assured the medicines they are receiving are safe, effective, and of good quality. Additionally, when medicines are unregulated, unaffordable and inaccessible, the demand by the public for cheaper medicine could as a result increase, making them more vulnerable to buying CFM.

Further, the results did not vary significantly between the questionnaires' results of the public and pharmacists', and the FG experiences, views and beliefs. The level of knowledge towards CFM among the public was low, but high among the pharmacists, and this would be a valid finding since pharmacists are HCP who ought be more aware of medicines and their related issues. The study revealed that despite the efforts in the last few years to raise public awareness towards CFM, the majority of respondents reported not knowing or having a full understanding of what CFM meant. Respondents lacked the required knowledge that would help them identify and avoid buying CFM, and reported that their main source of CFM awareness was TV. Moreover, the respondents and participants expressed the need for the government to be more transparent and strict in handling CFM cases.

Alongside, the thesis demonstrated the confusion related to the role of the hologram when it is not present on every medicine package that is available on the market, although there were four different campaigns that took place in Lebanon, informing patients to look for the hologram, to assure patients that the medicine is the original and not counterfeit (Lebanese pharmaceutical importers association, 2015). Thereupon, in order to avoid confusion, all medicines whether locally manufactured or imported, should have a security measure to assure patients that a medicine is safe to use, when the public may not know the

difference. The Administrative Reforms created a task force with the LPIA 2009-2010 to introduce a national barcode on all imported and locally manufactured pharmaceuticals, (Lebanese Pharmaceutical Importers Association, 2015) however, there were no reports to indicate if it was implemented.

The respondents and participants of this thesis shared their opinions, and beliefs, expressing mistrust towards pharmacists, the government, MoPH, OPL, regulatory authorities, and customs, when trust is considered an essential element in good governance (Bouckaert et al, 2000). In fact, the availability of CFM demonstrated the on-going responsibilities that pharmacists have in ensuring that their patients receive safe and effective medicine. Community pharmacists are considered highly accessible when compared to other healthcare professionals, for the extended opening hours and availability for advice without prior appointments (Eades et al, 2011). A study in Lebanon surveyed the LAU community (949 out of 8360) that included staff, students and administrators to describe their awareness towards the role of pharmacists in Lebanon, showed that 55% reported to believe that pharmacist were salespersons (Sholy and Zeenny, 2012). In support, respondents and participants of this study reported believing that pharmacists were salespersons; and businessmen/women; promoting certain medicines like CFM, with the priority to sell and make money, as a result would not mind selling and/or promoting certain medicines like CFM. Although according to the public FG participants' there are many pharmacists who care about and spend time with their patients, yet, some believed there are some who willingly compromise their ethics, pharmacy practice, and patients' health, and do not merit the publics' trust.

By the same token, a study in Sweden investigated the views and expectations of customers regarding health information in Swedish pharmacies, found a gap between respondents' positive attitudes towards pharmacists and their low expectations towards the pharmacists' ability to provide health information (Larsson et al, 2010).

In reference to the public FG participants, the few who trusted their pharmacists believed that pharmacists would not knowingly carry CFM in their pharmacies, because they care about their patients, therefore, pharmacists would make sure to get the medicine from a trusted source. The mistrust expressed by participants towards pharmacists might have been due to cases they had experienced with pharmacists or heard of, that shattered the respect and trust between pharmacists and patients. With the availability of CFM, patients need to rely on and trust their pharmacists to help them avoid the use of CFM. In this case,

patients most probably do not expect to check with their pharmacist if the dispensed medicine is genuine/authentic/original or counterfeit, nevertheless, the availability of CFM may require them to ask this question. Chapter Four of this study, addressed public awareness towards CFM in Lebanon, and majority of respondents reported they would avoid getting CFM, by getting their medicines from a trustworthy pharmacist. This would add to the responsibility that pharmacists have towards their patients, if they were aware of the availability of CFM. The problem may arise when the public put their trust in pharmacists who may not be trustworthy. Several studies documented how pharmacists that had limited experiences with, or awareness towards CFM, exposed their patients to the risks of using CFM (Binkowska-Bury et al, 2013; Law and Youmans, 2011; Shahverdi et al, 2012).

In fact, the pharmacist FG participants expressed care towards their patients, acknowledging indirectly that for pharmacists who dealt with CFM, patients were not their first concern, rather the business was. A study described how pharmacy students felt towards patients, where students referred to themselves as the medicine for patient. For as much as the medicine has the ability to treat or relieve symptoms, pharmacists have the ability to listen with compassion and to care for patients (Vogt and Finley, 2009). Therefore, pharmacists must provide their patients with safe and effective medicines, as their duty extends from the patient to the community, for the primary obligation of pharmacists would be to their patients.

Furthermore, the pharmacist FG participants referred to situations when CFM became more available, such as in cases with medicine shortages, in that case, pharmacists' role would be to protect patients from using CFM by providing other alternatives rather than choosing a substitute that may be counterfeit. Pharmacists have a duty to understand the risks that the shortage of medicine may pose on a patient, especially when CFM are available (Smearman, 2006), therefore, should plan for alternative options from reliable sources, to recommend the medicine most appropriate for the patient.

Subsequently, in cases when pharmacists have reasons to believe that other pharmacists are dealing with CFM, they would have an obligation to act. Chapter Six addressed the role of whistleblowers, who raise concern about wrongdoing, in this situation, by acting to inform regulatory authorities to take appropriate measures against the offending pharmacists. The whistleblower concept was already introduced by the Lebanon Anti-Bribery Network (LABN) (The Lebanese Transparency Association, 2008; U.S. Department of state, 2014)

in collaboration with the Lebanese Transparency Association and the Centre for International Private Enterprise. They launched in November 2009, the Code of Ethics and Whistleblower Protection Procedures for assisting small and medium enterprises to apply it in their companies. They also provided a workshop for owners and directors of companies on the importance of ethics and on ways of applying the code. The standards were to increase the levels of transparency, integrity and good governance that could play a key role in reducing corruption (U.S. Department of state, 2014). LABN was a reaction to a problem that disturbed many of the Lebanese population that did not approve of the corruption, and introducing it to the Code of Ethics for pharmacists would also be for the welfare of the public. A draft law on whistleblower protection was submitted on June 24, 2010, to the Lebanese parliament by the National Network for the Right to Access of Information in Lebanon. The bill is for protecting corruption whistleblowers, to prevent prosecuting people who expose corruption. The bill still awaits approval of Parliament's general assembly and the Cabinet to be enacted into law (U.S. Department of state, 2014). Once the whistleblowers' bill becomes enacted into law; it would encourage healthcare professionals to report poor care; and in cases of CFM, it would protect the patients, the public, and society from the harm of CFM use, especially when done in good faith and in the public's best interest (Bolsin et al, 2005).

Notably, pharmacists traditionally, have three legal responsibilities: careful and proper storage, preparation, and dispensing of prescription medicines (Smearman, 2006). Physicians are responsible for choosing the appropriate medicine for patients, and that would be considered risk assessment, however, pharmacists are responsible for the proper medicine use, and that would be considered risk management (Smearman, 2006). As healthcare professionals, pharmacists are responsible for what they do, or do not do, therefore, must use their professional judgment in situations that require a specific action or decision (General Pharmaceutical Council, 2015). Countries such as the UK, the USA, and Canada have a **Code of Ethics** for pharmacists with principles; that are based on moral obligations and virtues. The Code is used as a guideline for pharmacists in their relationships with patients, colleagues, other healthcare professional and their communities, when making professional choices or decisions (American pharmacist association, 2013; Canadian pharmacist association, 2014; General Pharmaceutical Council, 2015).

According to the General Pharmaceutical Council's standards of conduct, ethics and performance; as healthcare professionals, pharmacists must meet the set standards. The

code includes the following seven principles/standards: 1) Make patients your first concern; 2) Use your professional judgment in the interests of patients and the public; 3) Show respect for others; 4) Encourage patients and the public to participate in decisions about their care; 5) Develop your professional knowledge and competence; 6) Be honest and trustworthy; and 7) Take responsibility for your working practices (General Pharmaceutical Council, 2015). The Code is intended to state publicly the principles that are considered the base behind pharmacists' roles and responsibilities towards the patients, community and society. The principles specify the behaviours; attitudes and values registered and practicing pharmacists, must or are expected to comply with (General Pharmaceutical Council, 2015). According to hearsay of registered pharmacists in Lebanon, and the OPL website; pharmacists do not have a Code of Ethics which sets out the standards of conduct; that registered pharmacists must follow (General Pharmaceutical Council, 2015). Developing or adopting a Code of Ethics for pharmacists as healthcare professionals, would be considered essential for pharmacists to abide by. Therefore, it would be necessary to set new practice standards, for pharmacists to accept their social mandate to ensure patients receive safe and effective medicines (Hepler and Strand, 1990).

Another key point is when participants expressed their disappointment and mistrust towards the government and MoPH, in the fact that they could have provided better control, services, and equality before the law that caused participants to feel powerless against the government's actions. The mistrust could have been due to the lack of confidence in the system, to act fairly, and reach just prosecutions (Harisalo and Stenvall, 2002) especially in the 2010, and 2012 scandals when the outcome of the investigations were unknown or not clear. Similar findings were reported by many studies (Newton et al, 2006b; Seiter, 2009; Akiny, 2013) when the public trusted that the healthcare system would protect them from harm however; the exposure of CFM through the media, the dishonesty, lack of transparency, and lack of respect for the public by the system might have affected that trust. The public's trust in medicine could become doubtful and this could affect the overall public health. Thereupon, according to respondents and participants of this study, the law should be revisited, strengthened, implemented and enforced.

Members of the public would expect the government and responsible authorities to have acted as authoritative institutions that safeguard the public's interest. Instead there was lack of transparency, control and implementation of the laws (Mroueh, 2012; Shaaban, 2012). As a result, the existing laws would need to be revisited to be more severe, to deter or limit

counterfeiters activities. According to participants' attitude towards the government and regulatory authorities, the CFM cases reported by the media and news articles (Chakrani, 2012) demonstrated the careless attitude and lenient approach used in protecting the public from the availability of CFM in the Lebanese market. There were no official reports found by the regulatory authorities, or MoPH on any CFM reported cases in Lebanon. Also, one study reported (Gibson, 2004) that in some countries governments do not want to declare the extent of the problem, weakness of the system, or lack of success in dealing with CFM, when there may be a conflict of interest, and this might be the case in Lebanon. Participants of this study went on to describe the selective approach of punishment used by authorities, describing the negligence and minimum control that were obvious by the very few offenders who were punished. The CFM scandals that took place in January 2010 and November 2012 (Chakrani, 2012), both were related to the same person, indicating the need for strict control and implementation of the laws, as the offenders continued to bring CFM into the country. Unfortunately, the number of people affected and possibly killed by CFM is unknown. Furthermore, participants explained how such scandals continued to support their loss of confidence and trust in the institutions that are present to protect them and look for their welfare.

Equally important is the medicine supply chain; before the medicine reaches patients, it has to go through a number of phases and controls, in the supply chain. The phases start with locating the source of the raw material then the active ingredient is extracted from the raw material, which is used to manufacture the finished product (Koh et al, 2003). A pharmaceutical company produces the finished product and once the finished product is final, the distribution starts through wholesalers. The wholesalers will distribute the medicine to pharmacies and hospitals that would dispense or administer the medicines to patients. Due to globalization, counterfeiters can infiltrate any of the above-mentioned phases especially in cases when the medicines change hands many times before reaching pharmacies (Koh et al, 2003). Therefore, tight control would be required when the sources are different, as the European Union (EU) Falsified Medicine Directive worked on this part, to better track and authenticate medicines as they move via the supply chain until they reach the patients. The Directive became applicable January 2013, however, time will determine its success (National Pharmacy Association, 2014). When the supply chain, as was supported by focus group participants, is not tightly controlled, counterfeiters would be able to find a way to infiltrate CFM through the system to make its way to pharmacies. For this reason, there would be a need to employ market surveillance and supply chain monitoring to identify counterfeiters.

Access to essential medicine is considered a fundamental right, with human rights placing obligations on countries to ensure that all the people have access to medicine (Cullet, 2003). After all, human rights are entitlements that belong to all human beings by virtue of them being humans (Nussbaum, 1999). The FG participants suggested that corruption might have played a role in the availability of CFM, denying people the right to have safe and effective medicine. In support, according to the Global corruption report “corruption in the pharmaceutical supply chain can take many forms: products can be delivered or stolen at various points in the distribution system; officials may demand “fees” for approving products or facilities, for clearing customs procedures, or for setting prices; demand for favours may be placed on suppliers as condition for prescribing medicines; and counterfeit or other forms of sub-standard medicines may be allowed to circulate” (Cohen, 2006). As a result the patients end up using CFM that would cause them more harm.

Must be remembered that consumers in counterfeiting are considered the actual force behind the counterfeiting business (Chan et al, 1998). After all, when there are medicines with extremely high prices, patients may end up seeking cheaper alternatives that may be counterfeit (Wertheimer and Norris, 2009), or may end up with no medicine at all. According to a survey report on prices of medicines in Lebanon that used an international standardized methodology for the WHO (Karam, 2004), Lebanon is considered a ‘brand/innovator name’ country, and possibly brand medicines are used more extensively, since there were no incentives to prescribe and dispense generic equivalents (Karam, 2004). Additionally, it was reported that the monthly cost of one chronic brand name medicine (i.e., Tenormin[®]- Atenolol) for hypertension was almost 2 days salary for the lowest paid government worker (Karam, 2004). In 2001, the imported brand names in the Lebanese market accounted for 78%, when 22% of medicines were generics (Karam, 2004). In comparison to the USA almost 90% of medicines used are generics, however in the EU the percentage is lower, and is highly variable across countries, when the highest percentage is in the UK and Germany and generic use is between 50-70% (Sheppard, 2010). Generic use is the lowest in Spain and Italy where it ranges from 25-30%, since they have a less mature generic medicine markets (Sheppard, 2010), similar to Lebanon.

In order to provide the full benefits of generic medicines, educational programs for prescribers, dispensers, and patients would need to address generics medicines, for more cost effective alternatives for patients, and for medicine shortages. When members of the public choose to buy cheaper medicine (CFM in this case) for financial reasons, generics may be an alternative option. Although, studies reported that patients were confused and

not sure if “generic brands” of medicines were in fact counterfeits (d'Astous and Gargouri, 2001; Lybecker, 2008). Many studies also reported that, lack of patients’ knowledge about CFM led them to have more of a negative attitude towards generic medicines (Bang et al, 2000; Liang, 2006a; Marcketti and Shelley, 2009).

As a matter of fact, a study looked at consumer’s perception on generic medicine in Iraq, and found that consumers there lacked knowledge of generic medicine and recommended more education of the public towards generics (Sharrad and Hassali, 2011). Since Iraq is a neighbouring country to Lebanon, the finding of the study may be similar with the Lebanese as well, however future studies could address this issue. The more knowledgeable people become about CFM and generics the stronger they would feel about the positive benefits of generic medicine (Ajzen and Fishbein, 1980; Bang et al, 2000). It would be crucial at this time to remember that, as per the WHO definition, that generic medicines can also be counterfeited, therefore, education and awareness would be vital, provided the MoPH follows a strict process of controlling the safety and quality of generic medicines that would be approved for use in Lebanon.

Henceforth, education should include the differences between generics and CFM, and the advantages of using generics. Additionally, the need for the public to be educated regarding Internet pharmacies, and the danger they pose to patients (Ivanitskaya et al, 2010; Gerasimchuck, 2011), especially in cases when patients search for bargains over the Internet to avoid buying expensive medicines, and visits to physicians’ clinics (Ivanitskaya et al, 2010). The Internet or online pharmacies are considered a global distribution channel for CFM, especially when offering medicine at very low cost, with the increase in medicine costs, pushback from pharmaceutical companies, and bad economy (Ivanitskaya et al, 2010; Ghamrawi, 2013). The fraudulent Internet pharmacies disregard the safety; potency, stability, quality; and sterility of medicine, placing the public’s health at risk (Gerasimchuck, 2011; Ghamrawi, 2013). According to the initial report by National Association of Boards of Pharmacy (NABP) on June 2012, 9,734 (96.7%) of the online pharmacies were non-compliant with the state and federal laws (Ghamrawi, 2013). The FDA warned that medicines bought via the Internet pharmacies may be counterfeit, expired, contaminated, wrong medicine, incorrect dosage, and manufactured in unknown conditions (Weiss, 2006; Ivanitskaya et al, 2010). On 24th June 2014, the EU Commission approved implementing regulation to protect the public’s health, and also introduced a standardized European logo for mail order pharmacies, allowing members of the public to differentiate between trustworthy pharmacies and doubtful ones (European commission,

2015).

Consequently, education is essential, and the aim of the educational campaigns and programs regarding CFM would be to make the public aware, to learn and most importantly to understand the risks and consequences of CFM use. By the same token, a study showed that once people become aware of the risks associated with counterfeit use, their evaluations of and feelings toward counterfeits would change and as a result would stop using them (Allred et al, 1994). The educational programs need to train, educate and reach out to include the different communities and the different age groups, in different regions of the country. Awareness and education of the public and stakeholders, combined with continuous collaboration between the MoPH and regulatory authorities could have and an impact on the availability of CFM. Future studies could further assess the impact of education and the collaborations.

In order to educate patients, pharmacists themselves should be aware and educated about CFM, its risks and the consequences of its use. In 2010, the MoPH became aware of the availability of counterfeit Plavix[®], and withdrew it from the market, and that meant that pharmacists were not able to identify Plavix[®] as counterfeit. The results in Chapter Three demonstrated that the CFM provided by MoPH, were not easily identified by visual inspection, making it more difficult for pharmacists to identify a counterfeit. This would add on the responsibilities and duties of pharmacists to make sure the medicines in the pharmacy are safe and effective. Pharmacists would need to rebuild their image, through personal efforts of pharmacists, and with the support of the OPL and the MoPH. The pharmacist's role could be more evident and publicized; highlighting the positive role pharmacists could have in improving patients' health outcome, and the role they have in decreasing the chances of dispensing CFM, as documented by many studies (Pickard et al, 1999; Tsuyuki et al, 2002; Adler et al, 2004; Ziance, 2008; Langebrake and Hilgarth, 2010; Law and Youmans, 2011; Abramowitz et al, 2012; Super et al, 2014). Pharmacists could maintain their professional competence through continuing education, workshops or seminars, however, this would not be limited to new products and advances, this would include any information that could have an impact on health, and certainly CFM could have a huge negative impact on patients and public health. Therefore, they have a duty to be up to date with all issues related to public health. Consequently, pharmacists in serving individuals or their community, would have a duty to tell the truth and to act with integrity, and avoid actions that would compromise the best interests of patients. Pharmacist focus group participants supported this when they expressed the need to buy medicines from a

trusted source, and the need to inform and educate their patients about CFM.

As an illustration, neighbouring countries, have taken measures in preventing CFM; in Jordan, a law has been proposed to protect patients and the pharmaceutical industry (Hall, 2010). In April 2012, a two days workshop took place in Jordan for promoting the health and safety of the people there. The workshop was directed for the law enforcement officials, judges, prosecutors and members of the Jordan food and drug administration, Ministry of Health, Customs, and the Public Security Directorate (Hall, 2010). Moreover, a joint effort among the authorities in Jordan have increased, making regular raids on pharmacies, increased the number of inspectors, and had new amendments of CFM Law by increasing penalties, that led to the drop of CFM (Taleb & Madadha, 2013). In the United Arab Emirates, a central laboratory was built to test medicines sold in pharmacies, and Egypt issued a decree banning unregistered medicines (Hall, 2010), and the impact of their intervention is to be evaluated in the future.

Important to realize the need for political awareness, will and readiness for cooperation, such as the European Commission's 2004 launch of strategies to address the enforcement of IP rights within and outside the European community, and the measures endorsed by trade ministers of the Asia Pacific Economic Community in 2005 to increase their capital to deal with counterfeiting. The national and regional anti-counterfeiting initiatives would encourage government ministries and law enforcement bodies and inspire them to utilize and allocate more resources to control counterfeiting (Keplinger, 2008). Similar initiatives would be worth considering in Lebanon as well.

Moreover, in the UK, after the 2007 case when thousands of counterfeit cancer and central nervous system medicines reached patients, the MHRA increased regulatory vigilance and aggressive public education as well as high profile prosecutions of counterfeiters, that caused a decrease in counterfeit activity (Taylor, 2012).

Under those circumstances, many international pharmaceutical companies launched awareness campaigns for their patients and the health system community to regain their trust and provide them with all the support required to reassure patients of the quality of their medicine (Lybecker, 2007; IFPMA, 2011; Pfizer, 2015). The pharmaceutical companies would need to continue with their awareness campaigns and being transparent with their patients about any of their medicines especially when suspecting a CFM.

On the positive side, the Lebanese authority strengthened its regulation to consider the import, distribution or sale of CFM a crime, an intellectual property violation and a breach of Lebanon's copyright law (Collection of laws for electronic access, 1999; Republic of Lebanon, 2010). Therefore, offenders who are convicted of counterfeiting crimes are sentenced to imprisonment for a minimum of five years and a penalty between \$66,700 to \$100,000. If the offender is a pharmacist, the licensure for practice is also revoked (Collection of laws for electronic access, 1999; Republic of Lebanon, 2010). The current IP and CFM laws constitute a base for controlling counterfeiting, though, the government would need to combat CFM by effectively implementing the existing legislative frameworks, by supporting the law enforcement bodies (Keplinger, 2008). However, the weak and corrupt enforcements contribute to the spread and wide distribution of CFM due to the difficulty in finding, arresting, prosecuting and convicting these criminals (Nelson and Chang, 2006). The weak regulations in Lebanon and the lack of enforcement increased the risk of CFM infiltrating the country, leading to corruption. Corruption was a theme that emerged from the discussions of the four FG, as participants believed that CFM circulated in the country with the knowledge of officials, regulatory authorities, and inspectors who they believed being on the payroll of counterfeiters. Lack of enforcement amplifies the risk of CFM infiltrating the market, by encouraging counterfeiters to operate with less fear of being caught or punished (Morris and Stevens, 2006; Aldhous, 2005; Akiny, 2013). For these reasons, the study suggested the need to revisit the CFM law provided it is implemented and enforced effectively against all offenders in a just manner.

According to participants of this study, the government runs the law enforcement bodies, where some corrupted politicians are restraining the law enforcement bodies from implementing and enforcing the law, in addition to influencing and affecting the decisions of some of the juridical bodies, especially in cases such as CFM. To improve the regulatory framework, extra measures should start with general political and system reform; i.e., new parliament election law, and juridical independence. The major step to stopping the corrupted political system is by having a new parliamentary election law. The new election law should be fair, transparent, and representative of the peoples' choice. With the new elected leadership, a transparent and reformed political system could be created. The new established government, the outcome of these reforms, would give the law enforcement a better chance of being implemented. The outcome of a new election law will enhance the government's accountability towards the parliament that leads to better performance of the ministries and public institutions i.e., law enforcement. As for the juridical system, judges are currently appointed by politicians, therefore, the political

reform should give the juridical system total independence. Consequently, the law would be implemented and enforced against all offenders, in a just manner. Of course, raising awareness among the government and members of the judiciary system of the serious consequences due to CFM availability would be essential, in addition to effective and deterrent penalties under national laws.

Lebanon's historic and cultural heritage dates back to over 6,000 years to the Phoenicians and the following civilizations that occupied Lebanon, and interacted with the Lebanese over the years. History shows that bribery and corruption in Lebanon dates back to the Ottoman Empire (1516-1918) (Werner, 1983; Ministry of finance, 2011; Sidani and Thornberry, 2012; Neal et al, 2015). Transparency International, the global coalition against corruption, defined corruption as "an abuse of entrusted power for personal gain" (Transparency International, 2014). In 2001, the UN Centre for International Crime Prevention reported that over 43% of companies in Lebanon admitted to always, or very frequently, paying bribes, with another 40% saying they did so sometimes (Abdelnour, 2001; Neal et al, 2015). A reported study showed that, 73% of business owners reported that corruption was a serious problem in the Lebanese public sector, yet more than half admitted that the more people, they knew in the public sector, the easier was the process of paperwork. Among respondents, 61% reported paying bribes to accelerate the issuance of formal documents (Abou Jaoude, 2013; Neal et al, 2015).

The Lebanese MoPH in collaboration with WHO conducted a transparency study in October- November 2007, using a standard tool developed by WHO; "Measuring transparency to improve good governance in the public pharmaceutical sector" (World Health Organization, 2009). The aim was to provide a comprehensive picture of the level of transparency and vulnerability to corruption in the function of the public pharmaceutical system: registration, promotion, inspection, selection, procurement and distribution of medicines, in order to identify weaknesses in the system (World Health Organization, 2009). Three national investigators, selected by the MoPH, collected data through a series of interviews with 50 carefully selected key informants. The results of the study did not show corruption; rather it showed the vulnerability to corruption. The medicine distribution area was considered minimally vulnerable to corruption, however, medicine registration, inspection and procurement, were marginally vulnerable to corruption. The medicine promotion and selection functions were moderately vulnerable to corruption and the process required more legislation and regulation to regulate and enforce transparent and efficient practices. As for the other functions; a higher level of transparency was

required, by making the procedures and decisions taken publicly accessible to all. In addition, the laws and regulations needed to be updated, taking into consideration the continuous advancement and development in the pharmaceutical sector. Therefore, their study suggested the implementation of recommendations and development of a code of ethics and the concept of conflict of interest to be introduced by law to be applied in practice where applicable (World Health Organization, 2009). No data was found on the implementations of the suggested recommendations.

Moreover, the perceived level of public sector corruption in the Transparency International Corruption Perceptions Index for 175 countries around the world categorised Lebanon as high; 136, in comparison with Egypt 94, Jordan 55, Saudi Arabia 55, USA 17, UK 14, and Canada 10 however lower than Syria 159 and Iraq 170 (Transparency International, 2014). The problem is that there is a culture of corruption in many countries, where behaviour of entitlement is acceptable when in many countries they are prohibited or unacceptable (Wertheimer and Norris, 2009). Hence, for the supply chain as an example, understanding the sources of vulnerability to corruption, policy makers should tackle the decision points of the supply chain most vulnerable to corruption to control its widespread, however, it could be overcome if it is characterized and known (Wertheimer and Norris, 2009). Consequently, The agents and wholesalers should be motivated to protect their reputations, and for the offenders to be held liable.

Additionally, as a means to control corruption within the healthcare profession, the Lebanese order of medical doctors (OML), in collaboration with the MoPH, OPL, NSSF, and the union of government employees launched in December 2011, the “unified prescription”. The prescription has triplicate copies, one for each; the physician, pharmacist and patient, with a barcode specific for each physician for better control, among other features to avoid counterfeiting it (Saarti, 2014). The purpose was to avoid the monopoly of medicines that pharmaceutical companies have in collaboration with some physicians, and can also allow for generic substitution, if the physician accepts the substitution (Saarti, 2014). This would allow for precise statistics limiting unnecessary use of medicines thereby avoiding related side effects. This will enable the OML to monitor the medicine use, misuse, or any discrepancies. The triplicate prescription would also stop physicians, pharmacists and pharmaceutical companies from monopolizing medicines, liberating the medicine market and relieving patients of the high cost of medicines (Weatherbee, 2015). Although the law passed in 2011, yet it was reported that the unified prescription was to be implemented as of June 2015. The adoption of the unified

prescription forms would make a difference for the country, when patients shift to generic medicine instead of brand names (Weatherbee, 2015). Moreover, the unified prescriptions would enhance the monitoring of medicines dispensed in the country (Weatherbee, 2015). Future studies could evaluate the implementation of the prescription and its effectiveness.

After all, trust promotes economic growth, however, corruption harms the economy, tears apart the individual's morals, respect for the law, and the faith in others (Uslaner, 2004). Corruption may continue to occur when there are no efforts to stop it, and studies show that in Lebanon corruption is part of the culture, and cultures are slow to change, and may even be resistant to it (Neal et al, 2015). Therefore, more studies on corruption within the healthcare system would help determine the effect and impact it has on public health.

In reality, pharmacists in a developing country like Lebanon would have a more challenging role in controlling and stopping CFM from reaching patients, due to the lack of legislation, weak or absent laws and regulations that should protect against CFM. Additionally, without adequate awareness of the consequences regarding CFM use, the MoPH and policy makers will be drastically underestimating the direct costs involved by the use of CFM on the number of chronically ill, leading to a surge in unfunded future liabilities of unknown dimensions (Wertheimer and Norris, 2009). Counterfeit medicine poses a high and serious risk to public health and quality of health care. Additionally, the CFM can have a broad macroeconomic problem for poor countries, especially when the foreign exchange is spent on CFM that are mostly useless, and as a result, when patients' health deteriorates, they will eventually become a burden on the country (Wertheimer and Norris, 2009).

In the long run, the public and patients in particular, once educated about CFM should always check with their pharmacists and ask questions about the medicines they are using and report anything unusual about their medicine. Therefore should know their medicine well; such as what the medicine looks like, smells like, tastes like, and feels like, and its related side effects in addition to the desired effect. Medicine safety should not be taken for granted; and responsible parties should take adequate control measures in order for members of the public to trust, that the system is protecting them and cares about public health.

As has been noted, the public need for affordable medicines encourages counterfeiters to produce CFM to satisfy the demand, when there is minimum or absence of social

conscience and penal sanctions (Lebanon Pharmaceuticals and Healthcare, 2010; Lebanese Order of Pharmacists, 2012; Shaaban, 2012). When the enforcement agencies and regulators are not efficient or just in their inspections of shipments or pharmacies, plus weak penalties for counterfeiters, the availability of CFM would become inevitable (Gibson, 2004). In order to control the availability of CFM, pharmacists, HCP, patients, MoPH, regulatory authorities, and the media all would have to collaborate to promote the well-being of patients by securing safe and effective medicine.

8.3. Limitations of the study

This study would be the groundwork for further studies on CFM in Lebanon; however, the study had the following limitations:

1. The nature of CFM in Chapter Two did not identify the other substances or excipients present in the CFM samples identified by the MoPH, since the objective was to determine if the CFM samples were the same or different than the original, and how the results may affect public health.
2. The number of houses visited in the South and Bekaa for determining the extent of CFM was low; and a larger sample may have provided a better representation of the region. Therefore, further investigation of these two regions would be required to give a better indication of the CFM prevalence. In addition the sample was highly educated, and may not be representative of members of the public with lower level of education and may have provided a different extent than what was found.
3. The study population of Chapter Four, may not appear to be diverse enough; as respondents were reported to be mainly from the city, when there are three main cities in Lebanon; Beirut (capital), Tripoli (north) and Saida (south). The areas visited were the North, South, Beirut, and Mount Lebanon, and the three main cities were among the areas visited. However, knowing which city may have provided a better insight into the level of awareness at specific geographical regions, and would have provided a better reference for targeted future awareness and educational campaigns.
4. The administration of the questionnaire at public places might have affected the provided information, for respondents might not have been able to answer at their own leisure. Using electronic or mail questionnaires would have provided them with more time to think about their answers, however, might have had a low response rate.
5. The study samples of the questionnaires were random, and those who participated in the questionnaires were in the ages between 18-40 years old, that may have been more willing to participate than the older age group. Having more respondents of the older age group might have provided different data.

6. The questionnaires did not ask for respondents' income bracket, if on any type of insurance to help determine if there was a relationship with awareness or attitude towards CFM, since the cost and price of medicine are factors that encourage the availability of CFM (Newton et al, 2009).
7. The questionnaires did not ask for respondents' ethnicity or religious background, due to cultural constraints, as people might be offended or misunderstand the intention behind such questions, and refuse to complete the questionnaire.
8. The study did not address the Internet pharmacies and online purchasing of medicine and whether members of the public are aware of it as a possible source of CFM.

8.4. Practical implications

The study provided data that were not readily available neither by the MoPH nor the OPL or any official authority. The study demonstrated the vulnerability of pharmacists and patients in their ability to detect CFM, and their reliability on a system that would control the safety and quality of available medicine. Additionally, the study demonstrated the need for the MoPH and regulatory authorities to reactivate the central laboratory in order to regularly and randomly sample the medicines at point of entry into the country and randomly at different locations where medicines are available.

Moreover, the study findings suggested for the MoPH and regulatory authorities to consider being stricter in implementing and enforcing the law, including the medicines ordered from the Internet. Collaboration between the MoPH, OPL, pharmacists, pharmaceutical companies, and parties involved in the pharmaceutical supply chain would be considered a necessity, to control the influx of CFM, in order to prevent CFM from reaching patients. The collaboration between MoPH and all stakeholders should be on three main areas: prevention, incident handling and investigation.

The presence of holograms, tamper evident seals or any other authenticating measure on medicines may not be always reliable, therefore, detection of CFM should be relied on awareness and vigilance of pharmacists and members of the public, by encouraging to report any suspected medicine. Educating the public and pharmacists, and all stakeholders would be considered essential; to control and prevent CFM use. Future campaigns may need to put more efforts on using different approaches than what was used before, to reach more people. Furthermore, the results demonstrated the need to establish a well-structured reporting system for the public, and the need for the government and regulatory authorities to implement and enforce the CFM law. Moreover, educating all other stakeholders (government staff, regulators, inspectors, customs, ...) to control and prevent CFM use would also be important. Consequently, education would also need to target generic medicine, for the public to trust and understand the benefits of controlled generics, when brand name medicines dominate the Lebanese market (Business monitor international, 2015), in addition to Internet purchasing of medicine and online pharmacies and their related risks.

The study suggested the loss of trust and confidence in pharmacists, the healthcare system, manufacturers, professional organizations, government and regulatory authorities. The

study also suggested the need for the OPL to post a Code of Ethics for pharmacists to publicize the role of pharmacists and to be used as a guide for pharmacists in their pharmacy practice. Additionally, control of CFM in Lebanon could be accomplished by full collaboration with international organizations, provided the counterfeiting problem is handled and controlled on the national level. Moreover, if CFM are not controlled, there would be a risk that pharmaceutical groups might reconsider their presence in Lebanon due to the negative effect counterfeiting would have on their medicines and businesses, and this would be ideal for counterfeiters.

8.5. Recommendations

The MoPH, regulatory authorities and OPL need to guarantee the highest standards of medicine quality and safety, since counterfeiters operate without the overhead costs of infrastructure, regulatory compliance and expensive active ingredients (World Health Organization, 2012a). Preventing CFM from reaching patients would be through collaboration between MoPH and all stakeholders focusing on prevention, incident handling and investigation.

8.5.1. Prevention

8.5.1.1. Develop an official definition for counterfeit medicine

Developing a CFM definition would eliminate confusion among regulatory authorities when evaluating any suspected CFM. However, when the definition is different between countries, it would limit the exchange of information, and the understanding of the true extent of CFM globally (World Health Organization, 2012a). Therefore, when developing or deciding on a CFM definition, it may be appropriate to consider the available definitions, to adapt or build on the existing ones if needed. One definition to consider would be the WHO's, that is followed by many countries (World Health Organization, 2012a).

8.5.1.2. Educate

Educational programs should provide accurate and up to date information that fills knowledge gaps (Hirsch et al, 2007). Considering all the available CFM facts, awareness would be an important tool to control the availability and use of CFM. Counterfeiting medicine has been going on for years, and education would need to include the public, pharmacists, pharmacy students, professionals, customs officials, police officers, and anyone concerned. Interactive educational/awareness campaigns may be a better approach allowing members of the public to better understand the related CFM risks and consequences to its use. MoPH and OPL need to collaborate to provide information and educational campaigns regarding CFM addressing its potential harm on patients and public health. The educational programs would need to be organized on regular bases, as conferences, training sessions, e-learning programs, and workshops. Official sites could be referred to for practical advice on identifying and preventing distribution of CFM such as

WHO (World Health Organization, 2015), Royal Society of Great Britain (Royal Pharmaceutical Society of Great Britain, 2009), and the International Pharmaceutical Federation (International Pharmaceutical Federation, 2015a).

Pharmacists are expected to be aware of CFM, responsible and vigilant, especially in choosing the most reputable and reliable sources for the medicine supply (Royal Pharmaceutical Society of Great Britain, 2009; Cordina, 2010). To protect pharmacists from being responsible towards their patients for using CFM, awareness and mandatory educational programs would be essential to increase pharmacists' awareness and knowledge towards CFM. Therefore, MoPH and OPL in collaboration with pharmaceutical companies; may need to consider providing training programs about the technologies they are using on their products, to help pharmacists identify and detect CFM before it reaches patients. In addition, to collaborate with schools of pharmacy to educate future pharmacists about counterfeiting and CFM.

Repeated campaigns seem to be associated with better awareness for reinforcing the messages (Dumesnil and Verger, 2009). Continuous campaigns should target a wider and more focused population to increase creating awareness about the severity of the CFM problem among all stakeholders. Such as targeting all users of the supply chain by implementing a continuous educational program engaging all stakeholders such as policy makers, supply chain operators, and law enforcements. The educational campaigns would need to use several types of exposure such as TV, Print media, ... (Dumesnil and Verger, 2009).

The MoPH would also need to engage the public by informing them about the dangers of CFM use and of buying medicine from untrusted sources such as the Internet (Montoya and Jano, 2007). The public and pharmacists can play an essential role in the control, use and spread of CFM. The pharmacist's role is not limited to counselling patients on how to take their medicines, but also to know the source of patients' medicines. Medicine from the Internet could cause major harm to patients' health and even death (National Association of Boards of Pharmacy, 2012). That does not negate the role of regulators or the government where continuous follow up and implementation of the law should be applied and announced for any CFM related cases.

Studies found that the cost of healthcare could be estimated; by the number of admitted cases due to CFM (Newton et al, 2006b; Seiter, 2009; Akiny, 2013). This would need

awareness and knowledge towards CFM that could be accomplished through educational campaigns for all HCP who handle or deal with medicine to be able to report CFM related cases.

8.5.1.3. Establish medicine control laboratory

Counterfeit medicine is frequently designed to deceive pharmacists and patients into thinking that it is the original (Royal Pharmaceutical Society of Great Britain, 2009). The control of CFM availability could be achieved by establishing an independent medicine control laboratory that would not be influenced by any political party. The laboratory would test the medicines that enter the country for quality and safety. The laboratory is supposed to test the sample of medicine that are imported into the country, and based on their results the medicine would be dispensed in pharmacies (Lebanon Pharmaceuticals and Healthcare, 2010; Abou Jaoude, 2014). The laboratory would allow the regulatory authorities to regularly and randomly sample test the medicines that enter the country and those already available on the market, for better control of the influx of CFM, reducing the risks related to CFM use, in addition to testing for bioequivalence to ensure medicines' efficacy and safety. The random testing or onsite inspections should test samples of shipments at customs, warehouses, wholesalers, and any location that may have medicine, including pharmacies. It is reported that since there is no central laboratory, the system is chaotic (Abou Jaoude, 2014), however, if establishing the medicine control laboratory was not possible then reactivating the central laboratory would be the alternative option.

8.5.1.4. Regulate supply chain

According to the former member of Lebanon's parliament; not all CFM in Lebanon are from abroad, some are prepared in Lebanon, as there are mafias that collect empty packages of products from hospitals and would repackage them, and then they reintroduce them again to the market, with no product content (International Pharmaceutical Federation, 2015a). Therefore, counterfeiting medicines should be treated on a national level, not only as an international problem. The MoPH needs to ensure procurement from reliable sources, since medicines sold via non-traditional distribution channels such as the Internet, and the grey market, have a higher risk of being counterfeit (Chambliss et al, 2012). Moreover, the Ministry of Industry and MoPH would need to collaborate to control the availability of CFM, especially medicines sold on the Internet. Additionally, to check that all agents, suppliers, wholesalers; and distributors are registered and licensed to supply pharmacies with only, MoPH registered medicines.

The long supply chain only needs a single weakness point for counterfeiters to take advantage off and infiltrate the supply chain. Therefore, limiting the number of times a medicine changes hands between the manufacturer until it reaches the pharmacy and patients would help reduce CFM through the supply chain (Rudolf and Bernstein, 2004). Consequently, to control the penetration of CFM into the legal channels of the supply chain, frequent, and random sampling of medicines by regulatory authorities and inspectors, at airports, ports and borders, customs, wholesalers, pharmacies, dispensaries, and any location where medicine is available, would be appropriate to discourage and control the availability of CFM, and that as a result might develop trust in the system.

The lax regulations and enforcements of existing laws could have provided counterfeiters with different ways to introduce their products into the supply chain. Therefore, the MoPH and regulatory authorities would need to consider securing the supply chain to make it more difficult for counterfeiters to sneak through it their CFM, using strict control from the manufacturer site until it reaches the pharmacies and then patients. It would be essential to regularly control the multi-entry points or gaps in the supply chain to limit the infiltration of CFM.

The MoPH needs to be more proactive and conduct background check and early authentication on the importers or new suppliers (wholesalers, dispensaries, agents) before being approved, by early validation of manufacturing sites, and formal registration or validation of all importers, checking the wholesalers licensing status, the date and place of incorporation, years in business and form of entity, and if there are any civil or criminal litigation against the company (Finlay, 2011; Chambliss et al, 2012). The already registered suppliers would need to undergo site checking annually by the MoPH inspectors to verify all conditions are still met. The status of suppliers would need to be posted on the MoPH and OPL websites for all who need to verify their status.

Furthermore, the MoPH needs to address medicine safety by developing standards for identifying, validating, authenticating, and tracking and tracing the dispensed medicines. In addition, identifying and validating the technologies used for securing the supply chain against counterfeit, substandard, adulterated, expired, pirated, and misbranded medicine (Gerasimchuck, 2011). The MoPH would need to collaborate with regulatory authorities and criminal enforcements to improve and secure the supply chain from CFM (Finlay, 2011; Gerasimchuck, 2011). The domestic manufacturers would also need to go through

rigorous enforcement by MoPH that the standards and safety practices are consistent with either public health standards or national security interests (Finlay, 2011).

The problem of medicine shortages could be minimized, by planning for it ahead of time to minimize the chances of CFM infiltrating the supply chain and the market, by inventory management, the use of therapeutic alternatives, and precautions against stockpiling (Chambliss et al, 2012).

8.5.1.5. Update innovative technology

The increase in counterfeiters sophistication in producing CFM identical with the original medicine, would require pharmaceutical companies to update their technological solutions to ensure the protection and traceability of medicines to secure the supply and distribution chain. Implementing the national barcode or the Data Matrix (2 dimension barcode) on all imported and locally manufactured pharmaceuticals in Lebanon will allow batch traceability, however; there are no reports that it was implemented yet (Lebanese Pharmaceutical Importers Association, 2015). The Data Matrix, could be used for increased medicine traceability, using a two dimensional barcode that would contain medicine information such as medicine name, dosage, strength, container size, lot or control number (Sanofi, 2014). The Data Matrix codes are read when the medicine is dispensed enabling automatic detection of counterfeit or expired medicines (Sanofi, 2014). The MoPH would need to take action on implementing the barcode, or other alternative security measures that would be one measure in helping protect patient safety.

Consequently, in order to verify the authenticity and reduce the chances of medicines being counterfeit, track and trace may be the foundation for improving patient safety, by giving the manufacturers, distributors and pharmacies a systemic method to detect and control counterfeiting, medicine diversions and mishandling (Koh et al, 2003; Pharma IQ, 2015). Serialization, a security measure allows accountability and traceability of every pharmaceutical in the supply chain to assure product safety, however presents added cost (Pharma IQ, 2015). Pharmaceutical companies, MoPH and regulatory authorities, would need to focus on packaging and dosage form authentication, however, the detection technology must be simple to use and cost effective (Chambliss et al, 2012).

8.5.1.6. Adopt a Code of Ethics for pharmacists

In accordance with the LABN work, OPL should adopt a Code of Ethics for pharmacist to comply with in Lebanon. The purpose of the code would be to provide guidance on the ethical framework for healthcare delivery with patients, community, colleagues and other HCP. The code can be referred to in cases involving the behaviour and/or conduct of pharmacists. There are Codes of Ethics for pharmacists that the OPL can adopt from, such as; the International Pharmaceutical Federation (FIP) Code of Ethics (International Pharmaceutical Federation, 2014). The American Pharmacists Association (APhA) Code of Ethics (American pharmacist association, 2013). In addition, the Australian Code of Ethics (Pharmaceutical Society of Australia, 2014), and the standards of conduct, ethics and performance in England, Scotland and Wales (General Pharmaceutical Council, 2015). All provide almost the same guidance for pharmacists. In order to save the image of the honest and duty bound pharmacists, the OPL should consider adopting a Code of Ethics for pharmacists to use as a guideline, and to publicize pharmacists' duties and obligations towards their patients, community and public health.

In addition, encourage whistleblowers to use their professional judgement in the interests of patients and the public, and to inform the authorities when they become aware of other pharmacists or HCP whose actions may cause harm to patients and society (General Pharmaceutical Council, 2015). This practice would allow pharmacists to maintain their credibility and the public's trust in their practice. The role of pharmacists in controlling the availability of CFM is described in **Appendix 8.III**.

8.5.1.7. Control corruption

There is a need for greater accountability, and officials need to take charge and not ignore the problem of corruption. The extent of corruption is difficult to determine due to the secrecy of its nature, however, government officials and leaders need to put efforts into creating a tight process that does not leave gaps for corruption to sneak through the system.

In order to control corruption in the pharmaceutical system, it would be best for the main decision points along the supply chain to be controlled and strictly supervised, and those are; manufacture, registration, selection, procurement, distribution, prescribing and dispensing (Cohen et al, 2007). Each of these points would require consistent and transparent procedures to control the processes; otherwise corruption would be inevitable,

especially when the country's culture is susceptible for it. Therefore, to improve transparency and accountability, intervention and anti-corruption strategies need to be applied to protect access to safe, effective and quality medicines.

Nevertheless, the increase in the number of purchases of medicine over the Internet signifies that the public in Lebanon may also be exposed and vulnerable to CFM via this route as well. Around 50% of medicines sold from unregulated Internet pharmacies are CFM (Kirby and Kirby, 2012). Additionally, it was noted that lifestyle medicines such as Viagra® are mostly sold over the Internet (Luu, 2005). Getting medicine through the Internet is a possibility that is not well addressed or acknowledged in Lebanon, even FG participants did not mention anything about it or even considered it as a source. Possibly, they have not had any experience with medicine from that source.

The public and pharmacist awareness towards CFM showed that the CFM campaign launched in 2008 may not have reached all the public and pharmacists, or added to their knowledge. The finding demonstrated that there was a difference between awareness and knowledge, as the latter might develop over time with continuous experience, education, involvement, and practice. Giving information is not enough, engaging the recipients would be the critical part of education to enforce the information.

8.5.1.8. Create non-profit organization(s)

The need to create non-profit organization(s) that would be dedicated to developing anti-counterfeiting resources, to help control and stop CFM, by involving a group of health professionals and members of the public with different backgrounds. The organization would need to engage legislators, to make them aware of the concerns and issues related to CFM, in addition, must be vocal about the CFM problems they would face, to impact policies and ensure they are voicing the concerns and worries of the public. The non-profit organization could coordinate with MoPH and OPL and any related organization to disseminate alerts about the most recent and up to date CFM incidents (Chambliss et al, 2012). The non-profit organization could collaborate with organizations such as Partnership for Safe Medicines (PSM) (The partnership for safe medicines, 2015) that is composed of a group of non-profit organizations and individuals that have policies, procedures and programs that protect members of the public through awareness regarding CFM use (The partnership for safe medicines, 2015).

8.5.1.9. Create an official website for counterfeit medicine

There is no information network for pharmacists and the general public to refer to for information or updates on CFM. As a result, responsible parties need to create an official CFM website for all stakeholders, to respond to, and alert stakeholders and the general public about CFM. In addition, the site should include an updated Watch list of high-risk medicines, and manufacturers with unsatisfactory medicines (Wertheimer and Norris, 2009; Taylor, 2012). The site would also make the Internet users aware of the risks and consequences of using CFM or buying medicine via the Internet. The MoPH, regulatory and official authorities (customs, borders, ports, police...), OPL, pharmaceutical companies, and politicians, would need to collaborate and to publicize all information related to CFM on the official CFM website (Burki, 2010), to use it as a means of communication with all stakeholders on issues or cases related to CFM. Pharmacists, the public and physicians have the right to know if there are suspected medicines on the market, and the related risks due to their availability (Wertheimer and Norris, 2009).

8.5.1.10. Collaborate with International organizations

The public, MoPH, OPL, pharmaceutical companies and regulatory authorities would need to collaborate with International organizations such as WHO and Interpol, to exchange information related to CFM and help determine the appropriate measures to control the availability of CFM.

8.5.2. Incident handling

8.5.2.1. Implement and enforce the law

The lack of appropriate legislation, and the minimum regulatory control of CFM are considered factors that would contribute to the availability of CFM. Therefore, the MoPH and regulatory authorities should strengthen the law and introduce more stringent legislation to implement and enforce the law against offenders, to deter or prosecute counterfeiters (Finlay, 2011) to control the availability of CFM. Additionally, the MoPH would need to facilitate the availability of inexpensive medicine, that are safe and effective.

Moreover, the MoPH would need to collaborate with the Ministry of Interior Affairs, and customs to control the spread and infiltration of CFM into the country and pharmacies. Furthermore, the MoPH and regulatory authorities would need to implement and enforce the laws against offenders.

This task would become even harder with patients who order their medicine over the Internet, using online pharmacies, or mail order. The Internet now is considered a global distribution channel for CFM (Ivanitskaya et al, 2010). There are no laws available related to purchases of medicine over the Internet in Lebanon. The Internet, and unofficial Internet pharmacies has given criminals a new and safe outlet for their criminal activities, therefore, there is a need for a law to control the purchases using the Internet, especially for medicine.

8.5.2.2. Establish counterfeit medicine reporting system

The study demonstrated the need for officials and regulatory authorities to be transparent when dealing with and reporting all CFM cases. Patients and pharmacists should report CFM through establishing a centralized and standardized reporting system, such as the Medwatch that encourages voluntary reporting of suspected CFM (USFDA, 2015). The system could be called “**CFM-Alert**” and it would be accessible to all stakeholders; HCP, regulators, pharmaceutical companies, and the public (Mackey and Liang, 2011). Once the suspected CFM is reported then it should be investigated quickly and efficiently by a system not an individual. The suspected medicines should be removed from the shelves until further notice is received from the MoPH, regulatory authorities, or other responsible authorities. Moreover, suspected medicine should be sent for analysis and assessment, to evaluate the risk it poses on the public, communicating that risk with the evidence to the prosecutors (Chambliss et al, 2012; Taylor, 2012). The reporter of suspected medicines would have the option of identifying himself/herself or be kept anonymous, in either cases patients’ safety should be maintained (Mackey and Liang, 2011). The reporting system should be a visible icon on the MoPH and OPL websites linking users directly to the reporting system.

8.5.2.3. Establish pharmacovigilance centre

Establishing a pharmacovigilance centre would be an essential component in public health programs for tracking, recording and analysing the effects of medicines to determine and

maintain the quality and safety of medicines. The centre would a tool for reporting; adverse medicine reactions, medicine monitoring, medicine surveillance and post-marketing evaluations, identify risks and adverse effects in the shortest possible time to avoid and minimize harm to patients. In addition, the centre would educate the healthcare team and members of the public about medicine safety to protect public health (World Health Organization, 2006b). Therefore the established centre would aim to monitor medicine safety in the Lebanese market, and as a result would be able to detect CFM when assessing medicine safety. The pharmacovigilance centre is an essential component in public health programmes that use medicine to optimize the use of health resources and prevent potential tragedies, such as CFM use (World Health Organization, 2006b).

8.5.3. Investigation

When incidences are reported, the available data could be followed up, investigated and studied by regulatory authorities, or other interested parties such as academics. The MoPH and the regulatory authorities would need to follow-up with the evidence, and prosecute the offenders of the reported incidents (Taylor, 2012), fulfilling their duties, to regain their credibility and trust among the public. The investigation would need to emphasize on tracing the CFM back through the supply chain to its source (Taylor, 2012). Therefore, in addition to the tight control at the ports of entry and at local manufacturers, continuous inspections and tracking down of every reported incidents or suspected medicine, would be essential in controlling the availability of CFM.

The data that develops should be communicated back to the public to inform them about the risks regarding CFM, or the outcomes related to the reported cases (Mackey and Liang, 2011).

8.6. Future Research

The study suggested some changes or modifications, and all should have monitoring of implementation and evaluation of outcomes to determine if the desired objectives were achieved. When the objectives are not achieved, it would be important to determine the areas that would require further modifications or may require the use of different measures.

The different studies in this thesis have assessed the nature, extent, awareness and attitude of both the public and pharmacists towards CFM. The thesis suggested the importance of continuous education of the public, pharmacists and all stakeholders to be able to control the availability of CFM. Therefore, future research should aim to assess the impact of the thesis findings on controlling CFM use, and drug resistance, harmful effects, price controls, implementing and enforcement of the law, by assessing the economic, environmental and social impact of the study.

Additionally, future studies could assess the influence of education and socio-economic status on awareness towards CFM, and public demand for CFM could be further investigated to determine what would be required to decrease the demand for counterfeits. Furthermore, future studies would need to evaluate the knowledge and use patterns of generics to determine the public's perception of generic medicines and CFM. Consequently, investigating the extent of pharmacist knowledge and involvement in limiting the CFM availability, and their understanding of the associated consequences of CFM would be essential in understanding the role Lebanese pharmacists have in protecting their patients from using CFM.

The study recommended establishing an independent medicine control laboratory that would not be influenced by any political party, if not possible then the reactivation of the central laboratory to control the availability of CFM. The laboratory would be testing the medicines that enter the country and those manufactured and already available in the country for quality and safety. Future research should assess the sampling, analysis and collection of CFM at the laboratory, and the source of samples collected, whether from different areas such as customs, warehouses, wholesalers, dispensaries and pharmacies, to determine the number of recorded entries used to detect CFM in Lebanon.

The study also demonstrated the need to re-evaluate the existing laws and implementing and enforcing the laws, therefore, future studies would need to assess and analyse the legal

gaps, to ensure that laws are relevant and up-to-date, and the penalties are rigorous and more severe than trafficking illegal drugs.

The lack of data on reported cases and their outcomes requires future studies to assess the consequences of CFM, identifying safety of healthcare in Lebanon, and the burden of CFM on national healthcare, to determine how many cases of CFM were related with admissions to hospitals, or lead to death, in addition to the cost of healthcare.

The political instability, continuous scandals and the corrupted system might have been the reasons behind the mistrust in this study. Therefore, future research should further investigate the reasons behind the mistrust, views and beliefs towards the government, official offices and pharmacists. The nature of trust, corruption, and human value, need to be further investigated, to better understand why the public and pharmacists do not trust the system, the pharmacists, the government, MoPH, and OPL, to determine how to regain the trust.

The study revealed the need for greater accountability and the need to create a tight control to prevent corruption from sneaking through the system. Future studies would be required to assess the control system used for the supply chain; controlling of manufacturing, imports, and distribution of medicine, to determine if the system used was efficient in ensuring medicine quality. Additionally, future studies would need to assess the use of medicine via the Internet pharmacies, and the criteria used by the public for buying medicine online, and their awareness of the risks these medicines would pose to public health, to determine the measures that would be required to control its use.

The study suggested the need for collaboration between MoPH, OPL, pharmaceutical companies, regulatory authorities, and WHO and INTERPOL; therefore, future studies should assess their collaboration to determine if there were any contributions and improvements in the control of CFM availability.

The author proposed recommendations for the pharmacists, and MoPH, in addition proposed the initiation of an external institution, and can be referred to in **Appendices 8.II, 8. III, and 8.IV, respectively.**

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Appendices

Appendices 1.I – 1.IV

Appendix 1.I.

Incidences of counterfeit medicine in developed countries

Year	Country	Incidence
2005 and 2006	UK	Lipitor® (atorvastatin), detected in the legal supply chain: lacked sufficient active ingredient (MHRA, 2012).
2007	UK	Zyprexa® (olanzapine), for treating bipolar disorder and schizophrenia. Detected in the legal supply chain: lacked sufficient active ingredient (MHRA, 2012).
2008	USA	According to the FDA, Heparin (anticoagulant) caused the death of 246 patients between January 2007 and March 2008 (U.S. Department of Health and human services, 2015).
2008	Japan	Nagoya Customs arrested Japanese men for attempting to smuggle 5,000 CFM smuggled from China using the Express Mail service (Intellectual property rights protection, 2009).
2009,	USA	Estimate of 46 medicine cargo thefts occurred, valued at a total of \$184 million (Autor, 2011).
2010	USA	Warehouse theft; estimated \$75 million worth of prescription medicine, including chemotherapy, antidepressants, and anticoagulant. These products have not yet been recovered (Autor, 2011).
2014	UK	UK seizes £8.6 million worth of CFM, such as dysfunction medicines, analgesics, psychotherapeutic agents, anabolic steroids, beta blockers, ... Medicines and healthcare products regulatory agency. UK leads the way with £8.6 million seizure in international operation targeting dangerous counterfeit, controlled and unlicensed medicines (MHRA, 2014).
2014	France	French customs seized ten tons of counterfeit Viagra® (Sildenafil) and Cialis® (Tadalafil) originated from China. (Radio France international, 2014).

Appendix 1.II.

Incidences of counterfeit medicine in the Arab countries & Israel

Year	Country	Incidences
2007	Jordan	Approximately \$16.9 million CFM confiscated by Jordanian officials. Most imported from China and India. Closed 150 / 1700 pharmacies linked to counterfeit traders (Halteh, 2008).
2008	Jordan	431 pharmacies were in violation of pharmaceutical regulation, and 14 with proven links to the counterfeit industry were closed (Halteh, 2008).
2009	Saudi Arabia	Saudi police captured nearly 4 million CFM anti-depressants and arrested several drug traffickers ⁴⁷ . Authorities shut down an unlicensed clinic for weight loss and captured a large quantity of CFM (Al-Barakati, 2009).
2009	Egypt	Ministry of Health and Population estimated that 10 % of pharmaceutical products were counterfeit (Interpol, 2009). Attacks on six combined warehouses led to the seizure of nearly a dozen containers of hundreds of thousands of CFM originated in China and passed through Syria before arriving in Egypt, all bound for the Middle East (Interpol, 2009).
2010	Syria	Officials captured equipment used to make and package CFM, ending the trade of CFM to Iraq, Turkey, Lebanon, Iran and Egypt (Faucon, 2010).
2012	Lebanon	Brother of Lebanese state minister was arrested in November 2010, for his links to CFM importation (Safe medicines, 2013).
2014	Dubai	The Department of Economic Development raided two warehouses and seized over one million items of counterfeits, with a street value of Dh 17 million, the goods included counterfeit weight loss medicines, and performance enhancers/cosmetics (United Arab Emirates interact, 2014)

Appendix 1.III.

Incidences of counterfeit medicine in different regions of the world

Year	Country	Incidence
1990	Nigeria	Cough mixture was diluted with a poisonous solvent, killed 100 children (Deisingh, 2005).
1995	Haiti	Fatalities of 100 children due to ingestion of cough syrup containing glycerine contaminated by diethylene glycol (antifreeze) (Lybecker, 2007).
1996	Haiti	Consumption of counterfeit syrup for fever caused death of 59 children (Deisingh, 2005).
1998	Brazil	Ineffective contraceptive pills resulted in unwanted pregnancies (Deisingh, 2005).
2001	China	192,000 patients died from CFM, and in the same year Chinese authorities “closed 1,300 factories while investigating 480,000 cases of CFM worth \$57 million USD” (Cockburn et al, 2005)
2001	India	Police found 660kg of CFM, 1000kg of raw materials and packages bearing the logo of a reputable firm, from one factory (Deisingh, 2005).
2008	Turkey	Investigations revealed that pharmacists, doctors, and nurses were involved in repackaging CFM and expired medicines (Bate, 2009).
2009	Uganda	Interpol and the WHO-IMPACT conducted a raid in the central and eastern districts of Uganda and discovered five tons of CFM (United Nations department of public information, 2013).
2013	Nigeria	The INTERPOL's Medical Product Counterfeiting and Pharmaceutical Crime Sub-Directorate; registered the arrest of one person fro smuggling CFM (Ibuprofen, Coartem, Maloxine) to Nigeria from China, indicating the involvement of an organized criminal group (Interpol, 2015).
2013	Philippines	The INTERPOL's Medical Product Counterfeiting and Pharmaceutical Crime Sub-Directorate, arrested five traffickers attempting to traffic slimming medicines, analgesics, antibiotics, and customs authorities confiscated 40-foot container. Case was tied to an organized criminal group (Interpol, 2015).

Appendix 1.IV.

Map* of Lebanon and the six governorates.



*Adopted from: World Trade Press. Best Country Reports. Available at: http://www.bestcountryreports.com/Political_Map_Lebanon_Provinces.php. Accessed October 2012.

Appendices 2.I – 2.V



Thursday, April 15, 2010

Your Excellency the Minister of Health Dr. Khalife,

I will be conducting a research project at the University of Brighton, England in summer 2010, which is financially supported by LAU. The project will deal with counterfeiting of drugs in Lebanon. I am kindly requesting a sample of each of the following counterfeit drugs. The drugs are Cipram (Citalopram), Plavix (Clopedogril), Viagra (Sildenafil), Coozar (Losartan), Zithromax (Azithromycin) and Tarivid (Ofloxacin). In case of unavailability, any other counterfeit drug in the same class is acceptable. The study aims at analyzing the samples you provide, to determine the magnitude of counterfeiting, whether the drug consists of active substance, low quantity of active substance, substitution of the declared active substance with a cheaper one or absence of the active ingredient.

Your support and collaboration will be greatly appreciated. The Ministry of Health will be acknowledged for support of the project.

Sincerely,



Lydia Sholy, R.Ph, Pharm.D.,
Clinical Assistant Professor
Assistant Dean for Students Affairs

المختار محمد خليفة
مدير شؤون الطلبة
الجامعة اللبنانية الأمريكية

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Appendix 2.II.

Photos of the major differences noted between counterfeit and original medicine through physical examination

Appendix 2.II.A. Photos of Panadol®



Photo 1. The left box is the original Panadol® and the right box is the counterfeit. The original has the hologram but the CFM box does not. The manufacturer is different for both boxes (gsk versus SB).



Photo 2. The left box is the original Panadol® and the right box is the counterfeit. The manufacturer information is different between the original and CFM boxes of Panadol®, and the fonts are different between the two boxes.



Photo 3. The left box is the original Panadol® and the right box is the counterfeit. The batch number, date of manufacture and expiry date printed on a white rectangle for the original Panadol® box, versus on a blue background for the CFM box.



Photo 4. The left box is the original Panadol® and the right box is the counterfeit. The sides for both original and CFM Panadol® boxes looked the same.



Photo 5. The left blister is the original Panadol® and the right blister is the counterfeit. The Panadol® blisters look different. The original had gsk printed on the blister, the CFM blister had SB printed on it.



Photo 6. The left blister is the original Panadol® and the right blister is the counterfeit. The white side of the Panadol® blisters looked the same, with a slightly different white.



Photo 7. The tablet on the left is the original Panadol® and the tablet on the right is the counterfeit. The original and CFM Panadol® tablets looked the same, however the imprint was different.



Photo 8. The tablet on the left is the original Panadol® and the tablet on the right is the counterfeit. The colour of the inside tablet of both original and counterfeit Panadol® were the same; white.

Appendix 2.II.B. Photos of Amoxil®



Photo 9. The left box of Amoxil® is the original and the right box is the counterfeit. The two boxes of Amoxil® were different in size, and the original had “TM” next to Amoxil®, the CFM box did not, and the colour of the two boxes were different. The chemical name was spelled as “amoxycillin” on the original box, but was spelled “amoxicillin” on the counterfeit box. The strength (500mg) on the original box was printed in red, and black on the counterfeit box. The manufacturer’s name was different; GlaxoSmithKline was printed on the original box, and Beecham for the CFM.



Photo 10. The box on the left is the original Amoxil® and the box on the right is the counterfeit. The two boxes of original and CFM Amoxil® were different in their width, and the original had TM next to Amoxil®, the CFM box did not.



Photo 11. The box on the left is the original Amoxil[®] and the box on the right is the counterfeit. The label on the Amoxil[®] boxes were different for the original and CFM. The manufacturer was different for both boxes and the information printed on the CFM box were not consistent with the original.



Photo 12. The box on the left is the original Amoxil[®] and the box on the right is the counterfeit. The original box had the hologram placed on it, the CFM did not. The original box had TM next to Amoxil[®], the CFM box did not.



Photo 13. The blister on the left is the original Amoxil® and the blister on the right is the counterfeit. The two Amoxil® blisters were different, the original had TM next to Amoxil®, the CFM box did not, and the spelling of amoxicillin was different for CFM blister.



Photo 14. The capsule on the left is the original Amoxil® and the capsule on the right is the counterfeit. The two Amoxil® capsules had the same colours.



Photo 15. The Amoxil[®] capsule on the bottom is the original and the top is the counterfeit. The writing on both capsules was on the opposite sides. The original capsule was more slender and longer.

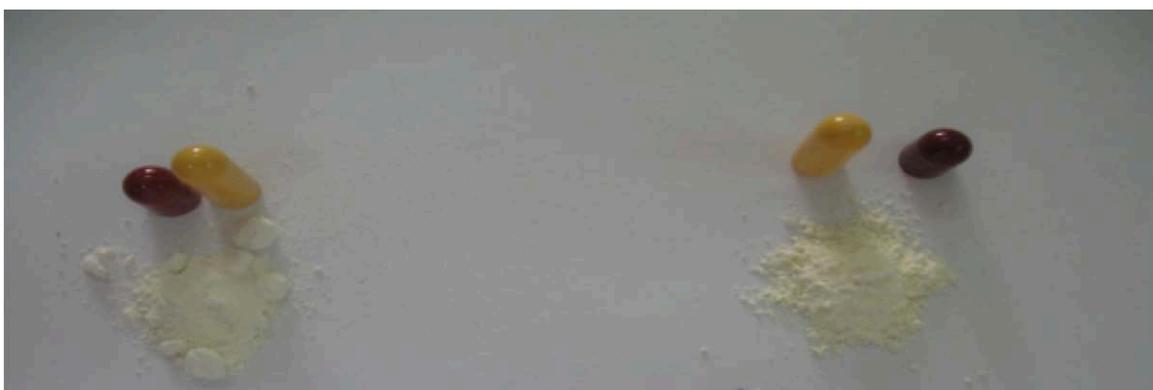


Photo 16. The capsule with powder on the left is the original Amoxil[®] and the capsule with powder on the right is the counterfeit. The colour of the powder of both Amoxil[®] capsules were the same.

Appendix 2.II.C. Photos of Cialis®



Photo 17. The box and blister on the left are the original Cialis® and the box and blister on the right are the counterfeit. The two Cialis® boxes were different, the original had the hologram, the Lilly logo was different for the two boxes and the original had a yellow drawing towards the top left corner on the box. The blisters were also different. The colour yellow was more orange for the CFM blister in addition to the Lilly logo was also not the same.

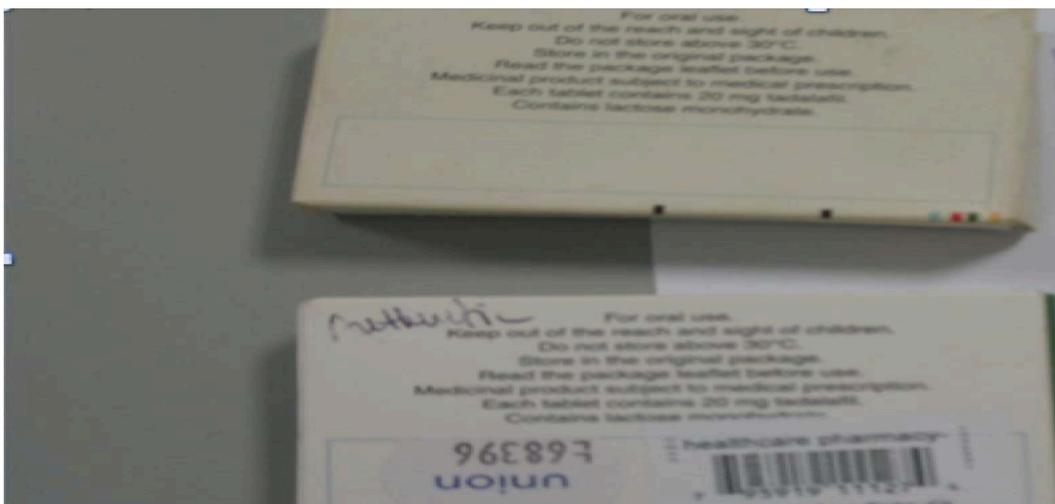


Photo 18. The box on the bottom is the original Cialis® and the box on top is the counterfeit. The backside of both boxes of Cialis®, the original and the CFM were the same.



Photo 19. The box on the bottom is the original Cialis[®] and the box on top is the counterfeit. The font size looks different for both the original and the CFM Cialis[®] boxes, and the electronic coloured lines on lower left side of the original box were not present on the CFM box.



Photo 20. The tablet on the left is the original Cialis[®] and the tablet on the right is the counterfeit. The two tablets of Cialis[®] had the same shape but different shades of yellow, the original was yellow mustard and the CFM was light yellow.

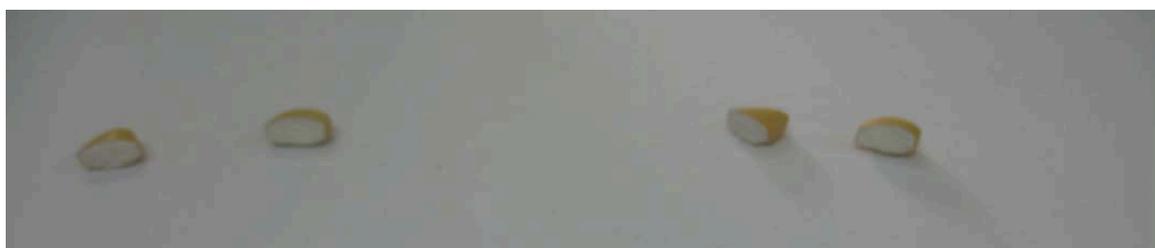


Photo 21. The tablet on the left is the original Cialis[®] and the tablet on the right is the counterfeit. The colour of the inside tablet of both original and counterfeit Cialis[®] were the same; white.

Appendix 2.II.D. Photos of Viagra®



Photo 22. The box on the left is the original Viagra® and the box on the right is the counterfeit. The original and counterfeit boxes of Viagra® looked different. The counterfeit box did not have the Pfizer logo and the patterned opening on the front side of each side of the boxes. The blue line on the left side of the box was a different shade of blue, and the dark blue box on the upper right corner on the box was a different shade of dark blue.

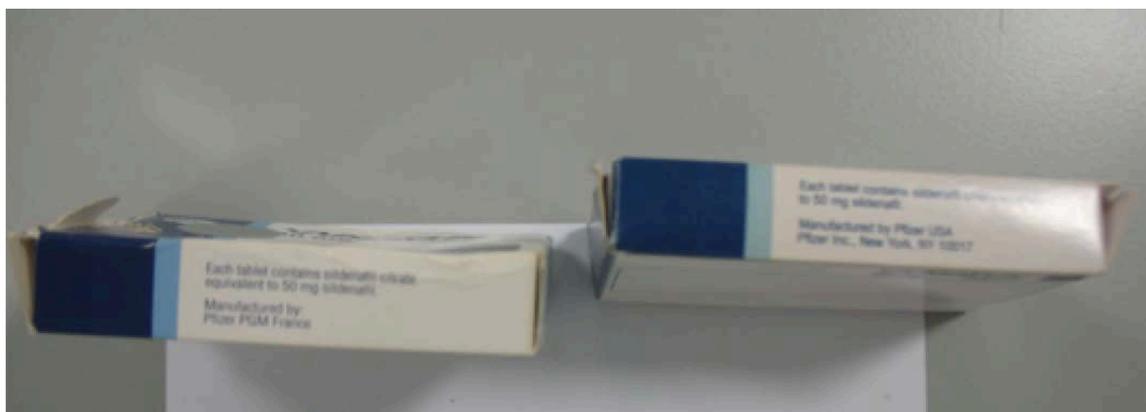


Photo 23. The box on the left is the original Viagra® and the box on the right is the counterfeit. The side of the original and counterfeit Viagra® were different. The manufacturer's address was different.



Photo 24. The box on the left is the original Viagra[®] and the box on the right is the counterfeit. The writing on the right opening side of the boxes had different font sizes for the original and counterfeit Viagra[®].



Photo 25. The box on the left is the original Viagra[®] and the box on the right is the counterfeit. The Left opening side of the original and counterfeit Viagra[®] were different. The original side was light blue



Photo 26. The box on the left is the original Viagra[®] and the box on the right is the counterfeit. The writing on the backside of the original Viagra[®] box had larger font size than the counterfeit Viagra box.



Photo 27. The blister on the left is the original Viagra® and the blister on the right is the counterfeit. The two blister of original and counterfeit Viagra® looked the same, however the colour of the print was lighter blue for the original.

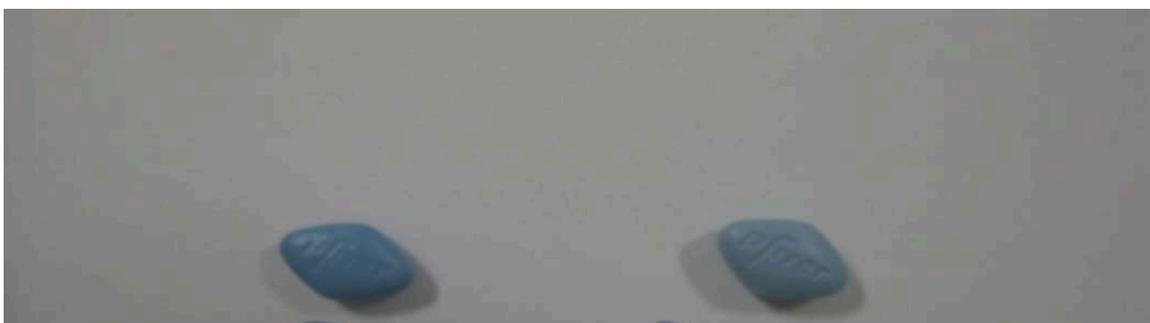


Photo 28. The tablet on the left is the original Viagra® and the tablet on the right is the counterfeit. The two tablets of original and counterfeit Viagra® were the same. The blue colour was lighter for the CFM and the imprint on the tablets were more visible on the CFM due to the lighter colour.



Photo 29. The tablet on the left is the original Viagra[®] and the tablet on the right is the counterfeit. The two tablets of original and counterfeit Viagra[®] were the same. The blue colour was lighter for the CFM and the imprint on the tablets were more visible on the CFM due to the lighter colour.



Photo 30. The tablet on the left is the original Viagra[®] and the tablet on the right is the counterfeit. The colour of the inside tablet of both original and counterfeit Viagra[®] were the same white.



Photo 31. The left box of Plavix® is the original and the right box is the counterfeit, and both had the hologram placed on their boxes. The Plavix® looked different. The strength of Plavix® was next to Plavix® on the original box, and below Plavix for the counterfeit box. The Information on the boxes were different and not consistent with the original Plavix® box.



Photo 32. The box on the left is the original Plavix® and the box on the right is the counterfeit. The backside of the original and counterfeit Plavix® boxes were different and the information was printed on different parts of the two boxes.



Photo 33. The box on the bottom is the original Plavix[®] and the box on the top is the counterfeit. The sides of the original and counterfeit Plavix[®] boxes looked different. The strength is printed below Plavix[®] rather than next to Plavix[®] as it was printed on the original box.



Photo 34. The blister on the bottom is the original Plavix[®] and the blister on the top is the counterfeit. The two blisters for the original and counterfeit Plavix[®] looked the same, however the print on the counterfeit was more faded.



Photo 35. The blister on the bottom is the original Plavix[®] and the blister on the top is the counterfeit. The two blisters for the original and counterfeit Plavix[®] looked almost the same. The rounded shape of the pill container for the original was not the same for the counterfeit.



Photo 36. The tablet on the left is the original Plavix[®] and the two tablets on the right are the counterfeits. The original Plavix[®] tablet was pink orange, and the counterfeits were pink brown.



Photo 37. The tablet on the left is the original Plavix[®] and the tablet on the right is the counterfeit. The original Plavix[®] tablet was pink orange, and the counterfeit was pink brown.



Photo 38. The tablet on the left is the original Plavix[®] and the tablet on the right is the counterfeit. The colour of the inside tablet of the original and counterfeit Plavix[®] were the different. The colour of the original tablet was white, while the counterfeit Plavix[®] was brownish.

Appendix 2.III.

Lists items used for visual inspection adopted from the Tool for Visual Inspection, of the five counterfeit samples of medicines provided by the Ministry of Public Health.

No.	Item	Yes %	No %	Unknown
	Packaging			
1.	Does the container and closure protect the product from the outside environment?	100	0	0
2.	Is the container safely sealed?	0	0	0
3.	Are the container and the closure appropriate for the product inside?	100	0	0
	Label			
4.	Is all information on the label legible?	100	0	0
5.	Is the trade name spelt correctly?	100	0	0
6.	Is the dosage form clearly indicated on the container label? Are the storage conditions indicated on the label?	100	0	0
7.	Does the symbol [®] follow the trade name?	83.3	16.7	0
8.	Is the active ingredient name spelt correctly?	83.3	16.7	0
9.	Are the storage conditions indicated on label?	83.3	16.7	0
	Manufacturer and Logo			
10.	Are the manufacturer's name and logo legible?	100	0	0
11.	Are the manufacturer's name and logo correct?	67	33	
12.	Does the logo or hologram (if change colour when viewed angles?	100	0	0
13.	Is the manufacturer's full address correct?	67	33	0
14.	Are the manufacture and expiry dates indicated on the label?	100	0	0
	Batch or lot number			
15.	For blister or foil strip packed medicines, is the batch number/expiry date indelibly impressed or imprinted onto the strip?	33.3	66.7	0
16.	Is the package insert printed on the same coloured or same quality paper as the original?	16.7	83.3	0
17.	Is the ink on the package insert or packaging	100	0	0

	smudge-proof?			
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Continue Appendix 2.III.

Lists items used for visual inspection adopted from the Tool for Visual Inspection, of the five counterfeit samples of medicines provided by the Ministry of Public Health.

No.	Item	Yes %	No %	Unknown
	Physical characteristics of tablets or capsules			
18.	Are the tablets/capsules uniform in shape?	83.3	16.7	0
19.	Are the tablets/capsules uniform in size?	83.3	16.7	0
20.	Are the tablets/capsules uniform in colour?	50	50	0
21.	Are the tablets/capsules free of embedded surface spots and foreign particle contamination?	100	0	0
22.	Is the sample examined free of empty capsules?	100	0	0
23.	Are the tablets/capsules free of breaks, cracks, splits or pinholes?	100	0	0

Appendix 2.IV.

Description of the major differences noted between counterfeit and original medicine through physical examination.

Feature	Findings
Packaging	The boxes all looked almost identical to their original until the packages were next to their original, then the differences became more apparent.
Tablet/Capsule	The dimensions of each tablet and capsule were measured using callipers and recorded in Table 2.3. The tablets were broken in half to check if the inside colour was the same or different than the original. The counterfeit Tablets and capsules all looked the same as the original, but when put next to their original to compare, the differences became more apparent. For counterfeit Panadol [®] the imprint of the name was more pronounced on the original than the CFM. For counterfeit Amoxil [®] , the capsule size was smaller, the content of the capsule were yellowish rather than white. The colour of the original capsule was composed of two colours yellow and burgundy; however, the counterfeit capsule was more brownish than burgundy. The writings on the capsule were opposite of the original (Appendix 2.II.B-Photo 15). As for counterfeit Viagra [®] and Cialis [®] , the colours were slightly different, light blue and light yellow, respectively, but the rest looked the same. The tablet of counterfeit Plavix was more brownish and when broken the inside pill colour was brownish, not white.
Package insert	Amoxil [®] 's package insert was totally different, and the spelling of amoxicillin was different than on the box. Panadol [®] 's insert was larger than the original and the content/heading was changed in counterfeit insert. Plavix [®] 's insert looked the same but with different sub headings than original and the trade mark for Plavix was subscript (Plavix [®]), while it was written as Plavix without the trade mark. Viagra [®] 's insert was also apparently different, the font was so tiny and the sub headings were also different. Cialis [®] 's insert looked the same, however, the title on top was missing and the subheadings, font and content were not the same as original.
Hologram	The only CFM provided by the MoPH that had a hologram placed on its box, was Plavix [®] , however, the hologram was not different from the official hologram used in Lebanon, which was placed on the original box.

Appendix 2.V.

Raman Spectrum of the hologram on the box of counterfeit Plavix®

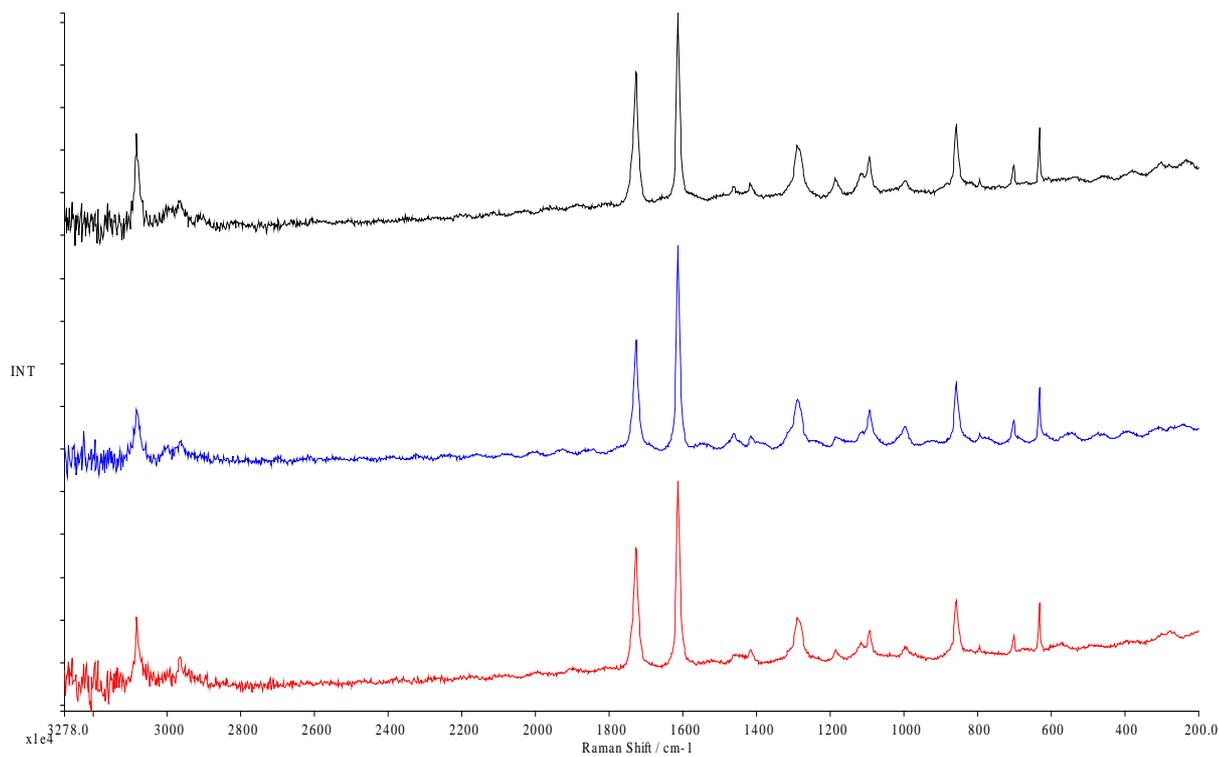


Figure 1b. Raman spectrum of the holograms on Cipralex® and Plavix® boxes. The black line represents the hologram of Cipralex®, the blue line represents the hologram of genuine Plavix®, and the red represents the hologram of counterfeit Plavix®. (Cipralex® was used as an extra box with a hologram on it to compare.)

Appendices 3.I – 3.III

Appendix 3.I.

Data Collection Form (DCF)

1. Number of household members: Please specify _____
2. Family members, No. of:

a. Infants & Toddlers (0 - < 2 YO) _____	b. Children (2 – 11) _____
c. Adolescent (12-17) _____	d. Adults (18 – 64) _____
e. Elderly (> 64) _____	
3. Highest level of education of any member of the family

a. primary school	b. secondary school	c. technical college
d. university	e. graduate school	f. Other, please specify _____
4. Home address
(area of living, i.e., Sin El Fil) _____
5. Do you go to (use) the same pharmacy to get the medications? Yes No
6. Do you get the medications from a different source other than a community pharmacy?
(Dispensary, red cross, army...) Please specify _____
7. Is there a medicine cabinet in the house? Yes No
8. Are medicines generally stored in one place? Yes No
9. Are medicines out of the reach of children? Yes No
10. Who is in charge of giving the medicines? _____
11. Who buys the medicines? _____

12. Please fill the below table

Name of medication	Reason	Duration	Source of medication	Getting better/does it work? How do you know?	Price

Continue Appendix 3.I.

Data Collection Form (DCF)

Photos of all packages of medications:

Please check if done for all medicines:

Med #1 Name (Trade and Generic) _____

Item #	Photo of	Check if done	Comments, if any
1.	Front of package		
2.	Back of the package		
3.	Side 1 of package		
4.	Side 2 of package		
5.	Side 3 of package		
6.	Side 4 of package		
7.	Expiry date of medicine		
8.	Blister, front		
9.	Blister back		
10.	Pill front (imprint) Logo		
11.	Pill back (imprint) No.		
12.	Closer photo of hologram, if present		

Med #2 Name (Trade and Generic) _____

Item #	Photo of	Check if done	Comments, if any
1.	Front of package		
2.	Back of the package		
3.	Side 1 of package		
4.	Side 2 of package		
5.	Side 3 of package		
6.	Side 4 of package		
7.	Expiry date of medicine		
8.	Blister, front		
9.	Blister back		
10.	Pill front (imprint) Logo		
11.	Pill back (imprint) No.		
12.	Closer photo of hologram, if present		

Etc...

Appendix 3.II.

Committee on Human Subjects in Research - Medication use evaluation (Brown Bag)


Committee on Human Subjects in Research (CHSR)
Lebanese American University

لجنة الأخلاقيات
الجامعة اللبنانية الأميركية

Date: July 28, 2010
CHSR tracking number: LAULS28072010-1

To: Dr. Lydia Sholy
Lebanese American University
School of Pharmacy

Protocol title: Public Awareness Survey on Counterfeit Drug use in Lebanon and Brown Bag Exercise (survey)

Dear Dr. Sholy,

Thank you for submitting to the CHSR the above named study for review. The CHSR has reviewed the new research form, Informed consent waiver form, questionnaire and the brown bag exercise. The committee has granted you approval to conduct your study for a period of 1 year.

There are four conditions attached to this approval letters:

- 1-No subjects may be enrolled in any study procedure prior to CHSR approval date or after the expiration date. (Principal investigators and sponsors are responsible for initiating continuing reviews proceedings)
- 2-All protocol modifications must be approved by CHSR prior to implementation.
- 3-All protocol deviations must be reported to CHSR.
- 4-Recruitment methods approved by CHSR must be strictly adhered to.

If you have any questions concerning this information please contact the CHSR office at +961-1-786456 ext 2860

Committee on Human Subjects in Research
Lebanese American University

28 JUL 2010

APPROVED

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Page 1 of 2

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Continue Appendix 3.II.

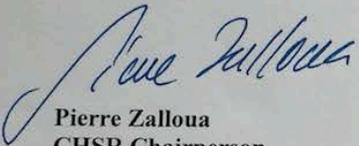
Committee on Human Subjects in Research - Medication use evaluation (Brown Bag)


Committee on Human Subjects in Research (CHSR)
Lebanese American University

لجنة الأخلاقيات
الجامعة اللبنانية الأميركية

Review Summary	
Type of review	Full board
Study status	Open for subject enrollment
Action	Approved
Released for enrollment	July 28, 2010
Expires	July 28, 2011

Sincerely yours,


Pierre Zalloua
CHSR Chairperson
Lebanese American University

Committee on Human Subjects in Research
Lebanese American University
28 JUL 2010
APPROVED

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Page 2 of 2

Appendix 3.III.

The categories of counterfeit medicines found in households

Region	Category	List of meds
Beirut	<ul style="list-style-type: none"> • A medicine without which it would lead to death, but the effects of which are routinely monitored and dosage adjusted. 	Januvia
	<ul style="list-style-type: none"> • A medicine without which the patient would suffer long-term consequences, but no symptoms would arise if activity were decreased. 	Acotral (TG), Elantan.
	<ul style="list-style-type: none"> • A medicine without which it would not lead to death, but symptoms would become more severe. 	Profinal XP, Yomesan, Atarax, Cataflam, Profinal XP, Di-antalvic, Daflon, Apo-ranitidine, Mosar, Ranicux, Amoxil, Clonac plus, Adol, Xyzal, Nurofenflash, Disflatyl, Atarax.
	<ul style="list-style-type: none"> • A medicine without which it would not lead to death nor would there be rapid onset of symptoms. 	Aspi-cor, Tofranil, Ferricure, Decalcit.
ML**	<ul style="list-style-type: none"> • A medicine without which it would lead to death, but the effects of which are routinely monitored and dosage adjusted. 	Glucophage, Avandia.
	<ul style="list-style-type: none"> • A medicine without which the patient would suffer long-term consequences, but no symptoms would arise if activity were decreased. 	Apo-acetazolamide,
	<ul style="list-style-type: none"> • A medicine without which it would not lead to death, but symptoms would become more severe. 	Ceclor, Augmentin, Clarinase, Ercefuryl, Cataflam, Augmentin, Lomotil, Profinal XP, Julmentin, Atepadene, Douzabin, Migrastop, Uvamin, Profinal XP, Di-antalvic, Mobic, 123, Spasmo-cibalgine, Ercefuryl, Augmentin, Cataflam, Rantag.
	<ul style="list-style-type: none"> • A medicine without which it would not lead to death nor would there be rapid onset of symptoms. 	Actonel plus, Anafranil, Apo-allopurinol, Ferricure, Tolexin Ge, Gyno-tardiferon, Ginvapast, Mebo.

*CFM=counterfeit medicine, ** Mount Lebanon

The categories of CFM* found in Beirut, Mount Lebanon, North, South, and Bekaa

Continue Appendix 3.III.

The categories of counterfeit medicines found in households

Region	Category	List of meds
North	<ul style="list-style-type: none"> • A medicine without which it would lead to death, but the effects of which are routinely monitored and dosage adjusted. 	Sintrom, Glucophage, Diamicron,
	<ul style="list-style-type: none"> • A medicine without which the patient would suffer long-term consequences, but no symptoms would arise if activity were decreased. 	Lipodar, fenogal
	<ul style="list-style-type: none"> • A medicine without which it would not lead to death, but symptoms would become more severe. 	Dulcolax, Ercefuryl, Ercefuryl, Aerius, Cyclovex
	<ul style="list-style-type: none"> • A medicine without which it would not lead to death nor would there be rapid onset of symptoms. 	Xanax, Actonel plus, Xanax
South	<ul style="list-style-type: none"> • A medicine without which it would not lead to death, but symptoms would become more severe. 	Spasmo-cibalgine, Nexium
	<ul style="list-style-type: none"> • A medicine without which it would not lead to death nor would there be rapid onset of symptoms. 	Pazolam
Bekaa	<ul style="list-style-type: none"> • A medicine without which it would not lead to death, but symptoms would become more severe. 	Dulcolax, Ranidine, Immodium, Lansomid, Flector EP, Algophene
	<ul style="list-style-type: none"> • A medicine without which it would not lead to death nor would there be rapid onset of symptoms. 	Biafine,

*CFM=counterfeit medicine, ** Mount Lebanon

The categories of CFM* found in Beirut, Mount Lebanon, North, South, and Bekaa

Appendix 4.I – 4.III

Appendix 4.I.A.

Committee on Human Subjects in Research - Public awareness towards counterfeit medicine questionnaire


Committee on Human Subjects in Research (CHSR)
Lebanese American University

لجنة الأخلاقيات
الجامعة اللبنانية الأميركية

Date: July 28, 2010
CHSR tracking number: LAULS28072010-1

To: Dr. Lydia Sholy
Lebanese American University
School of Pharmacy

Protocol title: Public Awareness Survey on Counterfeit Drug use in Lebanon and Brown Bag Exercise (survey)

Dear Dr. Sholy,

Thank you for submitting to the CHSR the above named study for review. The CHSR has reviewed the new research form, Informed consent waiver form, questionnaire and the brown bag exercise. The committee has granted you approval to conduct your study for a period of 1 year.

There are four conditions attached to this approval letters:

- 1-No subjects may be enrolled in any study procedure prior to CHSR approval date or after the expiration date. (Principal investigators and sponsors are responsible for initiating continuing reviews proceedings)
- 2-All protocol modifications must be approved by CHSR prior to implementation.
- 3-All protocol deviations must be reported to CHSR.
- 4-Recruitment methods approved by CHSR must be strictly adhered to.

If you have any questions concerning this information please contact the CHSR office at +961-1-786456 ext 2860

Committee on Human Subjects in Research
Lebanese American University

28 JUL 2010

APPROVED

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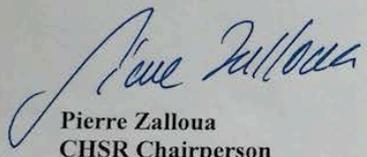
Continue Appendix 4.I.A

Committee on Human Subjects in Research - Public awareness towards counterfeit medicine questionnaire


Committee on Human Subjects in Research (CHSR)
Lebanese American University
لجنة الأخلاقيات
الجامعة اللبنانية الأميركية

Review Summary	
Type of review	Full board
Study status	Open for subject enrollment
Action	Approved
Released for enrollment	July 28, 2010
Expires	July 28, 2011

Sincerely yours,


Pierre Zalloua
CHSR Chairperson
Lebanese American University

Committee on Human Subjects in Research
Lebanese American University
28 JUL 2010
APPROVED

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Appendix 4.I.B

School of Pharmacy and Biomolecular Sciences Ethics Committee at University of Brighton - Public awareness towards counterfeit medicine questionnaire



**School of Pharmacy &
Biomolecular Sciences**

Huxley Building

Moulsecoomb

pabs.ethics@brighton.ac.uk

26 February 2014

APPLICATION FOR ETHICAL APPROVAL FOR PROJECT PROPOSAL (1303)

Project title: Public-Focus group

Investigator name(s): Lydia Boutros Sholy

Name of Supervisor (s): Dr. Paul Gard, Dr. Angela MacAdam and Dr. Sian Williams

Location of the work: Lebanon

The School Ethics Committee has approved the revised application.

Yours sincerely

The Review Team

On behalf of Chair, School of Pharmacy and Biomolecular Sciences Research Ethics Committee.

Appendix 4.II.

Pilot questionnaire

Public awareness on the use of counterfeit drugs

Introduction

The use of poor quality drugs will reduce the effectiveness of therapy and encourage drug resistance. Some medicines that are available on the market are counterfeit drugs (CFD). The objective of this questionnaire is to determine public awareness of CFD, and how people deal with CFD.

Your participation will be tremendously helpful in shedding light on this area.

General information and demographics

Please indicate your age by circling the appropriate option:

- a. Under 20 b. 20–30 c. 31–40 d. 41–50
e. 51–65 f. over 65

Sex: Male Female

How long have you lived in Lebanon? _____ Years _____ Months.

Where do you live?

- a. A city
b. A town
c. A village

Did you attend a: (please circle all that apply)

- a. Primary school b. Secondary school d. Technical College
e. University f. Post graduate g. Other, please specify _____

Your medicine use

1. Do you go to the same pharmacy?
 - a. Yes
 - b. No
 - c. Sometimes

2. Why do you go to a Pharmacy?
 - a. To get medicine
 - b. To buy para-pharmaceutical products (i.e., cosmetic products)
 - c. Other, please specify _____

3. If you take any medicine, what do you take it for?
Please specify _____

Awareness of counterfeit drugs

4. Have you heard the term “Counterfeit Drug” before being given this questionnaire?
 - a. Yes
 - b. No
 - c. Unsure
5. How do you think the quality of counterfeit drugs compares to the quality of authentic drugs?
 - a. They are the same
 - b. CFDs are better quality
 - c. CFDs are poorer quality
 - d. Don't know
6. How did you become aware of counterfeit drugs? (Please circle all that apply)
 - a. Billboards
 - b. TV
 - c. Pharmacy
 - d. Neighbours
 - e. Unsure
 - f. Others, please specify _____
7. Have you seen any advertisement/campaign about counterfeit drugs in the past 12 to 24 months?
 - a. Yes
 - b. No
 - c. Unsure
8. Did you learn anything from the advertisement?
 - a. Yes
 - b. No
 - c. A little
 - d. Unsure
9. Do you know how to identify a counterfeit drug?
 - a. Yes
 - b. No
 - c. Sometimes
 - d. Unsure
10. How would you differentiate a counterfeit drug from an authentic one? (Please circle all that apply)
 - a. Look for a Hologram
 - b. Colour of the box
 - c. Colour of the pill
 - d. Write up/Label
 - e. Effect of the drug
 - f. Other, please specify, _____
 - g. Don't know
11. Have you or someone you know, ever suspected that a purchased drug was counterfeit? (Please circle all that apply)
 - a. Yes, I have
 - b. Yes, someone I know has
 - c. No
12. If yes, what did you or the person you know do about it?
 - a. Told the pharmacist
 - b. Told the doctor
 - c. Told the insurance company
 - d. Nothing
 - e. Other, please specify _____

13. If you told some one, what was that person's response?
 - a. Took back (returned) the drug
 - b. Checked the package
 - c. Refused to return it, because it is open
 - d. Told you sorry, he/she can not do anything
 - e. Other, please specify_____
14. If someone suspects that a drug is counterfeit, what do you think would be the **most important** thing to do? (Please rank each one in order of importance, from 1 being the most important to 5 being the least important)
 - a. Contact the pharmacist. _____
 - b. Tell the doctor, _____
 - c. Throw the drug away, _____
 - d. Nothing, _____
 - e. Buy another box, _____
 - f. Other, Please specify_____
15. If someone suspects that a drug is counterfeit, what do you think would be the **FIRST** thing to do? (Please rank each one in order of importance, from 1 being the most important to 5 being the least important)
 - a. Contact the pharmacist. _____
 - b. Tell the doctor, _____
 - c. Throw the drug away, _____
 - d. Nothing, _____
 - e. Buy another box, _____
 - f. Other, Please specify_____
16. If we consider counterfeit products exist in Lebanon, how would you protect yourself from buying a CFD? (Please check all that apply)
 - a. Make sure the hologram is present
 - b. Get the drug from a trustworthy pharmacist
 - c. Buy the drug from a different country
 - d. Other, please specify_____
17. Please rank in order of importance (from 1 being the most important to 4 being the least important) the factors below, when deciding whether or not to buy a drug?
 - a. Name of drug_____
 - b. Price of drug_____
 - c. Effectiveness of drug_____
 - d. Country of origin_____
18. In your opinion, from which country do you think most counterfeit drugs originate? Please specify_____
19. In your opinion, who is involved in the chain of counterfeit drugs? (please check all that apply)
 - a. Wholesalers
 - b. Pharmacists
 - c. Manufacturers
 - d. Customs
 - e. Other, please specify_____
20. Do you trust your pharmacist?
 - a. Do not trust at all
 - b. Trust a little
 - c. Trust a lot
 - d. Completely trust

21. Do you trust your Dr. (Physician)?
 - a. Do not trust at all
 - b. Trust a little
 - c. Trust a lot
 - d. Completely trust
22. Would you like to be able to identify a CFD?
 - a. Yes
 - b. No
23. Do you consider education as part of the solution to combating/stopping CFD?
 - a. Yes
 - b. No
 - c. Maybe
24. Whom should we educate? (Please check all that apply)
 - a. The Public
 - b. The Pharmacists
 - c. The government
 - d. The wholesalers
 - e. The physicians
 - f. The nurses
 - g. Others, please specify _____
25. In your opinion, how should the awareness campaign be done? (Please check all that apply)
 - a. Through T.V
 - b. Through the NEWS
 - c. Through Billboards
 - d. Through Radio stations
 - e. Through leaflets
 - f. Others, please specify _____
26. In your opinion, who should be involved in the awareness campaign? (Please check all that apply)
 - a. Pharmacists
 - b. Physicians
 - c. Ministry of Health
 - d. The Lebanese order of Pharmacists
 - e. The order of Imports/ Exports
 - f. Wholesalers
 - g. Others, please specify _____
27. In you opinion, when should the campaign start? (Please check all that apply)
 - a. When there is a problem with CFD
 - b. Don't know
 - c. Other, please specify _____
28. In you opinion, how often should the campaign be done?
 - a. Once a year
 - b. Twice a year
 - c. Every other year
 - d. As needed
29. In you opinion, what is the role of the Ministry of Health in controlling CFD?
Please specify _____
30. In you opinion, what is the role of the Lebanese order of Pharmacists in controlling CFD?
Please specify _____
31. In you opinion, what is the role of the Pharmacist in controlling CFD?
Please specify _____

32. How would you like to learn about CFD from your Pharmacist?

- a. Leaflet/Pamphlets/Brochure
- b. Seminars
- c. Workshops
- d. Other, please specify_____

Thank you for your time.

Appendix 4.III.

Questionnaire - Public awareness towards counterfeit medicines (CFM)

Introduction

The objective of this questionnaire is to determine public awareness towards counterfeit medicine, and how people deal with it.

Your participation will be tremendously helpful in shedding light on this area.

General information and demographics

Please indicate your age by circling the appropriate option:

- b. 18-20 b. 21-30 c. 31-40 d. 41-50
f. 51-65 f. over 65

Sex: Male Female

How long have you lived in Lebanon? _____ Years _____ Months.

Where do you live?

- a. A city
b. A town
c. A village

Level of education:

- a. Primary school b. Secondary school c. Technical College
d. University e. Post graduate f. Other, please specify _____

Your medicine use

5. Do you go to the same pharmacy?
a. Yes
b. No
c. Sometimes
6. Why do you go to a Pharmacy?
a. To get medicine
b. To buy para-pharmaceutical products (i.e., cosmetic products)
c. Other, please specify _____
7. If you take any medicine, what do you take it for?
Please specify _____

Awareness of counterfeit medicines

8. Have you heard the term "Counterfeit medicine" before being given this questionnaire?
a. Yes
b. No
c. Unsure
5. How do you think the quality of counterfeit medicines compares to the quality of authentic medicines?
Please specify _____

8. How did you become aware of counterfeit medicines? (Please circle all that apply)
 - a. Billboards
 - b. TV
 - c. Pharmacy
 - d. Neighbours
 - e. Unsure
 - f. Others, please specify _____
9. Have you seen any advertisement/campaign about counterfeit medicines in the past 12 to 24 months?
 - a. Yes
 - b. No (if no, go to question #9)
 - c. Unsure
8. Did you learn anything from the advertisement?
 - a. Yes
 - b. No
 - c. A little
 - d. Unsure
9. How would you differentiate a counterfeit medicine from an authentic one? (Please circle all that apply)
 - a. Look for a Hologram
 - b. Colour of the box
 - c. Colour of the pill
 - d. Write up /Label
 - e. Effect of the medicine
 - f. Other, please specify, _____
 - g. Don't know
10. Have you or someone you know, ever suspected that a purchased medicine was counterfeit? (Please circle all that apply)
 - a. Yes, I have
 - b. Yes, someone I know has
 - c. No (if No, go to question #13)
11. If yes, what did you or the person you know do about it?
 - a. Told the pharmacist
 - b. Told the doctor
 - c. Told the insurance company
 - d. Nothing
 - e. Other, please specify _____
12. If you told some one, what was that person's response?
 - a. Took back (returned) the medicine
 - b. Checked the package
 - c. Refused to return it, because it is open
 - d. Told you sorry, he/she can not do anything
 - e. Other, please specify _____
13. If someone suspects that a medicine is counterfeit, what do you think would **be** the **FIRST** thing to do? (Please, select only one)
 - a. Contact the pharmacist. _____
 - b. Tell the doctor, _____
 - c. Throw the medicine away, _____
 - d. Nothing _____
 - e. Buy another box, _____
 - f. Other, Please specify _____

14. If we consider counterfeit products are available in Lebanon, how would you protect yourself from buying a CFM? (Please check all that apply)
 - a. Make sure the hologram is present
 - b. Get the medicine from a trustworthy pharmacist
 - c. Buy the medicine from a different country
 - d. Other, please specify_____
15. Please rank in order of importance (from 1 being the most important to 4 being the least important) the factors below, when deciding whether or not to buy a medicine?
 - a. Name of medicine_____
 - b. Price of medicine_____
 - c. Effectiveness of medicine_____
 - d. Country of origin_____
16. In your opinion, from which country do you think most counterfeit medicines originate? Please specify_____
17. In your opinion, who is responsible for the availability of counterfeit medicines? (Please check all that apply)
 - a. Wholesalers
 - b. Pharmacists
 - c. Manufacturers
 - d. Customs
 - e. Other, please specify_____
18. Do you consider education as part of the solution to combating/stopping CFM?
 - a. Yes
 - b. No
 - c. Maybe
19. Whom should we educate? (Please check all that apply)
 - a. The Public
 - b. The Pharmacists
 - c. The government
 - d. The wholesalers
 - e. The physicians
 - f. The nurses
 - g. Others, please specify_____
20. In your opinion, how should the awareness campaign be done? (Please check all that apply)
 - a. Through T.V
 - b. Through the NEWS
 - c. Through Billboards
 - d. Through Radio stations
 - e. Through leaflets
 - f. Others, please specify_____
21. In your opinion, who should be involved in the awareness campaign? (Please check all that apply)
 - a. Pharmacists
 - b. Physicians
 - c. Ministry of Public Health (MoPH)
 - d. The Lebanese order of Pharmacists (OPL)
 - e. The Lebanese Pharmaceutical Importers Association (LPIA)
 - f. Wholesalers
 - g. Others, please specify_____

22. In your opinion, what is the role of officials in Lebanon, in controlling CFM?
Please specify, _____
23. In your opinion, how often should the campaign be done?
- a. Once a year
 - b. Twice a year
 - c. Every other year
 - d. Other, please specify _____
24. How would you like to learn about CFM from your Pharmacist?
- a. Leaflet/Pamphlets/Brochure
 - b. Seminars
 - c. Workshops
 - d. Other, please specify _____
25. How should the offenders be handled?
Please specify, _____

Thank you for taking the time to fill out the questionnaire.

Appendix 5.I – 5.II

Appendix 5.I.

School of Pharmacy and Biomolecular Sciences Ethics Committee at University of Brighton –Public attitude towards counterfeit products and medicine questionnaire



**School of Pharmacy &
Biomolecular Sciences**

Huxley Building

Moulsecoomb

pabs.ethics@brighton.ac.uk

26 February 2014

APPLICATION FOR ETHICAL APPROVAL FOR PROJECT PROPOSAL (1303)

Project title: Public-Focus group

Investigator name(s): Lydia Boutros Sholy

Name of Supervisor (s): Dr. Paul Gard, Dr. Angela MacAdam and Dr. Sian Williams

Location of the work: Lebanon

The School Ethics Committee has approved the revised application.

Yours sincerely

The Review Team

On behalf of Chair, School of Pharmacy and Biomolecular Sciences Research Ethics Committee.

Appendix 5.II.

Questionnaire - Public attitude towards counterfeit products and medicine in Lebanon

The objective of this questionnaire is to determine the public views on counterfeit products and medicine in Lebanon. Your participation will be tremendously helpful in shedding light on this area.

You may omit or skip any question you do not want to answer.

I. General information and demographics

1. Please indicate your age by circling the appropriate option:

- c. 20–30 b. 31–40 c. 41–50
d. 51–65 e. over 65

2. Sex: Male Female

3. How long have you lived in Lebanon? _____ Years _____ Months.

4. Area of living (not address)? _____

5. Level of education: (Please circle all that apply)

- a. Primary school b. Secondary school c. Technical College
d. University e. Graduate school f. Other, please specify _____

II. Questions about counterfeit products in general

Below is a list of statements. Please circle the response that you feel best represents the way that you think.

No.	Questions	Very willing	Willing	Unwilling	Very Unwilling
		4	3	2	1
1.	Given good price and good quality are you willing to buy counterfeit pens	4	3	2	1
2.	Given good price and good quality are you willing to buy counterfeit clothes	4	3	2	1
3.	Given good price and good quality are you willing to buy counterfeit CD's	4	3	2	1
4.	Given good price and good quality are you willing to buy counterfeit videos	4	3	2	1

No.	Questions	Very willing	Willing	Unwilling	Very Unwilling
		4	3	2	1
5.	Given good price and good quality are you willing to buy counterfeit house hold products	4	3	2	1
6.	Given good price and good quality are you willing to buy counterfeit watches	4	3	2	1
7.	Given good price and good quality are you willing to buy counterfeit shoes	4	3	2	1
8.	Given good price and good quality are you willing to buy counterfeit Perfumes	4	3	2	1
9.	Given good price and good quality are you willing to buy counterfeit car parts	4	3	2	1
10.	Given good price and good quality are you willing to buy counterfeit musical instruments	4	3	2	1
11.	Given good price and good quality are you willing to buy counterfeit stereos	4	3	2	1
12.	Given good price and good quality are you willing to buy counterfeit toiletries	4	3	2	1

Below is a list of statements. Please circle the response that you feel best represents the way that you think.

No.	Questions	Strongly Agree	Agree	Neutral/unsure	Disagree	Strongly Disagree
		5	4	3	2	1
13.	Most counterfeit products are as good as the originals	5	4	3	2	1
14.	Many branded (original) products are highly priced; while counterfeit products are of better value	5	4	3	2	1
15.	Counterfeit products can be very dangerous	5	4	3	2	1
16.	It is easy to spot counterfeit products by their quality and price	5	4	3	2	1
17.	I have knowingly bought counterfeit products in the past	5	4	3	2	1

III. Questions about counterfeit medicine (CFM) in general

Below is a list of statements. Please circle the response that you feel best represents the way that you think.

No.	Questions	Strongly Agree	Agree	Neutral/unsure	Disagree	Strongly Disagree
		5	4	3	2	1
18.	Most counterfeit medicines are as good as the originals	5	4	3	2	1
19.	Many branded (original) medicines are highly priced; while counterfeit medicines are of better value	5	4	3	2	1
20.	Counterfeit medicines can be very dangerous	5	4	3	2	1
21.	It is easy to spot counterfeit medicines by their quality and price	5	4	3	2	1
22.	I have knowingly bought counterfeit medicines in the past	5	4	3	2	1
23.	Pharmacists that knowingly dispense CFM are very clever	5	4	3	2	1
24.	Pharmacists that knowingly dispense CFM are good businessmen/women	5	4	3	2	1
25.	Pharmacists that knowingly dispense CFM are unprofessional	5	4	3	2	1
26.	Pharmacist that knowingly dispense CFM are unethical	5	4	3	2	1
27.	Pharmacists carry CFM in their pharmacy because it is easy money	5	4	3	2	1
28.	Pharmacists carry CFM in their pharmacy for the big profit	5	4	3	2	1
29.	Pharmacists carry CFM in their pharmacy because the quality is acceptable	5	4	3	2	1

30. Other than medicine, are you willing to buy counterfeit products, given good price and good quality?

a. Yes

b. No

c. Not sure

Thank you for your time.

Appendix 6.I – 6.III

Appendix 6.I.

Pilot questionnaire

Pharmacist awareness and attitude towards counterfeit products and medicine

Your feedback as a practicing pharmacist will help us determine how aware pharmacists are of Counterfeit Product (CFM) in Lebanon. Your answers are appreciated to define the limitations a pharmacist can face and the role the government ought to play in controlling the use of CFM.

I. Professional responsibility

1. In your opinion, what is the definition of Counterfeit Product?
Please define: _____
2. In your opinion, where do most counterfeit products originate?
Please specify _____
3. How did you become aware of counterfeit product? (Please circle all that apply)
 - a. Billboards
 - b. Television
 - c. Ministry Of Health
 - d. A colleague
 - e. Other, please specify _____
4. Have you seen any advertisement about counterfeit products in the past 12 to 24 months?
 - a. Yes
 - b. No
5. How would you differentiate a counterfeit product from an original one?
(Please circle all that apply)
 - a. Hologram
 - b. Colour of the box
 - c. Colour of the pill
 - d. Write up/Label
 - e. Effect of the drug
 - f. Don't know
 - g. Other, please specify, _____
6. Do you know of pharmacists that dispense counterfeit products?
 - a. Yes
 - b. No
7. If yes, please circle the appropriate option:
 - a. The pharmacist was aware he/she was dispensing CFM
 - b. The pharmacist was not aware he/she was dispensing CFM
 - c. Not sure if the pharmacist was aware or not.
8. If the pharmacist was aware he/she was dispensing a CFM, in your opinion, should anything be done in this case?
 - a. Yes
 - b. NoPlease, specify why _____
9. How would you describe a pharmacist that knowingly dispenses CFM?
 - a. Business Man
 - b. Unprofessional
 - c. Unethical
 - d. Other, please specify _____

10. In your opinion, why would a pharmacist decide to carry CFM in his/her pharmacy? (Please circle all that apply)
 - a. Easy money
 - b. Big profit
 - c. The quality is acceptable
 - d. They still contain the active substances
 - e. Other, please specify_____
11. Who supplies your pharmacy with medications?
 - a. Wholesalers
 - b. Manufacturer
 - c. Ministry Of Health
 - d. Other, please specify_____
12. In your opinion, what % of pharmacists are aware of CFM?
Please specify_____
13. Do you routinely check the integrity of product suppliers / wholesalers?
 - a. Yes
 - b. No
 If yes, how?
Please specify_____
14. If a counterfeit product happened to be in your pharmacy, in your opinion, is it easy to spot it by its quality and price?
 - a. Yes
 - b. No
 If yes, how?
Please specify_____
15. In your opinion, should pharmacy staff at community/ hospital pharmacy, be held responsible for the screening of CFM?
 - a. Yes
 - b. No
16. In your opinion, who is involved in the chain of counterfeit Products? (Please check all that apply)
 - a. Wholesalers
 - b. Pharmacists
 - c. Manufacturers
 - d. Customs
 - e. Other, please specify_____
17. To your knowledge, has a product in your pharmacy ever been confirmed as counterfeit (unoriginal)?
 - a. Yes
 - b. No
 If yes, what did you do?_____
18. Which products do you consider to be at "high risk" for counterfeiting?
Please specify_____
19. Do you believe the pharmacist has a role in making the public aware of CFM?
 - a. Yes
 - b. No
 If yes, how?_____
20. Who should take the blame for CFM if something wrong happened to the patient?
 - a. Pharmacist
 - b. Government
 - c. Ministry of health
 - d. Lebanese Order of Pharmacists
 - e. Wholesalers
 - f. Suppliers
 - g. Other, please specify_____

Appendix 6.II.

Questionnaire - Pharmacist awareness and attitude towards counterfeit products and medicine in Lebanon

Your feedback as a practicing pharmacist will help determine how aware pharmacists are of Counterfeit Product (CFM) in Lebanon. The findings may establish the need for additional strategies to combat CFM.

You may omit or skip any question you do not want to answer.

I. Professional responsibility

1. In your opinion, what is the definition of Counterfeit Product?
Please define: _____
2. In your opinion, from which country do most counterfeit products originate?
Please specify _____
3. How did you become aware of counterfeit product? (i.e., TV)
Please specify _____
4. Are you aware of any campaigns about CFM?
 - a. Yes
 - b. No
 - c. Not sure
5. You can identify a counterfeit product from an original by:

Item	Yes	No
a. Hologram If yes, please describe		
b. Cost If yes, please describe		
c. Features of packaging If yes, please describe		
d. Features of suppliers If yes, please describe		
e. Effect of the product If yes, please describe		
f. Package insert information If yes, please describe		
g. Other If yes, please describe		

6. Do you know of pharmacists that dispense counterfeit products?
 - a. Yes
 - b. No
7. If yes, please circle the appropriate option:
 - a. The pharmacist was aware he/she was dispensing CFM
 - b. The pharmacist was not aware he/she was dispensing CFM
 - c. Not sure if the pharmacist was aware or not.
8. If the pharmacist was aware he/she was dispensing a CFM, in your opinion, should any actions be taken against them in this case?
 - a. Yes
 - b. No
 - Please, specify why _____

Below is a list of statements. Please circle the response that you feel best represents the way that you think.

No.	Statements	Strongly Agree	Agree	Disagree
		4	3	2
9.	“Pharmacists that knowingly dispense CFM are very clever”:			
10.	“Pharmacists that knowingly dispense CFM are good businessmen/women”			
11.	“Pharmacists that knowingly dispense CFM are unprofessional”			
12.	“Pharmacist that knowingly dispense CFM are unethical”			
13.	“Pharmacists decide to carry CFM in their pharmacy for the easy money”			
14.	“Pharmacists decide to carry CFM in their pharmacy for the big profit”			
15.	“Pharmacists decide to carry CFM in their pharmacy since the quality is acceptable”			
16.	“The law against CFM should be strengthened”			
17.	“The law against counterfeit salespeople should be strengthened”			

18. In your opinion, what % of pharmacists are aware of CFM?

Please specify _____

19. In your opinion, what % of products in Lebanon are counterfeit?

Please specify _____

20. Have you ever been offered CFM?

a. Yes b. No c. Not sure

21. How often do you check the integrity of drug suppliers / wholesalers?

a. Daily
 b. Weekly
 c. Monthly
 d. Yearly
 e. Do not check
 f. Other, please specify _____

22. To your knowledge, has a product in your pharmacy ever been confirmed as counterfeit (unoriginal)?

a. Yes b. No c. Not sure

If yes, what did you do? _____

23. Which products (product) do you consider to be at "high risk" for counterfeiting?

Please specify _____

II. Questions about counterfeit products

24. Other than medicine, are you willing to buy counterfeit products, given good price and good quality?

a. Yes b. No c. Not sure

25. Which of the following counterfeit products, given good price and good quality are you willing to buy? **(Please circle all that apply)**

- a. Pens
- b. Clothes
- c. CD's
- d. Videos
- e. Household products
- f. Watches
- g. Shoes
- h. Perfumes
- i. Car parts
- j. Musical instruments
- k. Stereos
- l. Toiletries

Below is a list of statements. Please circle the response that you feel best represents the way that you think.

No.	Statements	Strongly	Agree	Disagree	Strongly
		4	3	2	1
26.	“Counterfeit products can be very dangerous”:				
27.	“Most counterfeit products are as good as the originals:				
28.	“Many branded (original) products are highly priced; while counterfeit products are of better value”:				
29.	“It is easy to spot counterfeit products by their quality and price”:				

30. Have you ever knowingly bought counterfeit products in the past:

- a. Yes
- b. No
- c. Not sure

a. Demographic data

31. Age group:

- b. ≤30
- b. 31–40
- c. 41–50
- d. 51–60
- e. > 60

32. Sex

- a. Male
- b. Female

33. How long have you been practicing in Lebanon? ____ Years ____ Months.

34. Where is your pharmacy located?

- a. Beirut (Beirut)
- b. Mount Lebanon (Baabda)
- c. North (Tripoli)
- d. South (Sidon)
- e. Beqaa (Zahle)
- f. Nabatiye (Nabatiyeh)

35. Rate the socio-economic status of your patients/clients?

- a. Upper class
- b. Middle class
- c. Lower class

36. Did you get your pharmacy degree from:

- a. Lebanon
- b. Abroad, please specify _____

Thank you for taking the time to fill out the questionnaire

Appendix 6.III.

School of Pharmacy and Biomolecular Sciences Ethics Committee at University of Brighton - Pharmacist awareness and attitude towards counterfeit products and medicine questionnaire



**School of Pharmacy &
Biomolecular Sciences**
Huxley Building

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26 February 2014

APPLICATION FOR ETHICAL APPROVAL FOR PROJECT PROPOSAL (1351)

Project title: Pharmacist-Focus group: Awareness and attitude towards counterfeit medicine

Investigator name(s): Lydia Boutros Sholy

Name of Supervisor (s): Dr. Paul Gard, Dr. Angela MacAdam and Dr. Sian Williams

Location of the work: Lebanon

The School Ethics Committee has approved the revised application.

Yours sincerely

The Review Team

On behalf of Chair, School of Pharmacy and Biomolecular Sciences Research Ethics Committee.

Appendix 7.I – 7.VIII

Appendix 7.I.

Public Demographic Data Sheet

Please circle the answer that is most appropriate: (You may skip any question you do not want to answer)

1. Age group:

- c. Less than 30 b. 30–40 c. 41–50
d. 51–60 e. More than 60

2. Gender

- a. Male b. Female

3. How long have you been living in Lebanon? _____ Years

4. Language spoken at home (circle all that applies):

- a. English
b. Arabic
c. French
d. Armenian
e. Other

5. Area of living:

- a. Beirut (Beirut)
b. Mount Lebanon (Baabda)
c. North (Tripoli)
d. South (Sidon)
e. Beqaa (Zahle)

6. Level of education (Please circle highest degree completed):

- a. Elementary school b. Secondary school c. High school
d. Technical College e. University f. Other, please specify _____

7. Occupation: Please specify _____

8. Are you currently using any medication?

- a. Yes b. No

Appendix 7.II.

Pharmacist Demographic Data Sheet

Please circle the answer that is most appropriate: (You may skip any question you do not want to answer)

1. Age

- a. Less than 30
- b. 31-40
- c. 41-50
- d. 51-60
- e. More than 60

2. Gender

- a. Male
- b. Female

3. How long have you been living in Lebanon? _____ Years

4. Area of living:

- a. Beirut (Beirut)
- b. Mount Lebanon (Baabda)
- c. North (Tripoli)
- d. South (Sidon)
- e. Beqaa (Zahle)

5. Pharmacy degree from:

- a. Lebanon
- b. Abroad, please specify _____

6. Area of practice (please circle more than one, if applicable):

- a. Beirut (Beirut)
- b. Mount Lebanon (Baabda)
- c. North (Tripoli)
- d. South (Sidon)
- e. Beqaa (Zahle)
- f. Other, please specify _____

7. Practice _____ setting, _____ please specify _____

8. How long have you been practicing in Lebanon? _____ Years

9. Comments:

Appendix 7.III.

Questions guide for public focus group

No.	Question
1.	What do you know about CFM* (Define it)? (K)**
2.	How can you differentiate/ identify between counterfeit and non-counterfeit? (K&A ⁺)
3.	Why do people buy counterfeit medicine/products? (A)
4.	Who is responsible for the availability of counterfeit meds in the market? (A)
5.	If you discovered the medicine you have is counterfeit, what would you do? Who would you contact? (K & A)
6.	How would you avoid buying CFM? (K & A)
7.	What are the penalties for selling/dealing with CFM/ Is there a law? (K&A)

CFM=counterfeit Medicine, (K)**= knowledge, (A⁺)=Attitude

Questions guide for public focus group

Appendix 7.IV.

Questions guide for pharmacist focus group

No.	Question
1.	How would you define and differentiate CFM*? (K)**
2.	What measures are you taking to minimize the risk of carrying CFM in your pharmacies? (K&A ⁺)
3.	What is your opinion of other pharmacists who deal with CFM? Are you aware of any? (A)
4.	How is the hologram helping the pharmacist differentiate between medicines? (A)
5.	Who is responsible for the availability of CFM in Lebanon? (A)
6.	Are you aware of a law related to CFM in Lebanon? (K and A)
7.	How would you report a CFM? (K and A)

*CFM = Counterfeit Medicine, (K)**= knowledge, (A⁺)=Attitude

Questions guide for pharmacist focus group

Appendix 7.V.

**School of Pharmacy and Biomolecular Sciences Ethics Committee at the
University of Brighton - Public Focus Groups**



**School of Pharmacy &
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26 February 2014

APPLICATION FOR ETHICAL APPROVAL FOR PROJECT PROPOSAL (1303)

Project title: Public-Focus group

Investigator name(s): Lydia Boutros Sholy

Name of Supervisor (s): Dr. Paul Gard, Dr. Angela MacAdam and Dr. Sian Williams

Location of the work: Lebanon

The School Ethics Committee has approved the revised application.

Yours sincerely

The Review Team

On behalf of Chair, School of Pharmacy and Biomolecular Sciences Research Ethics
Committee.

Appendix 7.VI.

**School of Pharmacy and Biomolecular Sciences Ethics Committee at University
of Brighton - Pharmacist Focus Groups**



**School of Pharmacy &
Biomolecular Sciences**
Huxley Building

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26 February 2014

APPLICATION FOR ETHICAL APPROVAL FOR PROJECT PROPOSAL (1351)

**Project title: Pharmacist-Focus group: Awareness and attitude towards counterfeit
medicine**

Investigator name(s): Lydia Boutros Sholy

**Name of Supervisor (s): Dr. Paul Gard, Dr. Angela MacAdam and Dr. Sian
Williams**

Location of the work: Lebanon

The School Ethics Committee has approved the revised application.

Yours sincerely

The Review Team

On behalf of Chair, School of Pharmacy and Biomolecular Sciences Research Ethics
Committee.

Appendix 7.VII.

Public focus group transcripts

A. Transcript: Public Focus Group: SCAN-FG1-051414

(Moderator then starts reading the forms and explaining their content, urging participants to feel free to come back to her with inquiries at any time in the future. She also emphasizes the importance of the participants knowing what the topic at hand is and them being present as consenting individuals. She reminds them that the topic discussed is going to be medicine and counterfeit medicine, and what they [participants] know about those. She then emphasizes the importance of the consent form, informs participants that the session is going to be audio taped, and introduces the note taker. She then talks about the optional demographic form and reminds everyone of the anonymous nature of the meeting and the impossibility of linking a participant's identity to their filled out demographic form. "And in the event that someone feels uncomfortable being here at this moment or later on during the meeting, they are totally free to leave, of course," Moderator proceeds to say. She also explains the process of filling out the forms and sliding them anonymously into an envelope at the end of the meeting. She asks if anyone has questions, and answers someone's inquiry regarding where to sign.)

Participants asked short questions regarding the signatures, the forms, and the aim of the focus group. One participant expressed appreciation of the level of good organization and the methodology used.

Moderator informs participants that the discussion should be carried in Arabic, which is the country's [Lebanon] mother tongue.

Q1-A- "We are gathered here today to speak about medicine. My first question is 'What do you know about medicine?'" *(By the way, I would love to hear from everyone in the group rather than have one or two people answer all questions)*

S1 *(very confident; serious)*: "Medicine is one of the treatments for specific diseases; medicine is also one of the main and necessary treatments in the field of medicine."

S2 *(serious; confident)*: "I personally don't really believe in the power of medicine. I don't take medicine unless it's absolutely necessary. I do give medicine to my children, though, and that's to prevent their health from getting worse or to reduce their pain when they are ill."

S2 *(still confident)*: "I'm the type that doesn't like taking medicine much. I have a tendency to develop an addiction to medicine. However, in what concerns my children, I deem it too early for them to start choosing whether to take medicine or not; that being said, I give them medicine in order to prevent symptoms such as high fever."

S5 "Cover the pain but don't treat the cause."

S6 "Pills curative or preventative."

S7 "Placebo – psychological illness."

S3 *(confident, nodding)*: "It is one of the ways a person can overcome sickness; it helps you physically."

S4 *(confident, sounds serious, smiling)*: "At home, we try our best not to become dependent on medicine. My husband doesn't like giving our children medicine, unless we absolutely must do so."

Q1-B-Moderator: “What is medicine to you?”

S4 (*still smiling, looks just a little bit hesitant*): “It is a substance that heals a person, but I do try to stay away from it when I can. It’s important not to be dependent. If I have a headache, I think I shouldn’t directly take a Panadol. I used to do just that, but I’m changing because of my husband.”

S5 (*smiling*): “It’s a tranquilizer/analgesic.”

S6 (*very confident, seems like she knows what she’s talking about*): “In my opinion, it’s a chemical substance that solves a problem at times, but in most instances, this “solution” is more psychological than it is medical. Some people are convinced they may be treated/healed if they take a certain medicine.”

S1: “Should be taken as a last resort if the body can not heal it itself”

S3: “Necessary poison – last resort”

S: 2“Health and Safety”

S8: “Hospital medical doctor and pills”

S11: “Pharmaceutical crooks big money”

S7 (*smiling, enthusiastic*): “I, too, don’t take a lot of medicine. I always tend to think that I am being treated for something on the one hand, but developing bad side effects on the other. Unless I’m in dire need of it, I don’t take medicine.”

Q1-Moderator: “Ok, but when you think of medicine, what do you think about? What is medicine for you?”

S7 (*still smiling, receptive*): “When one takes medicine to me, they’re treated for a certain illness, but might suffer from bad side effects as a result, too. I always come across such findings when I do some reading or an online search.”

S8 (*serious, confident*): “Medicine for me is a chemical and/or natural composition to treat a certain disease. Sometimes it does what it’s meant to do, and at time fails at that: medicine either does not have the desired effect or has a bad effect even.”

S9 (*smiling*): “When I first think of medicine I think of an analgesic, a pain tranquilizer. On a different note, having to take medicine on a regular basis bothers me. I dislike being constrained by this activity, always needing to be on time and whatnot. So, when I think of medicine, it is a two-fold idea that comes to mind: either something I need to take to treat something now, or an annoying medicine which I need to take over a long period of time.”

S10 (*confident, smiling*): “I also think of it as a tranquilizer, and I commit to taking medicine, especially if it has been prescribed by the doctor. Why should I stop and get to a stage where I would have to start treatment all over again?”

Moderator: “I have heard the word ‘tranquilizer/analgesic’ more than once. What do you guys mean by that?”(*almost all participants agree that it is a substance that soothes pain*)

S11 (*smiling, enthusiastic*): “Medicine to me is a solution to a health problem. When someone is suffering or in pain, medicine can provide better and happier living conditions for a human being.”

S12 (*smiling, sounds confident*): “Chemical substances that have a temporary effectiveness which expires within a certain period of time, after which the patient returns to their initial situation/state, or even worse. Sometimes one has to take medicine and take it as prescribed as to 11 the resulting inability to take it in the future. My mother takes a lot of medicine. I always thank God that there is treatment available, but it’s a big catastrophe if the pill is not taken when the time to take it comes.”

Q2-Moderator: “Where do you get your information regarding medicine from? Whom do you ask for more information?”

S11 (*confident, smiling, enthusiastic*): “I always have my phone within reach. I go to Google for any question I have or topic I want to know more about, not only when it comes to medicine. My mother was at the hospital a while back. Following the doctor’s diagnosis, I went onto Google and did a fast Internet search *to try to make sense of what the doctor had told us*. Also, my neighbour is a pharmacist, so I very often knock on her door for questions I have, information I might be seeking, or advice of any sort. My third option is the doctor, who I bother sometimes, but turn to if I have a question, especially pertaining to my children’s health. I call up the doctor in the event that I have any doubt about certain treatment or its side effects.”

S2 (*confident, slightly smiling*): “I am usually really scared of the side effects medicine might have. I usually read the insert for more information. I have a laboratory studies background, so I always pay attention to the little details.”

S3 (*neutral for the most part*): “*I ask the pharmacist*. Whether it’s a over the counter medicine or one prescribed by a doctor I’m taking, I ask the pharmacist in case I have more questions or if anything is unclear.

S4 (*smiling, not really enthusiastic, though*): “I ask my doctor for more information; I’m scared to have read something and misunderstood. I prefer asking someone I trust, such as a doctor or a pharmacist. I try to stay away from reading information online or the one in the insert. *I read that once and was a little depressed after looking at all the possible side effects*.”

Moderator: “But who do you turn to first?”

S4 (*confidently*): “Usually we turn for the doctor first, of course, when they prescribe it, and the pharmacist for further questions.”

S5 (*enthusiastic, smiling confidently*): “I read the insert, but I agree with S4 that the information on that can be a little scary/startling (*S4 nods in agreement and others agree, too*). One must always ask, though, because we [the people who haven’t studied medicine] aren’t really well-informed when it comes to medicine.”

S6 (*smiling confidently, enthusiastic*): “I always start by reading the leaflet then I go to Google. I don’t always ask the doctor first, and if I do, I double check what he says. I know that some doctors have certain agendas behind prescribing a specific type of medicine.”

Moderator (*addressing S6*): “Just as a follow-up: how do you mean double check, and how do you do that?”

S6 (*assertively, confidently*): “*I double check almost everything I’m told, mainly by comparing what the doctor says, what the pharmacist has told me, etc, I cross-examine the sources*. I think the information on the insert is often exaggerated. Pharmaceutical companies do that to protect themselves to cover themselves in case someone sues them. And, you know, medical doctors sometimes prescribe a certain medicine produced by a

specific company because the latter sends him to a conference at the end of each year (*said jokingly, playfully*)”

(*Others laugh and nod in agreement and add forms of gifts a doctor might receive. They are mainly joking about it, taking it relatively lightly.*)

S7 (*smiling*): “Same thing for me. I agree with S6. I always read. I always look at the insert or do research, even if I’m taking something as common as Panadol. I ask Google way more often than I do the doctor, actually, to be honest.”

S8 (*confident*): “I do some reading, and if there’s something unclear I turn to Google, but I always come back to my doctor because I trust him. He is the one who prescribes the medicine, and he knows better. Sometimes I ask him about worrying or influencing information written about X medicine and *he comforts me by saying I shouldn’t pay attention to it.*”

Moderator: “What do you mean by influencing information?”

S8 (*serious*): “Warnings or side effects that might influence my opinion of the medicine I’m taking or scare me, for example. He [the doctor] tells me to not bother with/pay attention to that. Just like S6 said, the information on the insert is sometimes exaggerated. My doctor tells me that he wouldn’t have prescribed X type of medicine to me had he not been comfortable doing it. I do double check using Google, though.”

S7 (*responding to S8*): “I just wanted to tell you [S8] that there might be side effects the doctor may decide to not bother with. It’s crucial to read a lot and look at everything instead of relying heavily on the doctor. We can’t skip reading, because sometimes the doctor ignores some uncommon side effects which might be destructive for the patient.”

S9 (*smiling confidently*): “*I read the insert. I can’t take the medicine without reading. Even if the doctor says this medicine is good for you but I disagree, I don’t take it. I ask to be prescribed something else.*”

Moderator: “What do you mean “if you disagree”?”

S10 (*smiling, enthusiastic*): “I ask the doctor at the moment of him prescribing the medicine. I try to ask as many questions as possible, such as those pertaining to side effects, availability of the medicine across the country, substitutes, etc. And when I get to the pharmacy, I ask the pharmacist on duty the same questions all over again. And I come home and read the insert (*laughing here*)”

S11 (*smiling*): “I agree with S10 and with most of the things said. I trust my doctor. I can’t take medicine prescribed by someone I don’t trust. I also ask the pharmacist, for more information. I also read the brochure (insert) when I come back home. That’s all.”

S12: “I ask the doctor when I’m at the clinic, then the pharmacist, and if I come back home and have any doubt at all subsequent to reading the insert, I come back to the doctor with questions. Back in the day I had a health complication and it turned out to be the result of a medical mistake. I stopped seeing that doctor, so all was good. (*laughing toward the end*):”

S13 (*confident, neutral*): “I ask the doctor like everyone else. I also really trust my pharmacist, though, and I ask her reams of questions. On another note, I think that no matter how competent a doctor might be, the person themselves know their bodies more than their doctor does. I was prescribed something by my doctor once that I didn’t take because I knew it was going to have bad consequences. I shared my thoughts with my doctor—he was happy to hear that I hadn’t taken it.

(some participants look resentful; someone makes a comment about the doctor pledging for his own incompetence)

Moderator: “I just wish to comment on some of the things you guys said. You [S1] said something about annoying the doctor. Could you elaborate a little more on that?”

S1 (*frowning, serious, dissatisfied tone*): “Yes, and you know why I said that? I think that in Lebanon, doctors have a lot of patients and very little time. My gynaecologist is the only person who gives me 20 mins. Everyone else are always in a hurry and want to scramble you out of their clinic. We have a situation in Lebanon which is when a doctor is competent and has good reputation, the entire neighbourhood and probably the country chooses to go see him when they’re ill. There are a lot of things we patients don’t know about, but they do they don’t have time to tell us. When my mom was at the hospital, I wanted to ask the doctor a question but I couldn’t—he left before I could finish my sentence. Doctors are under a lot of pressure. I do ask the necessary when I’m at the clinic or hospital, and if I have more questions I might turn to the pharmacist.”

Moderator: “What about the pharmacist? Do you guys feel like you might be annoying him with your questions?”

S1: “I choose my doctor upon his/her competence and that’s why they have a lot of patients, actually, which renders me unable to ask everything in the little time I have. The pharmacy is different, though. Sometimes there is one or two customers, you one can talk with them more comfortably.”

S11 (*serious, confident, sounds like she speaks out of experience*): “At pharmacies, it is more about selling medicine, business. *A doctor is more human.* I disagree with S1; I think a lot of doctors still listen to us and are very helpful.

(S1 comments and says that it can be uncomfortable to ask a lot of questions when there are a lot of people waiting their turn).

S10 (*sounds dissatisfied, concerned, frowning, serious*): “When I gave birth, my gynaecologist sent me his paediatrician friend to come home and give me advice as to how take care of my child and explain the stages. He was very helpful and he gave me his card. People around me recommended ... A famous doctor. ...I called him on the weekend, so he made me feel bad about it, saying he needs to rest. My daughter went to hospital for 10 days for a belly button infection, which the other doctor had taken very lightly.”

Q3-A Moderator: “How important to you is the price of medicine? Do you choose to buy medicine depending on the price?”

S1: “depending on the case/situation. If it’s simple headache, I take something not very expensive.

(S13 and others agree)

Q3-B-Moderator: “Since you brought it up: what is the different between trade and generic medicine?”

S8: “Trade is the medicine released first on the market. Generic is when other companies start making it.”

Moderator: “So is generic medicine counterfeit?”

S8 (*enthusiastic, speaking confidently and loudly*): “No, it’s not. It has the same composition. The companies that decide to “copy” trade medicine get the same composition and ingredients and make generic medicine but under a name.”

S12: “To my knowledge, companies can’t make the same medicine produced by another company for the first 10 years.”

S3 (*a little confused*): “why is there the same composition of the same medicine but different name, though? I don’t know.”

(*a lot of participants say it’s a business, trade, that’s why there is panoply of name on the market*)

S11: “Depends on the companies.”

S10 (*confident*): “The name company makes the ‘same medicine’ but under different names and prices to test the market and gauge which product might sell better.”

Moderator: “Are they using the same ingredients, though?”

S10 (*still confident*): “Yes, of course they are, but perhaps the packaging is different and the price, indeed. It’s for a different audience.”

Moderator: “Any examples of the same medicine under different names?”

S10 (*confused, hesitant*): “I can’t recall a specific example now.”

S1 (*says fast and confidently*): “Panadol and Advil, for example.”

(*some participants disagree, saying that Panadol and Advil aren’t the same medicine.*)

(*a speaker gives the example of Augmentin and Amoxil*)

S10 (*smiling, shares a personal story*): “I was at the pharmacy once and a customer asked for another medicine for the one he has been prescribed was very expensive. The pharmacist said the sister company makes the same medicine for less money and pointed out that the effect is the same.”

S3 (*confident*): “In fact, over here it’s about the importers and what they decide to bring into the country.”

S12 (*confident*): “There’s medicine in Australia like Panadol, it’s called Panamax. It is not sold over here, we have to get it from Australia or from other countries where it’s sold.”

S9 (*serious, assertive*): “Panamax has a better effect when it comes to soothing the pain for me.”

S1 and S3: “Advil abroad is different from the one we get here. The packaging is different and the effectiveness is also different.”

S11: “Just as an example, I have heard about different factors going into medicine production decisions. For instance, Panadol in Lebanon and Panadol in Jordan are different because factors such as demographics, bodies, health, local genetic makeup, climate, etc play an important role. The ingredients are the same but there are different dosages/compositions.”

(*participants try to guess what the factors might be; some say climate, demographics, health, etc. Someone comments on the fact that people living in warm countries cannot take the same medicine as people living in very cold region: they have different bodies.*)

S12: “There is medicine whose country of origin is the UK, but is also made in Arab countries.”

Moderator: “Do you reckon there is regulation and supervision when it comes to medicine here in Lebanon?”

S1 (*frowning, serious, sounds dissatisfied*): “I highly doubt that. Although there is some inconsistent regulation, as it were, with some newly elected ministers occasionally discontinuing certain types of medicine for a short period of time to show the people that they are doing some work. Also, I think the business part of the process plays a very important role. When I go to the doctor’s clinic, I see a lot of pharmaceutical company representatives waiting to promote their medicine and advertise for offers on behalf of their companies.”

S11 (*serious*): “There is some regulation, but I’d say it’s about 5%. Not much worthy to mention.”

S2: “There is no regulation, if you ask me.”

S1 (*frowning, shaking head, resentful*): “When my father had cancer, we went to the Health Ministry to get medicine; they said it has been discontinued. We had to make a few calls and pull some strings to get it, because it was there, but they didn’t want to give it to us.”

S2 (*asking a question*): “I believe that the entire medical field and medicine as a science are a mafia. I know about that guy who invented cancer medicine from Lebanon, who was silenced. I have also heard about contracts pharmaceutical companies sign with importers for 10 years or so to monopolize the market. Should a new type of medicine be introduced, they would have to discontinue their own medicine and needless to say, that wouldn’t be to their advantage. There’s a lot of business in medicine and a lot of people think of profits and whatnot. They are the ones who exercise control and decide when to give medicine, not depending on health and safety concerns, but rather on monetary considerations.”

Moderator: “Would anyone like to comment on that?”

S11 (*confident*): “I have heard that some companies silenced this man and thwarted his invention, and that doctors couldn’t prescribe his medicine. There are contracts that are signed, and those companies are backed up politically and internationally powerful, not just locally. I am not saying that that doctor’s medicine can heal cancer, but he might have had some sort of solution which never few people were able to benefit from.”

S1 (*perplexed*): “But how can we be sure that it is indeed effective?”

S11 (*not sure, confused, put on the spot*): “I don’t really know. That’s what I have heard.”

S9 (*serious*): “There are people who took the medicine and said they had seen good results.”

S1 (*enthusiastic, confident*): Amid my work in media, there are sometimes campaigns and media focus that decide to put the spotlight on a specific person or cause. Media is the fourth estate, after all; they decide a country’s agenda and they have a lot of power. Maybe this person has people backing him up. I am not saying this is the truth but it’s something to think about.”

S2 (*frowning, dissatisfied*): “My sister works in a pharmaceutical company and she studied chemistry. Her professors at university used to tell her there has been medicine for

diabetes and other illness for years now, but those are not revealed because international pharmaceutical companies would face a lot of losses in profit margins.”

S1 (*responding to S1*): “But if that’s true and those same international companies make new, more effective medicine such as the one healing diabetes, they would sell it at a high price and would make enough money to cover the losses that discontinuing the old medicine has brought about.”

S2 (*responds to S1*): “But you know, it’s a corporate and political game played by international companies who not only abide by their own policies and bylaws, but also have agreements with other international and powerful companies that they need to honor. That might be why this person who made the cancer medicine couldn’t start prescribing and selling his invention.”

Moderator: “Do we make medicine in Lebanon?”

(sweeping majority says yes)

S9 (*smiling, confident*): “Yes, we do, and I am occasionally pleasantly surprised that some medicine is really effective in the sense that I sometimes see good results and am treated well. We don’t always have to take something imported from overseas. I’m happy that some medicine is effective at least.”

S10 (*nods, agrees with S9*): “There is medicine I take from Lebanon that’s way more effective than the one I once got abroad.”

Moderator: “What medicine is being produced here trade or generic?”

S1 (*confident, sounds well informed about the topic*): “Generic means a product we copied and made something similar to it but which is not the same—Just like wearing a Chanel that is not a Chanel”

S2: “Trade medicine usually goes through a long process of studies and research before it is put out on the general market. Generic does not have to go through this, as it draws on the findings and ingredients/compositions of the medicine that came before, so this is why it’s less expensive.”

(S3, S4, and S5 all agree with S2)

S6 (*agrees with S2*): “The mother company which introduced the medicine first must have worked for years on developing it and doing research and tests. Naturally, they need to charge extra for that. When another company picks up the medicine and makes more of it, they wouldn’t have to go through the same process, and this is why generic medicine is more affordable.”

S7 (*agreeing with what has been said, nods, and adds*): “Also depends on the work force and employees. There are employees that charge less in some countries, others that charge more, so this is a factor that determines the prices, too.”

(S8 agrees, no one adds anything)

Q4-Moderator: “What does counterfeit medicine mean to you?”

S2 (*confident*): “Medicine that isn’t regulated or supervised, or medicine that hasn’t been giving the authorization to be sold in a certain country.”

S6: “Medicine made at a sub-par lab where the conditions do not live up to international standards.”

S8 (serious): “Also, counterfeit medicine has exact same name. A counterfeit medicine Augmentin is also called Augmentin, but one is the original, the other is not. There’s an intent to cheat, to deceive.”

(sweeping majority agrees)

Moderator: “Are the terms **copy** and **fake** synonymous to you?”

S1 (*disagrees, says confidently, enthusiastically*): “They have different meanings, of course. copy might give same effect, treat the same thing. fake is good for nothing.

S11 (*just a little hesitant*): “copy is produced by a company other than the original, the name is close but the composition is the same. Some ingredients might be slightly different, though.”

Moderator (*addressing the ones who spoke about the distinction between the two words*): “So, are you guys saying the **copy** medicine is the one that has the same name as the original?”

S1 (*serious, confident*): “No, that would be fake copy meds could have a very similar name. It’s possible to take the same composition and ingredients but put the medicine under a different name.”

S11 (*confident, a little sarcastic toward the end*): “Making fake medicine is operating in bad faith. There’s a clear intent to deceive. A certain type of medicine might look like the exact original, while it might have been made in Burj Hammoud, for example. They might have used white powder, for all I know.”

S9 (*serious*): “I compare fake medicine to fake money. It deceives.”

S2 (*serious*): “There is always medicine on the market whose name is very similar to another very popular name. People sometimes buy it without noticing; others buy it purposely because it’s cheaper.”

S9 (*responds to S2*): “But that’s copy, in my opinion.”

S2 (*confused, very hesitant*): “I would say the one with the different name is fake and the different composition is copy”

Q6-Moderator: “But if you have to choose to use only one, which one would it be?”

S2: “fake

Moderator: “Ok, so you are saying medicine is **fake** if the name has been changed but the composition is the same, right?”

(S2 agrees)

S1 (*responds to the question, disagreeing, vehemently*): “I disagree, actually. fake is when different medicine is introduced as being the same product as the original. Fake as a word that means deceiving, tricking, cheating.”

(some participants agree—S9 reemphasizes the word ‘cheating’ and says it’s synonymous to مزور S11 disagrees with this, though, saying they’re different concepts.)

S3 (*agrees with S1*): “In my opinion, fake is the same name, but it has no use. مقلد has the same ingredients but a different name and people know that it is different than the original. We are aware.”

S4 (*confused*): “I don’t really know. I don’t know what the nuance between fake and copy is.”

(S5, S6, S7, and S8 agree with S1’s words.)

S12 (*confident, dissatisfied*): “We all know that Advil is originally American, but it’s also produced in Arab countries. On the back of the box, there’s usually this information in very fine print. We as patients tend to automatically assume this medicine is made in a certain country, but that’s not always true. This [Advil made in the Gulf] is fake for me. They are deceiving the people.”

S1 (*disagrees with S12*): “But that doesn’t have to be a deception scheme. Countries can apply for licenses to make a type of medicine and sell it. It’s legal and not usually done under the table.”

S12 (*agrees*): “Yes, and they do this mainly to save money by making the medicine themselves and selling instead of buying it at a higher price from abroad.”

Moderator: “So the price of the USA product and the one made in the Arab World is different, right?”

S1 (*assertive*): “Yes, surely.”

S12: “Not always. Sometimes one might not notice that it has been made elsewhere. If the print is too small and the packaging is similar to the original, we tend not to catch on the difference. We might occasionally request locally produced medicine, for different reasons: I remember my mother used to use a specific type of medical cream from France. At some point, she started buying the one produced locally and saw better results. The name was slightly different here, too.”

Moderator: “Did the pharmacist back then tell you the cream was originally French, but the one you were buying was produced locally?”

S12: “Yes, he was honest with us and he told us. But he told us it “seems” like the composition has been changed. That’s what he said—he wasn’t sure, but we knew it all along.”

Q4-b-Moderator: “Where did you first hear about **fake** medicine? When did you begin to become familiar with the concept?”

S2 [who is Jordanian] (*says jokingly*): “In Lebanon.”

(*everyone laughs*)

S1 (*confident, serious*): “In the media and it is not long time ago that we started hearing about ministers or country officials banning some medicine from entering the country.”

(*participants nod*)

(S11 agrees and says she thinks almost everyone heard/still hears about this mainly in the media)

S11: “I always hear about Panadol being sold at cornerstores instead of the pharmacy, where it belongs.”

Q12-Moderator: “Has someone experienced first-hand **fake** medicine/fallen victim to this?”

(*speakers say they have not, show signs that they have not*)

Witness: “I used to take medicine regularly. Got it from abroad, from an Arab country (Syria), actually. Few months later, my health started deteriorating. We didn’t know the reason, but after tests and medical visits, it turned out the medicine was counterfeit and has no treating effect whatsoever. We didn’t follow through on the litigation, but I did have to have a surgery following this patch. The name and the packaging were the same. I didn’t always buy it from the same pharmacy, though. I don’t have one pharmacy I always go to.”

S9: “This is a perfect example of fake medicine.”

S7: “I have an experience to share, but not medicine—It’s with using sunscreen/sunblock. It was Bioderma sunscreen which looked perfectly original: same name, same serial number. Few weeks later, I had something similar to a burn on my face. The skin ended up becoming even more red. I hadn’t been sitting in the sun any longer than I normally did. I went to my dermatologist only to discover that I wasn’t the first and only one to complain about the same thing. There was a whole batch of them on the market.”

S1 (*disagrees*): “No, I don’t think that’s possible.”

S6 (*disagrees with S1*): “Well, maybe because it’s sunscreen, it might have been influenced by over temperature, for example in the shipping process. It is a possible scenario (*responds to S1 who said it’s not*).

S2 (*agrees with S6*): “Yes, I think storage and shipping might have an impact.”

S10 (*shares a personal experience, jokingly*): “I was once using a type of cream, but then was prescribed another one by my doctor who said I should store what I was using at the time in the fridge. I informed him that the cream was expiring soon—he said it’s ok, just put it in the fridge and don’t bother with what’s written on it.”

S6 (*jokingly, sarcastically*): “Ask him if you can put it in the freezer and defrost it when you need to use it.”

S12: “Some dermatologists say you need to look at the cream and examine its texture, that’s how you’d know if it’s still good for use or not.”

S2 (*a little hesitant*): “To my knowledge, you can still use cream 2 months after its expiry date.”

S12 (*smiling, sarcastic*): “A friend of mine puts all medicine in the fridge. Her husband was undergoing a certain treatment, but was not seeing any results. She asked me to look at the insert: turns out that medicine isn’t supposed to be exposed to cold temperatures. She had no idea at the time.”

(*people laugh*)

Moderator: “Who do you think should inform patient about this and other useful information?”

S9: “*The pharmacist.*”

S12: “No one ever tells me anything. Neither the doctor nor the pharmacist give me additional information.”

S3 (*confused*): “I have a question. How do we know what is the proper way to store medicine?”

S9 + S10 (*respond*): “Your pharmacist should instruct you. Doctors usually say that, too. Especially with delicate products such as eye and ear drops.”

S2: “I am rarely ever informed about details and side effects by the doctor.”

Q5-Moderator: “How can we tell the difference between original and counterfeit medicine?”

S13: “The silver sticker differentiates between the two.”

S12: “The logo of the importers which the ministry has advertised a while back and there have been some media reports and articles on this, so it is only recently that we started paying attention. Before that we used to examine the box, the shape, the colours, etc. A guesswork, basically.”

S10 (*perplexed, hesitant*): “Me either; it’s hard. The Augmentin I was talking about earlier looked the same and had the same hologram as the original but was not, in fact. Officials took to the media and announced that the entire batch produced within a certain period of time was counterfeit back then. Otherwise, I would have never known.”

S9, S8, S7, S11, and S6 (*smiling, a little confused, hesitant*) said they “don’t know how to differentiate as we don’t think we have the necessary knowledge/information.”

S5 and S2 (*jokingly*): “we do the sign of the cross and we take it” better to say: “we do the sign of the cross and we take it”

S1: “I ask my neighbour-pharmacist.”

Q11-Moderator: “So are you saying that the pharmacist should be able to tell when medicine is counterfeit?”

(a lot of speakers agree that they should)

S2 (*confused*): “But based on S10’s story about Augmentin, apparently pharmacists had no idea that medicine was counterfeit, and that went on for months.”

(a couple of people agree with S2, saying that pharmacist are sometimes unable to tell)

S8 (*disagrees with them, confident*): “He should at least be able to trace it back to the source. Where did the counterfeiting start?”

S1 (*dubious*): “If they usually buy from Company X, then they once bought from Company Y, they should know.”

S5: “There’s a pharmacy in Ashrafieh that makes medicine. How can we know if those are good or not? They are the ones who make them, and there’s nothing else to compare them to.”

S9 (*jokingly*): “We keep trying and see”

S9: “I also know another pharmacy like that, but in Furn Chebbek.”

S10: “A relative of mine used an herb-based medicine made at a pharmacy for around a year to treat ulcer. Both of his kidneys stopped functioning. He had a kidney implant so he has one kidney now.”

(people react by showing signs of dissatisfaction, shaking heads, talking among each others, etc)

S12 (*serious*): “Herbs always have side effects if you don’t take them in moderation. One needs to know what to take and when to stop.”

Q12??-Mrs Farah: “How can we make sure that we are taking ‘good’ medicine?”

S12 (*enthusiastic*): “I trust my pharmacist blindly. I travel distances to get my medicine. I don’t steer away from this pharmacy. They’ve been great to me and my family.”

S2: “But I don’t think one should not stop trusting the doctor, either.”

S3: “I usually go to a pharmacy in Fanar. If the pharmacist—who is the owner—is there I ask her. I don’t like asking her brother for advice. I’m more comfortable talking to her, especially if it’s something not prescribed by a doctor, such as creams and what have you.”

S4 (*agrees with S3, and is a little confused, hesitant*): “Actually, it’s not my field so I don’t know. You just have to trust sometimes, I guess.”

Q14-9-Moderator: “Where does your trust in the pharmacist come from? What should the pharmacist do to gain your trust?”

S9: “It depends on where the pharmacy is and one’s environment, their entourage, the word of `mouth. You hear from people that this person is reliable and trustworthy, and you might end up putting your trust in them, too.”

S6 (*nonchalant*): “I don’t really care, honestly, I pass by any pharmacy and get what I need.”

S11 (*serious, confident*): “For me, there are many components for trust to be built. It’s the way a pharmacist talks, the way they interact with people, the way they welcome you into their pharmacy and listen to you and give you the time of day. Sometimes I need advice for something minor such as a cold if I don’t want to go to a doctor. If I ask a pharmacist for their advice and I feel better, I start trusting their judgment. It is something you build, trust doesn’t happen overnight. There’s a pharmacist I know who takes the imitative of telling what my options for cheaper medicine are, without me even asking.”

S6 (*confident, knows the factors that make her trust someone, didn’t need to think about them*): “I sometimes ask myself the question: is this person a real pharmacist who has studied pharmacy and is licensed to work? The way they talk also shows how informed they are. You can test them, too, to know if they’re informed about the latest advances and how up to date they are.”

S3 (*confident, proud, smiling*): “While working as a school in the past, my fingers became puffy and red and they used to hurt me a lot. I went to a doctor, who recommended I run a long list of blood tests. I went to my usual pharmacy and asked them for their opinion. They said I had an allergy to chalk. I used a cream they gave me and felt way better within a month.”

S1 (*frowning, dissatisfied*): “We once got medicine from one of the most famous pharmacies in the countries. People usually go there for products they can’t find elsewhere. Turns out we had been given the wrong dosage, which resulted in extremely serious consequences. We checked, and it turned out that the person who gave us the medicine was an intern who didn’t pay attention. We never tried to sue, though. We were also mistaken because we trusted blindly. *We still up until now tell people not to go there.*”

S2 (*sympathizes with S1, but disagrees slightly*): “I don’t think they’re the only ones to blame. The pharmacy owners are not fully responsible as it was the intern who gave you

the medicine. Plus, *had there been more regulation and supervision* with experts hired by the government making rounds, I'm sure they would have been more careful."

Moderator: "Have you heard of cases of **fake** medicine sold for a price cheaper than of the original?"

S10 (*confident, knows about the incident*): "Around the same time when everyone was talking about fake medicine there was a pharmacy in Ain el Remmené where one could get medicine for cheaper prices. It's "Pharmacie Habib". A lot of people would queue up there. This was around 5 years ago, but it was closed about 7 months ago.

S9: "There's some sort of window and high wall behind which the medicine is hidden. You can't see what happens in the back."

Q8 & 6-Moderator: "Do you reckon people know they were buying counterfeit medicine?"

S10: "I actually had the same question when I first heard about that pharmacy. I was told that it's because they buy a lot of quantities that they can afford the offers. I never went. I was dubious. I asked friends and pharmacists and they all discouraged me. Plus, I didn't want to stand there to buy medicine I wasn't sure about from people I didn't care about and save 2,000 or LBP 3000."

S2 (*serious, compassionate*): "Some people need to think about money nowadays, though. Not everyone can afford the luxury of expensive medical services, especially if they have 6 or 7 children."

Q8-Moderator: "Where is **fake** medicine produced?"

S1 (*confident*): "There are a couple of warehouses here in Lebanon that have been exposed for making counterfeit medicine."

S2 (*serious, sounds well informed*): "Neighboring countries, such as Syria and the Far East, where there's no or very little regulation."

S3 (*confused*): "No idea, but I reckon it happens everywhere."

S4, S5, S7, and S8 say they are not sure, but they agree with S2 on the neighboring countries idea and the fact that it could happen anywhere, and in Lebanon because of the chaos and lack of regulation/supervision.

S6: "I agree with S2, and I actually doubt it takes place in Lebanon, because making medicine is expensive and necessitates equipment and expertise. I don't think it's as simple as it sounds."

Q9-Moderator: "Hypothetically, some people are aware that they are buying counterfeit medicine and they purposely seek it out. Where can we get this kind of medicine?"

S2 (*impulsively, with confidence*): "Not necessarily from the pharmacy. I've heard that in Dahiya, Lebanon there are cornerstores selling all kinds of medicine."

(participants joke about random places one can get counterfeit medicine, such as thrift shops)

Q9-Moderator: "What is the first destination you think of when you think of counterfeit medicine?"

(A lot of participants say they don't know at first; some mentioned pharmacies, hospitals and dispensaries.)

S1: “Dispensaries is a top destination for counterfeit medicine; they are all over the place.”

Q8-Moderator: “Is there counterfeit medicine in hospitals?”

(opinions are divided between yes and no, with most people dismissing that, showing signs of shock and resentment).

S13 *(frowning, shocked, dissatisfied)*: “This is too shocking [referring to the possibility of finding counterfeit medicine in hospitals]. Do they not have good conscience and a sense of responsibility?”

S6: “There’s a difference between operating in bad faith by willingly giving people counterfeit medicine, and simply not knowing that medicine is counterfeit.”

Q14-Moderator: “Do you think pharmacists know—or have a way of knowing—the medicine they are selling is counterfeit?”

S6 (confident): “Of course they know—or have a way of knowing—the medicine they are selling is counterfeit.”

(others agree)

S6 *(changes her initial stance)*: “But it’s possible that they don’t.”

S1 *(assertive, disagrees)*: “I don’t think counterfeit meds can find their way into their pharmacy if they always buy their products from the same source.”

S2: “But they might need to buy from two or more different sources, as I don’t think one single source provides everything. Some of them don’t sell certain products because they don’t have a license.”

S1: “Ok, but pharmacists should check their sources before buying. Shouldn’t they investigate the source before signing up and doing business with them?”

Moderator: “How can pharmacists investigate their sources?”

S1 *(confidently)*: “They could go to the Syndicate of the Importers of Medicine, check licenses of the sources and whether certain products have met the set standards and qualifications.”

S2 *(assertive, confident)*: “When the entire debacle about bad meat happened, buyers said they were buying from the same source and they still got bad meat.”

S1 *(disagreeing, defying)*: “But meat is different.”

Q6-Moderator: “Is meat different? What does everyone think?”

(people argue about this, but the sweeping majority thinks meat is not different at all (in the sense that it’s more ‘OK’ for meat to be bad than medicine to be bad. According to them, it’s even worse as it can hurt someone faster).

S2: “People who go to 5-star hotels sometimes have food poisoning.”

S10: “I think with food, we always expect we might chew on something bad and have an upset stomach. We think of medicine as something to help us get better, not impact our health negatively.”

Q12-Moderator: “How do you feel knowing that you might be taking medicine that may or may not treat/heal you and/or even harm your health?”

S10 (*sounds dissatisfied, resentful, honest*): “There are a lot of things that run through my head when I think of this, of course. I worry and I am bothered and uncomfortable thinking that such a thing might come out of medicine, a product that is supposed to help me feel better. A meal is different. We all know that some bad chicken could be infected with salmonella, and that fresh cheese can cause some undesired effects. *That’s common knowledge.*”

Q4-Moderator: “What are the substances that are counterfeit in medicine?”

S13 (*a little hesitant, confused*): “*Counterfeit medicine doesn’t have any effect at all, so it doesn’t have effective ingredients.*”

Q4-Moderator: “OK, what exactly might it contain?”

(the following few contributions were interjected fast, without much emotion, but mostly, everyone was hesitant, confused, unsure, perplexed)

S11: “I would say tranquilizer with some white powder perhaps.”

S10: “I don’t know.”

S9: “I don’t know but I’d say they have no effect whatsoever.”

S8: “They contain substances that shouldn’t even be in there.”

S7: “I don’t know.”

S6: “I agree with what’s been said.”

S5: “not sure, maybe expired substances.”

S4: “I agree.”

S3: “Perhaps they divide dosages into smaller parts to make more medicine using the same quantities.”

S2: “They use cheap a lot of ingredients, and less of the expensive ones, regardless of how the composition should be.”

S1: “They use the cheapest chemical substances to make the most profit.”

Q8-Moderator: “Anyone knows anything pertaining to the process of making the medicine? How is medicine made? What comes before the pill?”

S6 (*hesitant at first, but then more confident when she quotes her friend*): “I don’t have a lot of details, but a friend of mine works with a pharmaceutical company and she once told me about the process. First, there are many studies carried out and then tests and quality appraisals. I know that medicine goes through different departments before it’s approved and put on the market.”

S1 (*hesitant*): “There is a specific process, of course. There’s research and studies that come first.”

Q12-Moderator: “Who is the first person from the medical staff you think of/have the most trust in when you have a question or when you’re seeking help?”

S1, S2 (*fast, impulsive, confident*): “The doctor, of course.”

S3: “If I have a question I go straight to the pharmacy, even before I call a doctor.”

S4: “There are my relatives who are doctors, whom I trust and turn to for questions and advice.”

S5: “The doctor and sometimes the pharmacy.”

S6: “The pharmacy perhaps a little more often than the doctor.”

S7, S8, S9, S10, S11: “The doctor.”

S12: “The pharmacist.”

S13: “The doctor.”

Q10-Moderator: “In your opinion, who is (are) the party(-ies) responsible for the presence of counterfeit medicine on the market?”

(people interject almost unanimously, mentioning the government, the Lebanese Ministry of Health, the Syndicate, pharmacists, etc).

S7 (*confidently*): “The Government.”

(almost everyone shows signs of agreement)

S11: “The Syndicate of Pharmacists are responsible for the presence of counterfeit medicine on the market.”

S13: “The Lebanese Customs are responsible for the presence of counterfeit medicine on the market.”

S9: “I would say the first person to blame is the pharmacist. I think pharmacists *are always aware that a medicine is counterfeit* when they are selling it to people.”

(opinions are divided here: some people agree with S9, others do not)

S10: “I would blame the Ministry of Health and the Syndicate.”

Q-13-Moderator: “S, according to you, it has happened for medicine to be discontinued abruptly following a revelation that they are counterfeit. Do you think pharmacist knew about this and kept silent?”

S9 (*confident, serious*): “Actually, I’ve never heard about medicine being discontinued because it’s counterfeit. From what I know through the media, they discontinued medicine for undesirable side effects. They just discovered the effects very, very late. In that case I don’t blame the pharmacist at all.”

S1 (*confident*): “Such as the Motilium scandal, which was the result of a series of efforts on the part of the media. After multiple reports and articles, the government came out with an announcement and discontinued the medicine because it couldn’t avoid the pressure. Everyone knew about it.”

S12: “Some pharmacies were closed down by the authorities for involvement with counterfeiting, such as ‘Pharmacy Habib’ mentioned earlier”

S3 (*addressing S12*): “Yes, but not right away. That pharmacy kept closing down then opening up again, until it was closed permanently a few months back.”

Q4-Moderator: “What is the latest incident/story you’ve heard or experienced pertaining to counterfeit medicine?”

S10: "Augmentin."

S12: "I'd say that company in Ballouneh which was making cancer medicine in the form of IV; it contained water instead of medicine. They were closed down, though."

Q12-Moderator: "If, God forbid, you discover that the medicine you have purchased/are taking is counterfeit, what is the first thing you would do?"

S9: "If I got CFM, I would call the concerned parties/the authorities."

S13: "If I got CFM, I would go back to the pharmacy and tell them about it."

Q12-Moderator: "And what do you expect to happen at this point?"

S13: "They would say they didn't know and apologize."

(people laugh, saying it's the expected scenario)

S12: "Turning to the Ministry and the Syndicate is not possible, in my opinion. I don't think my pharmacy sells counterfeit medicine so I trust them, I don't think they would do such a thing."

Moderator: "But let's imagine it has happened, what would you do? Who would you talk to?"

S12 (*very hesitant*): "I don't know. I am not even able to imagine this taking place."

S11 (*confident*): "If I got CFM, I would turn to the Public Prosecutor and file a complaint."

S10 (*hesitant*): "I don't have a law degree so I don't know. I would ask my lawyer-friend and I would talk to the pharmacy about it."

S9: "If there's a hotline I would call and I would give the name of the pharmacy and ask how to proceed from there."

S8: "I experienced this first-hand once. *I went to the pharmacy but I got intimidated. I gave them the medicine and left.*"

S6: "One should try to trace it back to the source. However, that also depends on the consequences a subject has experienced as a result of taking the medicine. It depends on the person and how much time and effort they're willing to invest."

S5 (*sarcastic, jokingly*): "They are going to say they don't know. So you would simply shut up and leave."

S4: "I don't know what I would do if it's too bad a consequence."

S3: "I would call a hotline and complain."

S2: "I go back to the pharmacy and talk to them."

S1: "As I work in the media I would spearhead an investigative report and write about it. Authorities won't be able to bury the story. They would not be able to do anything about it because I would circumvent their ability to hush the loud voices, which they usually do. The message spreads very fast through media."

Moderator: "What has been done in Lebanon to towards the production and dissemination of counterfeit medicine?"

S9: “Some pharmacies have been closed and I feel like some work is being done, but it’s slow and not as widespread and organized as it should be. There are lacunae and it could most certainly be way better, but it’s not as bad as some people think, at least in my opinion.”

(Some people show signs of disagreement, saying that not much work has been done and more is needed).

S11 (*dissatisfied, frowning*): “I don’t think enough effective measures have been taken, to be honest. They stopped one pharmacy, but they didn’t put together a plan to punish others.”

S12: “It turned out it was the minister’s brother who was involved in counterfeiting medicine anyway. Nothing much was done.”

Q14-&13-Moderator: “Going off of what you guys have said, what do you think should be the ways adopted to stop the production and dissemination of counterfeit medicine?”

S1 (*confident*): “There should be penalties and organized measures to penalize the ones who counterfeit medicine or those willingly involved in the process.”

S11 (*confident*): “They should take harsh measure and they would set a precedent that way. Others would be scared to do the same thing as their predecessors.”

S11 (*serious*): “Authorities need to trace it back to a source of course, but if the pharmacist is implicated willingly, they should be punished as well.”

S2 (*confident*): “*I think they should privatize The Syndicate of Pharmacists in Lebanon for better organization and more regulation.*”

S6 (*serious, very confident, speaking out of experience*): “I think when medicine is imported properly and lawfully, there is a long process of many stages the local company must go through: there are certificates pertaining to quality and the source which need to be issued and signed. It is not that simple to import medicine. If importers are held accountable and are asked to acquire all the necessary forms and signatures, that would reduce the possibility of the presence of counterfeit medicine drastically.”

Q9-Moderator: “How is counterfeit medicine finding its way into the country, though?”

S6 (*sarcastically*): “Because this is Lebanon. There is a lot of corruption. The government is corrupt. There are many loopholes and some people have immunity. They can do whatever they want.”

S11 (*confident, serious*): “There should be forms and certificates and sustainable supervision that doesn’t only hold people accountable once a year, but consistently checks for quality and adherence to international standards and local regulations.”

S1: “I think it is not only about regulation and supervising the company. Fighting corruption is an immense, large-scale project, actually. There is a lot of corruption and “freedom” at the port, there are groups who don’t adhere to standards and do whatever they want over there.”

Q6-Moderator: “Which products other than medicine are also counterfeit?”

S1: “Clothes are.”

(sweeping majority says that almost everything is now available in counterfeit)

S12: “Canned foods, among many others.”

Q13-Moderator: “What is (are) the penalty(-ies) for counterfeiting medicine in Lebanon?”

S6 (*sarcastically, she's sorry it's the case*): “It depends on your connections, on the ‘wasta’”

S9 (*hesitant*): “It should be years in prison, in my opinion, but I don’t really know what the exact penalty is, or if there is a penalty even.”

S11 (*serious, somehow angry*): “If it’s a pharmacist, they should revoke his license or freeze it for 10 years or something. The exact penalty and whether the subject goes to prison or not depends on what they did exactly.”

S10 (*confident*): “*I believe the person should be tried publicly for everyone to see and so that a precedent is set.* It doesn’t help to drag someone through months of litigation and not let all the others who are doing the same thing what the consequences of getting caught are.”

Q13-Moderator: “Do you think the implicated person should go to prison?”

(sweeping majority says yes, the person should go to prison. Opinions differ on the duration, though. Some think the person should be jailed for a long time, others said they should be jailed for life because they toyed with people’s safety and lives.)

Q13-Moderator: “If it’s a pharmacist who is indicted, we revoke their license; what if someone is not a pharmacist?”

S9: “I don’t think the person who is selling the medicine—the pharmacist in this case—should be the one given the biggest penalty. The person who is actually counterfeiting medicine—the source—should be the one who suffers the worst consequences, not the pharmacist.”

(some people disagree, they think pharmacist are just as implicated if they know that their medicine is counterfeit.)

Q13-Moderator: “What you think should the penalty be?”

S9, S6: “Depends on what exactly they did”

(someone brought up death penalty, but it was more of a joke)

S11: “Prison and fine.”

Moderator: “How much in fines?”

S13 (*serious, defiant*): “A lot of money should be paid. This infraction should not be taken lightly.”

S11: “It also depends on the situation. It’s on a case-by-case basis. If there are a lot of people involved the paid sum should be higher.”

S10 (*serious, defiant, angry*): “Money doesn’t mean anything for me. They would do it again. They should revoke the license but they shouldn’t go to prison because they would keep doing it.”

Moderator: “Do you think the ones making counterfeit medicine are pharmacists?”

(a lot of people say yes, some of them say not necessarily)

Q9-S2: “People who work in labs or who have studied biology or chemistry could be the one making it.”

S1 (*serious as usual, sounds well informed*): “There is more than one possibility. There might be people who take advantage of the fact that they work in a pharmaceutical company to make counterfeit medicine or establish connections with local buyers or importers or pharmacists. But there always should be someone from within the field to coordinate the process.”

(*someone says the person could be a doctor*)

S4, S5 (*confused, hesitant*): “I don’t know, I’m not sure.”

S6: “I believe there should be a minimum level of know-how, just basic knowledge to know how to go about making medicine. The average person, us here included, don’t know how to make a pill and make sure it’s pink, for example, and that it doesn’t fall apart.”

S7, S9: “I think someone from the field must have something to do with the process, undoubtedly.”

(*sweeping majority agrees*)

Q11-Moderator: “Why do people get into the counterfeit medicine business?”

Sweeping majority agrees that:

“People get into the counterfeit medicine business *for money, to make profits, to become rich fast*”.

Q14-Moderator: “In conclusion, what do you deem is the best solution to know more about counterfeit medicine?”

S9, 2, 3: “media , conferences”

S3: “This focus group has helped us a lot ... Word of mouth, we talk, we discuss, we get more information, we become aware.”

S1: “The media”

S6: “Organized and structured awareness campaigns, which should be planned professionally and on different levels as to cater to everyone: people who read, people who don’t, etc..

S7: “There should be distinct steps and cooperation with and efforts on the part of the government, but then again there is no government nor a president now (*sarcastic here*)

S9: “A certain party/authority to hold people accountable.”

S8, S10 and S12 agree with what has been said.

S12: “A lot of infractions are happenings and people are repeatedly breaking the law, but many incidents have been diligently covered up to protect certain people who have the money and power to keep doing whatever they are doing.”

Q14-Moderator: “So do you guys think that raising awareness of counterfeit medicine, its causes and dangers is an effective means to combat it?”

S10 (*sure*): “I would say it’s a necessity, actually.”

S11 (*confident*): “To limit counterfeiting, awareness is key. I would be creating a barrier for people who are counterfeiting or looking to get into the business. They would feel nervous and maybe—hopefully—change their mind.

-----End of focus group-----

Continue public focus group transcripts

B. Transcript: Public Focus Group: CNDJ-FG2-040914

Moderator: “First off, I would like to thank Father XXX and Ms. XXX for allowing me to hold this activity here. My name is Lydia Farah, I have a diploma in pharmacy from Lebanon and the United States. I am working toward a doctorate degree in Brighton University in Britain with a specialization in “Social pharmacy”. As you can see, there are some forms in front of each one of you. Those are important formalities we need to abide by, to uphold the person’s rights to consent to carry on a dialogue with me or not, out of respect for your privacy and the topics we are going to touch on during this meeting. I am going to read the form with you. Today, we are going to be talking about medicine and counterfeit medicine. The goal behind this focus group is to collect information and knowledge from you. I am going to be asking questions; I won’t be able to answer any of your questions or give you any sort of information before the focus group comes to an end, though. I want to hear what you have to say about counterfeit medicine and products and understand your point of view regarding this matter and the factors that inform your thoughts and opinions.”

(Dr. Lydia then starts reading the forms and explaining their content, urging participants to feel free to come back to her with inquiries at any time in the future. She also emphasizes the importance of the participants knowing what the topic at hand is and them being present as consenting individuals. She reminds them that the topic discussed is going to be medicine and counterfeit medicine, and what they [participants] know about those. She then emphasizes the importance of the consent form, informs participants that the session is going to be audio taped, and introduces the note taker. She then talks about the optional demographic form and reminds everyone of the anonymous nature of the meeting and the impossibility of linking a participant’s identity to their filled out demographic form. “And in the event that someone feels uncomfortable being here at this moment or later on during the meeting, they are totally free to leave, of course,” Ms. Farah proceeds to say. She also explains the process of filling out the forms and sliding them anonymously into an envelope at the end of the meeting. She asks if anyone has questions, and answers someone’s inquiry regarding where to sign.)

(hesitant) “Why did you choose teachers for your focus group?” someone asks

“I did not, actually. I requested that anyone available—regardless of their background and position at this institution—take part. I chose this particular institution because after all I needed to select a sample from society that will be willing to cooperate with me and be receptive to the idea of participating in a focus group. One suggestion was to approach a school, and that is why I’m here,” responds Ms. Farah.

Ms. Farah informs participants that the discussion should be carried in Arabic, which is the country’s [Lebanon] mother tongue.

She now invites everyone to have a light lunch before starting the focus group.

(pause for lunch—around 10 minutes)

Q1-A Ms. Farah: “The first question is, ‘What do you know about medicine?’ Objective: Knowledge & Attitude

(thinking, serious) S2: “Something that heals a certain disease.”

S5: “Treatment.”

S8 (*Serious*): “Something we take against our will.”

S7 (*Serious*): “A sedative/calmativ.”

S10 (*Hesitant*): “Something that needs to be taken in moderation and specific dosages.”

S11 (*Frowning, serious*): “It needs to be prescribed by a medical doctor, not by just anyone.”

S1(*serious*): “Chemical substances, could be natural or artificial and put together, in addition to what has been said. It could be for healing or for subsiding pain.”

S4 (*Serious*): “Neglecting to take the prescribed medicine could have the same consequences as not taking it at all.”

S7 (*Serious*): “Some types are taken on a short-term, others on a long-term or forever, chronically.”

Q1-B Ms. Farah: “When someone says the word ‘medicine’ in your presence, what is the first thing that comes to mind?”

S5 (*Serious*): “A patient.”

S3 (*Laughing*): “Hospital.”

S6 (*Laughing sarcastic*): “Ouf!” (common Lebanese interjection implying frustration and discomfort)

Q2- A Ms. Farah: “Where do you get your information about medicine from?” Objective: Attitude/ perception

S7 (*Serious*): “Internet.”

S2 (*Serious*): “I read the paper inside the box. I look at the ingredients, side effects, everything.”

S5 (*Laughing*): “I read the paper, too.”

S8 (*Laughing sarcastic*): “I don’t read anything. I do it blindly sometimes”

Q2-B Ms. Farah: “Who is your trusted source/reference? Your doctor?”

S8 (*Agreeing nodding*): “The doctor, of course.”

Q2-B Ms. Farah: “So, who is your go-to person? Your primary and most important source?”

S1 (*Thinking +Serious*): “My main source is the medical doctor, of course, but if I want to know some specific information about medicine, I turn to my uncle and wife.”

Ms. Farah: “So, some of you mentioned the Internet, relatives, the doctor, the package insert; would anyone like to add anything else?”

S10 (*Thinking + serious*): “I read the insert and ask my doctor, both. Sometimes the doctor says things that contradict what the insert reads, especially when it comes to side effects. He comforts me, asking me not to worry and says that not everything mentioned on that piece of paper is true.”

S9 (*Thinking + Hesitant*): “We could ask the pharmacist, too.”

Ms. Farah: “Why do you think your doctor sometimes asks you not to read the package insert?”

S10 (*Thinking + serious*): “He says that in certain medical situations, I must take a specific type of medicine, and I should not worry about side effects. There’s no other way to go. So, I put my trust in the doctor, if that’s the only solution.”

Q3-Ms. Farah: “What do you know about trade and generic medicine?” Objective: Knowledge, perception

(*many are hesitant, shake their heads, and say they haven’t heard of the two terms above/never made the distinction*)

(*Serious + thinking S2*): “Trade maybe means that a lot of people can buy it, and a big portion of the community has access to it. Generic medicine might not have been marketed well, thus making it not as accessible as trade medicine.”

(*Serious*) S8: “Trade medicine is prescribed by just anyone.”

Q4-Ms. Farah: “What do you know about counterfeit medicine?” Objective: Knowledge, perception, beliefs

(*Serious*) S8: “Fake, deceiving.”

(*Serious + thinking*) S11: “Has some ingredients that are cheaper, and it is itself cheaper—that’s why people buy it. Also, the name is usually partly similar to the original. It is made somewhere it doesn’t cost much to employ people and the primary resources are less costly, too. It doesn’t contain all and the same ingredients as the original, though. It usually has the same effect, more or less, though.”

(*Nods*) S7: “Counterfeit medicine is not made in the country of origin.”

(*Serious*) S3: “Not licensed.”

(*Agrees*) S6: “Not licensed.”

(*Agrees, serious, nods, and adds*) S7: “Different composition, or one that’s very close to the original. We all know that there is more than one composition of the same medicine, which comes in different dosages. Counterfeit medicine could be useless or of little effectiveness, because it is made outside of the original country of production. The composition is close but the ingredients are different.”

(*Serious, frowning*) S4: “A company might imitate a certain medicine to sell more than competitors. They try to mimic a certain type medicine and sell it at low prices, to have a competitive edge.”

Q7-Ms. Farah: “I am going to use the same words you guys have used in your answers: ‘Original’ and ‘Counterfeit’ medicine—What do you think of counterfeit medicine?” Objective: Knowledge, perception

(*Serious, frowning*) S11: “It is undoubtedly a mafia making counterfeit medicine to make money.”

(*Serious*) S8: “Lack of morals and good conscious.”

S5: (*agrees with others and adds*): “It is for marketing purposes.”

(*Sarcastic, laughing but aware of the seriousness of what she’s saying*) S6: “A crime.”

Ms. Farah: “OK, but what is counterfeit medicine exactly?”

(*Thinking, serious*) S1: “I reckon counterfeit medicine is expired medicine whose expiry date has been changed.”

(*Agrees, and adds, serious*): S11: “Medicine being sold as if it were the original, but isn’t.”

S6: “Placebo.”

Ms. Farah: “So do you believe there’s a difference between **copy** and **fake**”¹

(*nods, responds fast and enthusiastically*) S1: “Of course there is! **fake** means a problem at the level of the company [unreliable] as well as [bad] ingredients.” (pause, thinking)

(*cuts S1 off, and starts talking confidently and seriously, but starts growing increasingly hesitant toward the middle of her intervention*) S7: “I consider that **fake** is using the same name of the original product, or applying minor changes to the names and keeping the ingredients the same. This is done in an effort to market a certain medicine to a specific targeted audience or region. They change the package and the name in an attempt to market it where it’s impossible to market the original for different reasons”.

Q6-Ms. Farah: “In case the goal is not to make money from it, what could be another motivation behind making counterfeit medicine?” Objective: Knowledge, perception, values

(*enthusiastic and serious. Very confident*) S7: “The original medicine might be very expensive or not available on the local market. I am speaking out of personal experience: I take rheumatism medicine, which is French. In Lebanon, there is a similar local product with a name similar to the original medicine from France. It is way less expensive. The original isn’t imported to this country. If I were to get it, I need to either travel to France or ask someone to buy it for me while there. My doctor was the one who prescribed it—he said they were both the same.”

S3 (*thinks then addresses her question to S7*): “Is it as effective as the original?”

S7 (*nods*): “Yes, my doctor said I can take the one or the other.”

Ms. Farah: “What do you know about medicine made in Lebanon?”

(*serious, frowning a little but not to express contempt*) S7: “**copy** because it has a similar name, the same effect and uses; they are both for the same disease. The country of origin and production is the only element that differs, and the dosages. It has the same purpose and side effects.”

“Ms. Farah: OK, so in your opinion, the case of the Lebanese medicine you just shared with us is one of **copy** medicine. Does everyone agree?”

(*shakes head, disagrees, frowning*) S3: “I don’t—if it’s **copy** it can’t be licensed.”

(*laughing*) S9: “We’re getting a little confused trying to figure out the different between **copy** and **fake**”

(*enthusiastic, serious*) S7: “**Fake** isn’t licensed; it can’t. They *change the expiry date and the ingredients*. They could use an Aspirin pill and say it’s for blood pressure for all I know.”

(*frowning, irritated, agitated*) S4: “There is something very confusing to us people in this country, though: there is medicine labelled “for Middle East only”—it’s only sold over

here. Are people here different than the ones abroad? We don't know what the exact answer to that is, but we constantly try to find out."

Ms. Farah: "When you try to find answers, what runs through your mind?"

(irritated) S4: "I'd say *they care about "their" people* more than about us. There might be some harmful ingredients, especially on the long run. They include it in the composition for people over here, though. *They don't really care about us.*"

(doesn't exactly disagree, but adds seriously) S7: "*Bodies over here might be different, though, and they might react differently to the same medicine than bodies in a different region. Maybe that's why there's "for Middle East only" medicine.*"

(S11, S2, S5 and S10 agree with S7, nodding).

(frowning, sad) S3: "Why can't good medicine from France come into this country if it's effective and doesn't have bad side effects?"

Ms. Farah: "Do you think the Lebanese society has a voice when it comes to deciding what is imported and what is not?"

EVERYONE (laughing, agitated): "No! Of course not."

(laughing, sarcastic) S4: "*We have a lot of other things on our place and barely have time to even think about this.*"

(many nods, agreeing)

(serious) S11: "And a lot of people lack the necessary knowledge and awareness to know what they're taking."

S3: "It's legal to take any medicine made abroad, though, because one's allowed to travel and bring some, but the medicine isn't allowed to enter/be imported."

(serious, a little irritated) S11: "To some, whatever their doctor says is sacred—they carry out his instructions/prescription religiously. A lot of people believe *that they don't have the authority to argue with their doctors, discuss the prescription, or suggest another medicine.*"

(everyone agrees)

Ms. Farah: "Do you personally go to see a doctor willingly and consciously?"

(serious) S11: "Absolutely. And I give myself the liberty to either take the prescription or not, in case I'm not convinced. I of course don't ask my pharmacist about any medicine whatsoever. *A pharmacist's job is basically to liaise with private companies and agree on which medicine to market. Doctors here do the same thing. We always come across female promoters at the doctor's clinic marketing certain products.*"

(some show physical signs and facial expressions that they agree with what is being said)

(serious, irritated) S3: "What is more, *one doesn't choose which medicine they are given at while at the hospital.*"

(agrees, nods) S11: "I agree 100%. You have no way of knowing what you're being administered."

Q4-Moderator: "So one has to take whatever's available"

(sarcastic, laughing) S3: “They give you whatever’s available.”

(everyone agrees and laughs)

(serious) S1: “I would just like to come back to the topic of the *distinction between fake and copy* for a second. medicine is when *there’s an intent to deceive* [operating in bad faith] on the part of the company or the party selling the medicine, when it comes to changing the expiry date, the ingredients, etc. It is not the same case for There’s no intent to cheat/deceive, necessarily. can be a milestone reached by a local company that has grown and is now able to produce a similar produce of the same calibre. The name is changed and the packaging, too, but that’s done overtly. *It is clear to consumers that one is not the other, but the desired effects are the same.*”

(serious): “When we talk about counterfeit medicine, we are basically referring to imitating an “idea”. I don’t know that there’s medical/pharmaceutical inventions in Lebanon anyway. I don’t know what’s the reason behind this lack of invention, but it’s the way it is. This is what it is to me: lifting a medicine’s idea.”

Ms. Farah: “So, in your opinion, what can we say about/how can we classify/describe medicine made in Lebanon?”

(thinks, serious) S11: “If it’s the product of a study or an invention, it is just normal medicine, no different than the one abroad. But if it’s someone else’s “idea/invention” it’s We aren’t the ones who invented it.”

(thoughtful, confident, and serious) S1: “If a local producer doesn’t have the green light/approval of the original company to make the a certain medicine locally under the supervision of that company, then it’s The approval and seal of the original company means it’s medicine produced by a branch/franchise of the original company, similar to any other industry.”

Ms. Farah: “So just to repeat what you’ve just said: If the local company has the approval of the mother company, the medicine produced can be considered the exact equivalent of the original. Otherwise, the medicine wouldn’t be the same?”

S1: “If the package and the seal are fake, that’s If the local company has its own name and is producing good-quality medicine based on someone else’s idea, as S11 said, that’s They take the idea and make their own medicine under a different name/company.”

S11 (thinks and asks S1): “What does the original company get when another mimics its products?”

S1 (shakes head and responds seriously): “No, I was just referring to a branch of the original company here in Lebanon where medicine is made, just like any other products manufactured in franchises of the main company in different locations.”

(S11 agrees with S1’s explanation)

S2: “But that’s not **copy** in this case—It’s the original.”

Ms. Farah: “So, if it doesn’t have the approval of the original company, it’s **copy**, does everyone agree?”

(shakes her head and says) S3: “If any ingredient or component of the new product has been changed, then we cannot call it **Fake**.”

(adds seriously after having given it some thought) S8: “This makes the medicine **fake**.”

S3 (*disagrees, agitated*): “No, it’s not fake. The person/company made their own product; it’s theirs now. A case in point is Panadol. Many companies have made Panadol. My pharmacist friend told me that for some time medicine treating influenza, supposedly, was being sold, but it was just Panadol”. So should we consider this **fake**?”

S11: “It’s neither.”

S3 (*to S11, and everyone*): “Exactly! The same original company made the two. Why do we always have to consider something made by a Lebanese person counterfeit? If a Company A has made a certain medicine and Company B makes a similar one, but changes some of the ingredients, the new product wouldn’t be **copy**.”

Ms. Farah: “So if I understand what you’re saying correctly, you’re stating that the original has put out more than one type of medicine on the market?”

S3: “The original company made more than one type. If a local company takes a kind of medicine and changes something in it, that means they have created something new. So it’s not counterfeit.”

S11: “Correct. Medicine taken by a local company from the original and changed is not **fake**.”

(*disagrees, shakes head, irritated*) S8: “I disagree, of course it’s **copy**”

S3: “Well, that would make all medicine on the market , **copy**then, if you come to think of it.”

(*thinks, disagrees*) S8: “If a certain medicine doesn’t come from the initial country of production, with the same criteria and with an official approval/license to be sold, it is for sure either **copy** or **fake**.”

S3 (*to S8*): “Why?”

S8 (*irritated*): “If approval hasn’t been granted by the mother company, I don’t have the legal right to sell the new product.”

S3 (*to S8*): “You don’t have the right to sell the *same* product, but it’s legal to sell one you’ve altered/added to. Otherwise, the Lebanese government won’t approve their work.”

S10: “I’d like to share a personal experience with you. My doctor once said I should go to a specific hospital to take a specific medicine. When I told him that the other hospital has the same medicine, he disagreed, *saying it’s counterfeit at the other hospital*. According to him, the latter administers medicine that has a lot of side effects.”

Ms. Farah: “The doctor knew which hospitals administer these medicines?”

(*the majority laughs*)

(*serious, frowning*) S5: “I have a similar story to share. My daughter has allergies, so she needed to take “Claritine” all winter. I once walked into a pharmacy to buy it. It cost LBP 18,000, which confused me because I normally buy it for LBP 13,000. When I asked the pharmacist, he told me the cheaper one is counterfeit. He asked me for the name of the pharmacy where I had been getting the cheaper “Claritine”, but I didn’t give it to him; I didn’t want to hurt anyone.”

Ms. Farah: “And was the cheaper one your daughter was taking effective?”²

S5: “Absolutely—but back then I had no idea that it wasn’t the original.”

S11: “But the cheaper one is counterfeit only as per the opinion of the pharmacist selling the “Claritine” for a higher price. *There’s nothing to verify his claim, though.*”

(laughing, sarcastic) S8: “So is the pharmacist selling more expensive medicine the deceitful/sly one now?”

(the majority laughs)

Q5-Moderator: “How does one differentiate between original and counterfeit medicine?”

Objective: Knowledge, attitude

(hesitant. She doesn’t know what the item is exactly) S10: “There’s a certain logo, an emblem, a hologram maybe indicating that the product is the original one. *That was in the news. Something aluminium-like*”

S8 *(confused)*: “I’m not sure how to tell the difference, honestly.”

Moderator: “What is that thing indicating that the medicine is the original one?”

(laughing, sarcastic) S11: “We know what it is, but we don’t know its name.”

(People laugh and agree)

S7 *(agrees with S10 and S3)*: “There are specific logos: MERSACO SAL has one. There are also private companies that import medicine and package them underground in their own boxes/packages. They have a license to do that. There are those who have private jets, who get medicine whose source is unknown to us all. There’s the “Rahbani” in Jbeil (Byblos) who sell medicine no one else has—those also have their private jets. They aren’t held accountable. The hologram and packages can be very deceiving. Sometimes those are very close to the originals, but are counterfeit.”

Moderator (to S7): “Have you personally heard of any specific cases where supposedly original holograms are present on counterfeit medicine?”

S7 *(unsure at first, thinks and says)*: “I have only heard of such happenings; I haven’t experienced such a happening—forging of stickers, that is.”

Moderator: “Do you mean the sticker or the hologram?”

S7: “The Sticker.”

(serious) S10: “*I personally trust my pharmacist. I always buy my medicine from his pharmacy, and I don’t believe he ever deceives me.*”

S8 *(jokingly)*: “Two indicators can help one know whether medicine is good or bad: we either don’t get better at all, or suffer from side effects: getting poisoned or even dying.”

Q13-Moderator: “So, you’re saying the way to go about distinguishing between original and counterfeit is take the medicine and wait for the effect?” Objective: Attitude, knowledge

S8 *(laughing, jokingly)*: “Yes, naturally.”

S5 (*laughing, sarcastic*): “You can’t really know.”

(*everyone laughs*)

S4: “I want to talk about something that happened with people I know. A lady had cancer. She underwent treatment first time and saw results. The second time she got treatment was at a different hospital (a very reputable one in Beirut). Her health deteriorated. After investigation, it turned out she had been given water shots instead of proper medicine, although she was paying a lot of money to get the “treatment”. Her family filed a lawsuit, but couldn’t hold the doctor accountable as he had connections within the syndicate. This is a true story, and the woman passed away.”

(*everyone is shocked and show signs of surprise and agitation, such as gasps and opened eyes*)

Q13-Moderator: “Do you know this woman personally? And over the span of 10 months, did she not undergo any kind of tests?”

S3: “Yes, I do know her. She was told she wasn’t getting any better. *For 10 months, she was being injected with shots of water.* It is only when she came back and spoke with her first doctor that she and her family discovered what had been happening—and the hospital she was getting treatment at is very well-known, mind you. But it was too late.”

(*sighs of dissatisfaction and disapproval from some of the participants*)

Q5-Moderator: “Just to come back to the earlier question: how can we differentiate between original and counterfeit medicine? Would anyone like to add anything else?”

(*thinking, frowning*) S4: “It has become very hard to distinguish nowadays—all that is medical is controlled by mafias and even doctors are implicating themselves in deceitful practices.”

(*serious*) S1: “It’s very difficult. *The trust someone has in their pharmacist plays a pivotal role, too.*”

(*sarcastic*) S5: “Is this a test or something?”

(*some participants react, laughing*)

S6: “*They [pharmacists] negotiate with private companies and agree to sell their medicine in return of profit margin. That being said, one can’t just blindly trust the pharmacist.*”

S4: “You can sometimes tell from the mediocre quality of the package that the medicine is counterfeit, but this method doesn’t always work.”

Q5-Moderator: “So what do you think is a reliable way to tell the difference, and are we talking about or we need to agree on the terminology here.”

(*responds fast, enthusiastic*) S7: “fake”

S4: “You can usually tell from the package that medicine is “fake”

S11: “It is often out in the open that a certain type of medicine is Copy and those are sold to patients, who know what kind of medicine they’re taking is not the same as the original. For example, there is a lot of counterfeit medicine at dispensaries.”

Moderator: “Does staff there inform you that medicine is **copy**

S7: “They use the terminology to describe medicine from the same family as another type of medicine, with the same uses and effects. The composition is the same, but the name is different.”

(S11 and others agree)

Moderator: “Do they use the word? That’s what I’d like to know.”

S7: “Yes, they do.”

(disagrees) S11: “No, they also say that the two are ‘alike’ or ‘very close in composition’.”

(disagrees with S11) S1: “There are people who do use Copy freely.”

S7 *(disagrees)*: “We cannot really generalize, though.”

Moderator: “So are you told ‘this medicine is the same as the other, only cheaper’ or do you actually hear the word used?”

S5 *(hesitant)*: “Maybe”

(serious) S11: “Yes, I do all the time. I’m told ‘here, this is medicine, and it’s less expensive’. There are also people who ask pharmacist and dispensary staff for less expensive medicine, for financial reasons.”

Moderator: “Is this term used outside dispensaries? Do doctors encourage the use of medicine?”

(serious) S1: “Medical doctors use it, too, yes. They comfort us and give us permission to use medicine and comparing it to the original, saying the two are very similar—only one is local, the other is not. My wife uses a Copy medicine.”

(serious) S7: “I’d like to add something: my father works for the Lebanese Security Forces, who provide his medicine, too. When he has a prescription, he goes there to get his medicine. The ones available are given to him; and he is given “similar” meds for the ones that are unavailable. Even when my dad shows what he has been given to his doctor, the doctor almost always gives him permission to take those meds.”

S11: “Exactly. This happens in dispensaries, too.”

S4 *(serious)*: “Big organizations, like the military, give out and promote the use of Copy medicine *The name is the same, but the patient is informed that the medicine is Copy medicine. It is very common. But this affects the degree of our trust: should we trust or not?*”

Q2-Moderator: “So trust for you is...”

S11 *(sarcastic)*: “*We take medicine and pray to God we wouldn’t die.*”

(participants laugh).

Q6-Mrs. Lydia: “Why is there counterfeit medicine? What is the reason behind it? Is it only in Lebanon that those are sold?”

(the sweeping majority says “no”)

S8: “For trade and business purposes.”

S3 and S4: “For profitable business and trade purposes.”

S5: “Fast profit.”

S1: “No good conscience.”

S4: “Competition among companies.”

Q8-Moderator: “Then why do people buy counterfeit medicine?” Objective: Values, attitude

(the answers here were back-to-back and succinct. No emotional or non-verbal signs to note)

S11: “They don’t know it’s counterfeit.”

S8: “They either don’t know about the existence of counterfeit medicine, *or they do but neglect it, since counterfeit medicine is usually cheaper.*”

S10: “*There is a market because people can’t afford the real thing... Yes, it’s cheaper for the people who can’t afford.*”

S5: “Financial reasons have a role, too. The price of original medicine determines the decision to buy counterfeit medicine.”

S1 *(serious, confident about the statement)*: “*There’s a big chunk of our society that doesn’t have the necessary culture when it comes to health. They aren’t really concerned about taking good or bad medicine. They think on the short-term: getting rid of a headache, for example. A lot of people also tend to vilify medical doctors and pharmacists, assuming that those are just here to rip them off. Those thoughts still persist. Some wait till they are unable to move to go see a doctor.*”

S11: “Or the contrary—There are people who prefer asking a pharmacist over seeing a doctor.”

S7: “As to not pay the doctor.”

S5: “The financial capability of someone informs this decision, too.”

S11: “Some people don’t like doctors. I don’t really know why.”

S6: “They’re scared of being ripped off/manipulated by doctors.”

S11: “*Pharmacists are better than doctors when it comes to establishing rapport with people and forging personal connections. Once you put your trust in him/her, they make you feel like you don’t need a doctor. I don’t want to generalize, though. There are very skilled pharmacists who make their own medicine and buy it—usually those are very effective.*”

Moderator: “Does the pharmacist have the right to make their own medicine?”

(some participants click their tongues—a way to say no)

S11 *(thinks, hesitant)*: “I don’t know about the right, but it does happen, and usually what they sell is effective.”

S7 *(disagrees)*: “They don’t make their own medicine; they make meds based on the doctor’s prescription.”

S11 (*disagrees*): “No, no, they do make their own medicine and sell it.”

(*the majority agrees with S11*)

Q6-Moderator: “What are other counterfeit products you know of?”

S6 (*laughing*): “Everything.”

S10 (*sarcastic*): “Everything is counterfeit except for us.”

(*everyone laughs*)

S5: “Food products.”

Q3-Moderator: “Let’s try to tie this in with medicine. What is the difference between medicine made in France and local medicine?”

S11 (*serious*): “Just the name, but the composition is the same.”

Moderator: “I know we have already spoken about that, but I would like to ask this question again: what might the consequences of taking counterfeit medicine be?”

S8 (*serious*): “One is either poisoned or do not benefit at all.”

(*the majority agrees*)

S3: “One feels better, partly, but suffers from unexpected side effects.”

S5 (*serious*): “That’s exactly what happened to me. I took 6 pills, I gained a lot of weight. I still haven’t been able to lose all the weight. Following an interview via phone, it turned out that the medicine I took was still being tested. I was supposed to take the medicine over 3 months, but took it for 1.5 months and stopped. I gained 17 kilograms. I did benefit, though, but that wasn’t without side effects.”

(*everyone shows signs of shock and surprise and compassion*)

Q13-Moderator: “What did you do when you knew, though?”

S5: “The doctor asked me to stop taking it, and I did.”

Moderator: “And nothing else happened?”

S7 (*serious, frowning*): “We can’t really argue with or sue the doctor in this country.”

S11 (*asks S5*): “Who informed you about the medicine being in trial period? The doctor?”

S5 (*responds, frowning, to S11 and the group*): “They (doctor’s office) spoke with me on the phone and told me.”

S7 (*laughs*): “In Lebanon, one can only be thankful for staying alive after such a happening.”

S5: “Filing a lawsuit doesn’t really lead anywhere in this country, as I’ve said. And some people might not be financially capable of going through litigation.”

(*participants agree with S5 regarding the inability to file a lawsuit for financial reasons.*)

S7 (*serious*): “I know someone whose health deteriorated in one of the hospitals in Beirut. The hospital wasn’t clean/sanitary at all. The person’s family tried to get hold of a doctor for over a month and a half to talk to him about a potential surgery. They couldn’t meet

him, for a month and a half. When the family threatened to take it to court, they were not taken seriously by the hospital. They were ridiculed and told, ‘you can try’”

(people gasp and shake heads, disapprovingly)

S4: “My husband had a health problem which affected his eye and lip. His doctor, mind you a prominent one in Lebanon, suggested a first-of-its-kind surgery be done for the first time and that my husband be the first person it’s tested on. We refused, of course.”

(some participants shake heads, disapproving of the doctor’s behaviour)

S11: “Are we mice?”

S7: “You should have asked him to get you another man should the operation fail.”

(everyone laughs)

S3: “The cancer medicine they were testing is still not certified/licensed in Lebanon. The person who invented it went on TV and said he didn’t have the money to develop it. People do go to him and ask for the medicine, though. You know, when someone is dying, they hold on to any thread of hope. This doctor has not been able to register this medicine, and it’s been years.”

S7: “*That guy knows what he’s doing, though. He only accepts to give the medicine to people whose cancer is terminal, so in case something happens to them, he wouldn’t be accused of being the one who ended their lives. I’ve heard some people have seen results.*”

S3: “*It is not to the benefit of big companies to sell medicine that heals/treats fast; how would they keep selling?*”

S4: “Let alone the ones who let out a virus into the community.”

Moderator: “What do you mean?”

(the majority is confused)

S11: “What do you mean by that?”

S4 *(serious, she seems confident about her opinion)*: “They create a virus so that people start buying a specific type of medicine or using a certain medical service.”

Q11-Moderator: “What role do pharmaceutical companies play in the presence and dissemination of counterfeit medicine?” Objective: Attitude, perception

S3: “They have a huge role.”

S4: “They have a major role.”

S3 *(serious)*: “Should they enforce quality control and supervision on their medicine—and regardless of the fact that they might still be concerned about monetary gain—they would protect the consumers.”

S5: “They should be held accountable and supervised.”

S7: “*I’d say pharmaceutical companies have done their job; they can’t do anything else.*”

Moderator: “Are pharmaceutical companies making counterfeit medicine?”

S4, S9, S10: “No. Other companies.”

S4: “People from within pharmaceutical companies are leaking information pertaining to ingredients and compositions.”

S1 (*serious*): “Since we spoke about ethics and good conscience earlier, I believe it’s not out of question that pharmaceutical companies themselves are counterfeiting medicine to get rid of their stock. Parties that engage in counterfeiting are profit-oriented people who don’t give much thought to the good health and wellbeing of the community, but care about realizing profits and dodging losses.”

S7 (*hesitant, confused*): “So are you saying that some companies go around collecting expired meds from pharmacies for the sole purpose of changing their expiry date and putting them out on the market again?”

S1: “Exactly.”

S5: “Yes, they change the packaging and the expiry date.”

(*the majority agrees*)

S1: “And let’s be true to ourselves and acknowledge that there are countries where there’s supervision and culture and countries where there’s none of that.”

Q6-Moderator: “What characterizes this country?”

S4: “There’s nothing to mention in this country.”

S10: “No supervision, no rules.”

(*everyone laughs, sarcastically*)

Q11-14-Moderator: “Would you say there’s supervision and regulation in Lebanon?”

S1 (*seriously*): “Recently, in the pharmaceutical field, there have been important achievements indicating that serious work and efforts are being invested. Quality and price regulations and crackdowns have been taking place, which is great. Some big pharmacies have gone through litigation. Regardless of the political and economic backdrop to this, we should have hope and wish for more work to be made in this regard.”

S4: “I don’t know if others here do the same, but it is very common for people in this country to ask friends flying into the country to get them medicine from overseas—Canada and the U.S., such as Advil.”

(*S11 points out that it’s not just Advil, but an array of meds*)

S4 (*seriously and confidently*): “Advil is available in pharmacies in Lebanon, and it’s made in the US. However, it is not as good as the one you buy there, probably because it’s too old or even expired. All expired and bad medicine is brought to Lebanon. There is no control nor regulation, if you ask me. I’m sorry to say this, but it holds true: this country is run by thieves.”

S11: “This takes us back to the ‘Only for the Middle East’ meds.”

S4: “The ones you buy abroad and bring here are more “fresh” and effective than what we buy over here. (*sad, irritated*) *It saddens me to say that this country is protected by thieves.*”

S3 (*addressing Moderator*): “You did hear about this crackdown when medicine was confiscated, right?”

Moderator: “Could you tell us more about what happened?”

S3: “The story and evidence were buried, because (*hesitates*)...”

S7 (*interrupts S3 and says enthusiastically*): “because the minister’s brother was involved.”

Moderator: “And how was the minister’s brother affected?”

S7 (*sarcastically*): “He’s vacationing now because you know, the incident has shaken him.”

Q9-Moderator: “Besides pharmaceutical companies making counterfeit medicine, according to you; what could be another source for counterfeit medicine?” Objective: Knowledge, attitude

S3 (*confident*): “Big companies play a role in this, for sure.”

S7 (*confident, sounds well-*): “I just want to go back to the topic of third parties (brokers or “middlemen”) who buy damaged or expired stock from pharmacies and big companies (who sometimes willingly seek out those brokers). Those middlemen sell medicine to underdeveloped and developing countries. They of course buy medicine for very low prices and sell it at the original price, thus making a lot of money.”

S4: “*This kind of medicine is only sent to and sold in the Middle East. You won’t find it in Canada, for example.*”

(*S7 agrees with S4 by nodding*)

S7: “This kind of medicine falls into the category of counterfeit medicine, which is indistinguishable from the original. Now it is the responsibility of the Lebanese Ministry of Health and the Syndicate of Pharmacists in Lebanon to send medicine to laboratories test it and make sure it is the original product and is not harmful. (*hesitating, not sure about this piece of information*) I don’t know to what extent this takes place in Lebanon, though. It might or might not be happening, but based on the system in Lebanon and from what I know, I don’t think that happens. There are big companies overseas who do business with local distributors, who benefit by taking a percentage of the profit for each transaction.”

S3 (*frowning, looks dissatisfied*): “I don’t think testing and regulation take place. Otherwise, how would you explain medicine being discontinued in Lebanon ten years after being introduced, following claims of fatal side effects?”

Q10-Moderator: “Does anyone have anything to add regarding parties responsible for making counterfeit medicine, other than pharmaceutical companies?” Objective: Attitude, perception

S3 (*confident, agitated*): “I do.... Mafias.”

S11: “Other companies, not necessarily pharmaceutical—just other companies.”

S5: “One person working for a pharmaceutical company might defect and start a company on his own, selling counterfeit medicine.”

(*S3 disagrees vehemently, saying it’s impossible for something to do this by themselves, unassisted by anyone else.*)

S3: “He can’t do it solo. This kind of operation requires a lot of money and organization. He always needs to be backed up by someone powerful.”

S5 (*shows signs that she agrees with S3, partly*): “Yes, he needs someone to help him if he plans on operating in bad faith and deceiving his company.”

Moderator: “Ok, but I just want to clarify something: we should make the distinction between a well-known pharmaceutical company and “another” company. What are we referring to here in our discussion of someone defecting?”

S7: “Another company.”

S11: “It could be a pharmaceutical company or another company. Both scenarios are possible.”

S5: “There are plenty of illegal products entering the country which no one pays attention to.”

S7: “I know people, and I can give you their names, who have private jets—they import goods all the time.”

Moderator: “So are you saying there are two ways medicine is entering the country, via the Lebanese Ministry of Health or privately?—But is it possible that counterfeit medicine is entering the country via the Ministry itself?”

S3 (*confident*): “Yes, of course”

(*a few others agree too*)

S10, S11: “Via the Lebanese Customs too.”

S4: “There are illegal ports via which loads of merchandise enter the country.”

S7: “Let alone the private jets owned by families and people of power.”

S11: “It could also have entered in cooperation with a party that has enough power and control to allow counterfeit medicine to enter the country, no questions asked.”

Q9-Moderator: “Hypothetically, counterfeit meds have arrived in the country and they are now in warehouses. How are they moving from location X to their final destination, the pharmacy that is?”

S11: “The groups we referred to as a “company”, a “mafia” perhaps, are the distributors supplying pharmaceutical companies.”

S3: “The way for such distribution and marketing efforts could have been paved by getting a license to disseminate and market medicine, by the Ministry of Health. People can apply for a license.”

Moderator: “So those parties do get licensed?”

S3: “It is a possibility, yes. Especially when you have someone to back you from within; someone who has power to give grant you the license.”

Q9-10-Moderator: “So if I understand correctly, you’re saying that counterfeit medicine is entering the country based on an agreement with the government and the Ministry of Health? So the government is facilitating those operations?”

S3 (*agrees, confident*): “Absolutely.”

S8: “The government makes money off of this anyway through bribes.”

S4: “*Pharmacists seek out meds at lower prices, to maximize profits.*”

S11: “Actually, getting through to the pharmacist is the simplest stage of all, in my opinion, after passing through all of the other stages.”

Q14-Moderator: “What’s the role of the pharmacist in this chain of operation?” Objective: Attitude, perception

S11: “He sells and makes profits.”

S3: “Pharmacists are unlikely to refuse buying counterfeit medicine which have been approved and licensed by the government. Pharmacists are interested in cheap medicine whose market value is high and people want.”

S11: “Yes, it means he’s ‘covered’, protected.”

Q14-Moderator: “In your opinion, can a pharmacist know when medicine is counterfeit?”

S5: “Of course they can.”

S3: “Not always.”

S7: “No, not always.”

S11: “*He needs to know. It’s his job.*”

Q14-Moderator: “So in your opinion, a pharmacist should be able to know when a certain is counterfeit?”

S1: (*serious, sure of what’s he’s saying*) “I doubt it’s possible for the pharmacist to know if a certain medicine is the original or the counterfeit, if it’s already expired or not.”

Moderator: “Why is it not possible?”

S1: “He has no way of knowing, as the expiry date has been altered on the package itself.”

S11: “The package and what’s noted on it can be deceiving.”

Moderator: “So checking the expiry date, sticker, and hologram the only ways to know if medicine is counterfeit? What should one watch out for while examining the medicine?”

S11: “Maybe the notice?” (*doesn’t sound sure; she’s a little hesitant*).

S1: “Some seasoned pharmacists might have, based on their experience, other ways of testing the quality of medicine. This brings us back to our discussion about trusting the pharmacist. They can generally tell whether medicine is counterfeit or not, but it doesn’t mean pharmacists can’t be deceived. You can’t find an actual piece of paper with a “permission to import counterfeit medicine” stamp on it, but those are deals that happen under the table. The minister or the supervisor usually know what is going on, but they turn a blind eye because they are bribed.”

(*S10 comments as an aside: “but it’s a problem if pharmacists are easily deceived”*)

S3: “A pharmacist I really trust advises me on what to buy, especially when it comes to creams. He tells me what is effective and what is not. When I asked him about why he still sells some products he says are inefficient (or not as efficient as others), he pointed out that some people trust the name of big, popular companies and like to buy their products,

regardless of their effectiveness (*other participants show signs that they agree, by nodding*). Should he stop selling those products, he would lose customers, according to him.”

S4: “I just want to come back to the distinction between the two terms. Fake is medicine we take without any prior knowledge of it not being the original, but we choose to buy/take copy medicine because it’s cheaper.”

Q13-Moderator: “If one day, God forbid, you discover you had bought counterfeit medicine, what’s the first thing you would do?” Objective: Attitude, knowledge

S7 (*sarcastically, joking, saying it lightly*): “If we took CFM, we thank God we didn’t die or go to the hospital. *We will also stop going to that at that pharmacy where we bought counterfeit medicine.*”

(*the majority laugh*)

S9: “I would talk to my doctor about it.”

S7 (*disagreeing with S9*): “But the doctor has nothing to do with it.”

Q12-Moderator: “So are you guys saying that it’s difficult to tell when medicine is *really* counterfeit?” Objective: Knowledge, attitude

S1: “The situation in Lebanon is a little unique, so to say. Not only do we not have the proper mentality, but we also aren’t in the habit of reporting abuse or incidents of being deceived by pharmaceutical companies and their products.

S: “We basically have no one to turn to. If I turn to the authorities to complain, I will most likely be given a pat on the back and asked to be thankful that I’m still alive (*said sarcastically*). My uncle lost his ability to hear following a mistake made by a doctor. The latter thought we should be thankful that my uncle made it out alive.”

(*Participants show signs of dissatisfaction/irritation upon hearing this story*)

S8: “People’s lives are taken lightly.”

S7: “There’s no point of reference or particular authority to file complaints to.”

Q14-Moderator: “What do you think should be done to this effect?”

S1 (*thoughtful*): “*There should be clear laws—which many of them are present—but lack an organized mechanism to be applied. If I really trust my pharmacist and truly care about the wellbeing of the community, I would go back to the pharmacy and tell the people there about my experience, as to avoid similar ones in the future affecting my fellow citizens.*”

S7 (*thoughtful*): “We should vitalize the Department of Consumer Production and undo all political ties this might have to any political party. Politics and health should be separated. Complaints by dissatisfied consumers need to be taken more seriously and an investigation should be carried out to hold the guilty ones accountable and track down the source of counterfeit medicine.”

S3: “I would also argue that *I shouldn’t be the one discovering* that I have fallen victim to counterfeit medicine. Just like in any other countries, someone else’s full-time job (*MoPH*) to inspect and continually investigate corruption without succumbing to pressures or bribes. *Pharmacists would then think twice before buying counterfeit products.*”

S7: “I believe there should be a limited number of companies licensed by the government and allowed to import medicine. In case of violations, those *companies would be questioned*. Customers would also feel safer and more at ease knowing that there is someone protecting them.”

Moderator: “So, do you find it acceptable for a pharmacist not to know how to spot counterfeit medicine?”

S7: “To accept this and to accept the fact that it’s a pervasive reality are two different things. A pharmacist is not supposed to check for counterfeit medicine after having received a shipment of products from a supposedly respectable, trustworthy pharmaceutical company. The latter need to have its own laboratory, acting as a gate keeper for medicine before it’s distributed. Should a pharmacist be aware, to breaches and not report them, s/he will need to face the consequences. However, he should not be held accountable if s/he buys their products from a company they trust.”

S10 (*disagrees and says abruptly*): “I actually disagree; I think the pharmacist is not and should not be a businessman.”

(*some participants agree with S10*)

Q14-Mrs Farah: “So taking into consideration the situation in Lebanon—as described by you—what should a pharmacist do to make sure the medicine at their pharmacy is not counterfeit and to help consumers?”

(*The first 4 interjections below were said quickly and back-to-back. No emotional/non-verbal signs could be documented*).

S11: “They should know and be able to trust the source providing them with medicine.”

S1: “Inform the authorities.”

S7: “Not buy it.”

S3: “Know the source well; they should only buy from one of the world-renowned companies; those are licensed.”

S7 (*disagrees with S3*): “The local pharmacist doesn’t buy medicine directly from those companies, but rather through local distributors, such as MERSACO, “Fattal” and “Abou Adal.”

S3 (*agrees with S7*): “I agree with what you’re saying. The Lebanese Ministry of Health should hold local pharmaceutical companies accountable and be in the know regarding their sources.”

S4 (*furrowed eyebrows, signs of dissatisfaction and irritation*): “I just want to say that *our lack of trust in them [companies, government, pharmacies] has been brought forth by no one but themselves and their lack of professionalism and good testing and monitoring*: it is impossible that they test all products before release on the market. They should test samples and declare that all products under a certain brand are safe.”

Q9-Moderator: “Where does one go to get counterfeit medicine?”

S11: “I don’t know that people purposely seek out this kind of medicine.”

Moderator: “Do you think it’s possible to find **Fake** medicine that’s an exact copy of the original, with same composition?”

S3: “Yes, it’s possible.”

S11 (*looks and sounds really confused, asks hesitantly*): “If it’s exactly the same, why are you saying it’s **Fake**, then?”

S4 (*confident*): “To me, if it is not approved/legal, it’s **.Fake**

S7: “Expired medicine that’s not disposed of but instead is sold and distributed again on the market is **Fake**”

S11: “If it hasn’t expired, it’s **Copy**.”

S1: “If I mimic the same exact label and shape of this water bottle I am now holding, that’ll be **Fake** for instance.”

(*S7 and S10 agree*)

Moderator: “Does everyone agree with that?”

(*the majority show signs that they agree*)

-----End of focus group-----

Appendix 7.VIII. Pharmacist focus group transcripts

A. Transcript: Pharmacist Focus Group: AUB-FG1-060714

Moderator: “How do pharmacists in Lebanon define counterfeit medicine?”

S4 (*a little hesitant*): “Any medicine that’s not coming from the company itself. Anyone can sell it to you. It doesn’t have any effect on the patient maybe, so it’s something illegal you are dealing with. It may cause harm to people, including the pharmacist.”

S7 (*more sure/confident than S4*): “A counterfeit product is a medication coming from a source that’s not trustworthy; it’s a product we cannot define what is in it, so usually it doesn’t contain an active ingredient or an active ingredient different from the original product, or a toxic substance or an inert substance. So, it is a medication harmful to the patient.”

S6 (*agrees with S7; serious, sure*): “I agree with what S7 said. It is a product whose origin we don’t know; we don’t know how they made it. It could have been made under inappropriate conditions probably. On the other hand, business-wise, I think it’s an important product in terms of profit. It is something many people can profit from. So some pharmacists may look at this from a profit perspective and may want to have their hands on such products because let’s face it, they at the end of the day may provide some profit for the people who are dealing with it. It may be a form of profit for the pharmacists dealing with it.”

S5 (*confident, sure*): “It is a product illegally imported to the country. Also, it may cause harm as they previously mentioned and it may not cause harm so the composition may be the same active ingredient but with a higher or lower dose, so if it doesn’t cause harm it may be an ineffective medication.”

S3: “For me, counterfeit medicine is a product that doesn’t fit the requirements of the original product. So, if a medicine is made for the good health or to arrive to specific target it doesn’t do that for sure. It might harm, it must do good so we don’t know what’s inside and since in this country no one does this analysis to say yes it is good or bad, so we stick to the agent. But as S6 said, it might have wide market in our country since no one sees what is happening under the table in our country.”

S2 (*sure, confident*): “Any product that doesn’t go through the legal procedure to reach the patient. It is a product not coming from the agent himself. It could be an original product but not coming through legal procedure. It could be harmful or placebo-like product.”

S1: “I agree with what everyone said. It could be harmful or just a placebo with a higher profit margin. That’s it.”

Moderator: “In your opinion, what is the extent of counterfeit medicine in Lebanon? What is the percentage of medicine that is counterfeit in Lebanon?”

S1 (*sure, sounds like she had experience with this*): “I think it depends on the area.”

Moderator: “Do you want to divide the areas? We have Mount Lebanon, Beirut, the South, the North.”

S1 (*very hesitant*): “I’m not sure, but I think in the North and the South there are more counterfeit medicine.”

S3 (*sure*): “There is less control.”

Moderator: “So if you are to give an estimate of how much of their products is counterfeit. Would you say it is higher there than it is in Mount Lebanon?”

S1 (*unsure, partly informed*): “From what I know, there are a lot of counter there but I don’t know the percentage.”

S2 (*confident, sure*): “I have asked multiple pharmacists, from Mount Lebanon, and they all agreed that the more you go to the periphery, the higher the percentage of counterfeit drugs, but they don’t know the exact percentage because you need to have a very close relationship with the pharmacist who is dealing with counterfeit drugs to be able to know the percentage, otherwise it’s impossible. I have asked multiple pharmacists, they all agreed that they have been visited 10 or 15 years ago by people selling counterfeit medicine and they have had to refuse more than once.”

S3 (*sure, sounds like she speaks out of experience*): “Because they know who their target is. They know who will work with them. Of course it is not in Beirut.”

Moderator: “So Beirut pharmacies do not have counterfeit medicine and they don’t deal with counterfeit medicine?”

S3 (*unsure, not confident*): “I do not know. They might. But our pharmacy for example is 8 years old and rarely do we encounter someone who comes in and offer us such products.”

Moderator: “What do they say when they come and offer you counterfeit medicine?”

S3 (*sure, confident, has experience*): “They say it is a parallel market. They would never say it is a fake product. No way. And the people who sell them would never say it’s a fake product. Even if you go there as a pharmacist they would never say but I’m sure everyone knows”

Moderator: “How would you know the difference between the counterfeit medicine market and the parallel market?”

S3 (*still sure*): “I wouldn’t know but I think you buy counterfeit products without receipts, but the parallel markets are more serious. You buy everything and you have the agent sticker on the medicine and all. They have more offers, though. There are legal parallel markets. They are like a different drugstore.”

S2 (*sure, confident, out of experience*): “I have something to add. Pharmacist are afraid that wholesalers might be dealing with counterfeit drugs., So if the wholesaler is doing that you would be seeing counterfeit all over Lebanon. I’ve heard from pharmacists that they can’t recognize the difference between original products and counterfeit. However, when they buy directly from the agent it’s different. When they need something from the wholesalers is when they cannot be sure anymore.”

S4 (*sure*): “Actually, as you said, I believe that closer to the peripheries, we have plenty of counterfeit medicine because there’s no control there.”

Moderator: “So what you guys are saying, is it based on something you are guessing or something you know for a fact?”

S3 (*sure*): “It is something we have encountered in a way.”

Moderator: “Do you know of cases?”

S3 (*sure*): “Yes, boxes they want to register for the NSSF, which you suddenly look at and you realize ‘No, I cannot do this because this is not the legal one’.”

S1: “Those are usually at much lower prices.”

S3 (very confident, has experience): “Sometimes the level of understanding of people is different. Sometimes if you tell people that a product is counterfeit or bad, they wouldn’t take it well and not believe you. They would ignore. They would say this person is giving the medicine for 20% less than the original price. They don’t see the difference and the harm the cheaper medicine might cause. Some might not have any good effect, but they might harm.”

Moderator: “Has this ever happened? What did you tell the people and what happened?”

S3 (sure, frowning): “I had an old patient of mine once who came into the pharmacy and said I know you didn’t do this favour many times. I didn’t buy this box I need a signature for NSSF. He had already taken the medicine. The box and the colour are very different. I got one and compared. He said that it was a medicine that cost more than 100.000 people from the company when they visit him and instead of bringing cake or perfume, they brought him the medicine as a gesture. As a gift and it came out to be a fake one and the person had just had a heart bypass.”

Moderator: “So what was his reaction?”

S3 (*frowning, but smiling at the irony of the situation*): “He went crazy he took the medicine to the cardiologist but decided against telling his colleagues because he said they wanted to do something good for him.”

Moderator: “Were his colleagues pharmacists?”

S3: “No, no, they weren’t and I’m sure they didn’t know the medicine was bad anyway.”

Moderator: “May I know the name of the medicine at least?”

S3: “Plavix”

Moderator: “Was it around the same time the Plavix scandal happened?”

S3: “It was around 2 years ago.”

S6 (sure, following up): “I would like to build on what S3 said. Unfortunately in Lebanon we don’t know many things. We don’t know the population we say we are 3 to 4 million. But I’m sure we are more now. That said, we don’t know the exact percentage of counterfeit medicine either.”

Moderator: “Can I ask you why is it that we don’t know the percentage of counterfeit medicine?”

S6 (confident): “I think there is a lack of serious work on knowing stuff. It is pretty political. The whole political mess which we need to dedicate few seminars to later on, but the point that I wanted to make is I’m pretty sure that there is a good number of counter products in the country and the region.”

Moderator: “What is the percentage, though?”

S6 (a little hesitant, unsure): “I don’t know, but I would say around 15 to 20%. And they have the feeling because of the discount wherever you go to buy the products. Also, something touched on by S3 is the fact that those people take advantage of the ease of how medication flow between people. Anybody can get their hands on the meds without being a pharmacist or a doctor, and I think it is important that us pharmacists need to increase

awareness for those people. It is one of our responsibilities which we need to also address at a certain point.”

S5 (more sure than S6): “I agree with everything mentioned. These drugs are mainly available where the borders are more open, for example in the North and in the South. But they are also present and active in Mount Lebanon. I don’t know about Beirut, though.”

S1 (very sure): “They are present everywhere, all over the country, including Beirut.”

Moderator: “If you want counterfeit medicine, do you know where to go to get it?”

S1 (sarcastically): “Oh yeah, we would know who to ask.”

S3 (sarcastically): “They would find you. They would easily find you.”

S2: “Two months ago, I was sitting in a pharmacy with people I had been friends with for a few weeks. Once during the night shift, a male in his early 30s came in asking for Cytotec without a legal and clear prescription. He took out his OPL identification card said I have big connections and I am a pharmacist from Tripoli, does that work? We said no. He joked about it and bought other OTC drugs... and left. Second time he visited a week later during the night shift too. I also happened to be there. He asked us about Epentin and whether it was in shortage or not. We said yes many pharmacies don’t have it. He said he said Phenyton Italian made, do you want some? I guess this person was dealing with counterfeit drugs. This is one case. I have also heard from pharmacists that counter are mainly for two categories of drugs they are either drugs with high turnover or very expensive drugs. It is now very common to have counterfeit drugs for anabolic hormones and they are being sold at gyms, especially through the coaches. This is another place where counterfeit might be and actually we as pharmacist don’t have access to/control to.”

Moderator: “So they bypass the pharmacist and go straight to the coach?”

S2 (sure): “Yes, that’s correct.”

S5 (confident, shaking head): “As S2 mentioned, some of the dealers might be pharmacists unfortunately and also I think that some of the dealers may be working as nurses or technicians in some health institutions so I think some of the people working in the health system they are corrupt and working illegally.”

Moderator: “So dealers can vary from pharmacist, to people at the gym, etc. right?”

S3 (confident): “And there is no punishment which makes dealing with counterfeit medicine all the more easy.”

S2 (sure): “Especially when the people who have big connections and connections of really high value in the country. It is the easiest way to get whatever you want in the country.”

S7 (unsure): “To go back to the statistics, I also don’t know to what extent it is happening but I do believe it might be happening all over Lebanon. It might be easier at the borders for smuggling. But I think they are producing the medicine in Beirut too, so those might be present anywhere really.”

Moderator: “Do you think it’s a big percentage?”

S7 (little hesitant): “I also had the 20% in mind; I don’t know why, I might have heard it from someone. I can’t say I have heard about it personally or had hands-on experience, though.”

Moderator: “In your opinion, what is the source of counterfeit? Where do they come from?”

S7 (sounds unsure): “So as I said, they might be coming from abroad.”

Moderator: “When you say ‘abroad’, do you have a specific place in mind?”

S7 (a little hesitant at first): “I don’t really have a country in mind, but I guess from the region around here because the legal issues are shaken up so it’s easier to manipulate the medication. Also there isn’t so much tight regulations or follow-up at the borders. But I also believe there might be people working in the country and producing drugs here.”

S6 (sure): “I have pretty much the same feeling. I know in Syria there is a strong local manufacturing of some products and given the geographical proximity, I think that Syria may be a source for counterfeit. Turkey as well. We know that there is a lot of stuff going on over there. It is a big market where you have a lot of local manufacturing. So many Syrian pharmaceutical owners have moved their industries to Turkey and they are now producing there with so many different terms and without any real follow-up on the government’s part so I believe some products might come from there.”

S5 (sure, sounds like he has experience): “I agree with S6. I think a big number of these products are coming from Syria mainly and from Turkey and of course we do have some sites, some apartments, some garages over here where medicine is being produced. Or powder.”

Moderator: “What’s the difference between medication and powder?”

S5 (laughing): Any powder you can put in a capsule and it will be like a medication.

S4 (sure): “I agree and I want to add based on my experience. Someone came to the pharmacy where I worked. They offered us Phenyton when that was not available on the market and when patients were panicking. The guy offered Phenyton from India.

Moderator: “Did he tell you it’s from India?”

S4 (sure, talking about a personal experience): “Yes, and he showed me documents but I didn’t know whether they were illegal or not.”

Moderator: “What was your hunch back then? What were you thinking as he was offering you the medicine?”

S4 (sure): “Actually, if one is not aware of what is happening, they might buy it. It was for 1.5 dollars a box containing 100 tablets.”

Moderator: “And you have patients who desperately need it.”

S4 (confident): “There were two men trying to sell me Phenyton. I said I was just an employee and I don’t have the green light to purchase anything. They never came back. But I heard from many patients that they are bringing Phenyton because they tell me.”

Moderator: “So are they using a different name? Are they aware that there’s a different name they are using?”

S4 (confident): “Yes, they are. I mean patients were coming to the pharmacy and telling me they were getting Phenyton but there hasn’t been Phenyton for 2 months now.”

S3 (interrupts, sounds sure of the information): “8 months now, actually.”

S2 (sure, confident): “This is what they’re taking advantage of, drugs in shortage people needs, and drugs that are really expensive. If you’re a patient and your medicine costs more than 100.000, and someone pops up saying they have the same product for 5 dollars. What would you do?”

S3 (sarcastic, laughing): “You buy the 5 dollar product and you sell it for 50 dollars. Plenty of people, pharmacists do it, unfortunately.”

Moderator: “People or pharmacists?”

S3: “People.”

S2: “Both. In my experience, pharmacists do it, too.”

S1 (sure): “In my personal experience, I have seen boxes from Syria because I would always ask the origin they would say Syria. I know many people in the country who get the medication from the borders. They can get it easily.”

S3 (confident, sure): “I know people who work at the port of Lebanon and they are truly well connected and I agree with everyone who said they come from the region but I’m sure there are plenty of medicine coming from China and other locations. There are a lot of containers coming every day. Nobody talks about this, but it happens.”

Moderator: “What happened to that shipment that came in last November?”

S3 (smiling sarcastically): “That was the topic of that week. But there’s a new happening every week.”

Moderator: “What happened to the person who was involved in this shipment? I remember they sent a memorandum to withdraw the product from the market.”

S3 (sure, shaking head): “The agent is the only one who cares.”

Moderator: “But that was a memo sent from the OPL.”

S3 (sure, still shaking head): “They send memo from MERSACO, they check the lot numbers of the medicine in question. They make sure you don’t have it and they go out.”

Moderator: who does this?

S3 (sure): “The agent. He is the one who is involved/affected. I’ve never had any control from the OPL asking me about counterfeit medicine. They just pass by to see if there’s a pharmacist on duty. We are four pharmacists in one pharmacy where I work. They have to do it. They will never go somewhere they are sure they would find something fishy. They just cannot do it.”

S5 (sarcastic): “They are very busy”

Moderator: “Do they [OPL] know where counterfeit medicine is being sold, at which pharmacies?”

S2 (sure): “Yes, people with authority know. If we’re talking about the OPL or people who have influence. They know where things are going wrong, but they do not really “want to know”, either.”

S1: “They cannot do anything.”

S2: “They cannot.”

S6: "They can't really do anything."

S3: "These people are protected and everyone has interests and this is why they cover up for each other."

Moderator: "Why are those people protected?"

S2: "Many reasons, mainly financial."

S5: "Political issues."

S7 (shaking head, dissatisfied): "They have the protection of political parties."

S3 (sure): "Unfortunately, in this country, those who have influence and those in the political regime current or previous have financial interests in these products, especially in a country where nothing is well documented."

S1 (sure, confident): "I think there is another sources for this kind of medicine. The expired ones. Sometimes they have a big number of meds and they use them."

Moderator: "Who uses them?"

S1: "I don't know exactly. Might be the pharmacists, the agents, I don't know."

Moderator: "So what do they do with those expired meds?"

S1 (sure, sounds like she came across such a situation): "They could change the boxes, the expiry date, etc."

Moderator: "And would you consider that counterfeit?"

S1: "Yes."

Moderator: "You already touched on that, but I'm going to ask the question again: how can you differentiate between the original and counterfeit medicine?"

S3 (confident): "We only try the agent who imports the medicine. That's the only way to do it."

S6 (very confident): "If you're very familiar with your product, you can know. You really know the box, the leaflet, the label, you really know the sequence the manufacture writes on the box. Sometimes they are really good, though, and they can produce a comparable box, but when you really know the details of what you deal with, you can easily catch it."

Moderator: "How many products do you have in your pharmacy?"

S6 (put on the spot, hesitant): "I don't have a pharmacy but I know the products I deal with at my work very well."

Moderator: "How many products do you have?"

S6: "I work with 3 products."

S3 (shaking head, serious): "You cannot know everything. You have thousands of products with a lot coming out very day. If you have turnover, you might be able to know. But there are a lot of pharmacists who don't know the colour of the pill inside a box."

S6 (still sure, maintains his point): "Yes, but you're talking from a community pharmacy perspective. But when you look at it from the industry perspective, when you're working

with specific products, you become an expert in whatever small lot of products you're working with."

Moderator: "So are you saying that working in the industry gives you an advantage in the sense that you know more about specific products rather than have a lot of products to work with in a community pharmacy?"

S1 (serious): "But it is the pharmacist selling those meds to the patient, not the industry. So the pharmacist needs to be good at what he does."

S2 (serious, confident): "I agree with S6. I work in the industry too and I have been asked by physicians how would our patients know if this drug is counterfeit or real. What I did was I took the sample and I explained to the physician every single aspect of the product that identifies the product as the real one. The slogan, how the shades change colour, where to find the sticker and how would the sticker look like. All aspects that differentiate from the counterfeit product."

Moderator: "Is it possible for the counterfeiters to counterfeit what you have on the box?"

S2 (a little unsure): "I would say yes."

S7 (sure): "To what extent they can counterfeit a medication depends on how they go about it. They could do it perfectly, imitate the box, insert the pills, etc."

S2 (serious): "I remember a case in the USA when they opened the capsules and changed the content inside and they sold it back to pharmacy, so yes, it could be done."

S3 (laughing throughout at the situation): "But do people truly care about the box and how counterfeit is? I have seen a box of Panadol syrup at 4,000. The photo of the baby on the original Panadol has white skin. The counterfeit medicine has dark skin on the box. The person didn't think there was anything wrong."

S7 (laughing sarcastically): "Perhaps they might think it's a new publicity/marketing face of the baby."

S3 (sarcastic): "He probably didn't realize anything. He might have thought of it from a marketing perspective, though."

Moderator: "When the manufacturer changes something about the product, do they inform the pharmacist?"

S3; "Sometimes they do, sometimes they don't. Sometimes we pharmacists call them as well to ask a question if we sell medicine in bigger quantities and notice there is a difference between a box and the other."

Moderator: "So that's another issue here. When a manufacturer changes the box, then you may actually think it's counterfeit because it looks different? Is that a possibility?"

S3 (sure): "Not really; whenever I'm buying from the agent, I check if I have question."

S1 (confident): "And sometimes the patient asks questions, such as what happened once with Voltaren and Cataflam. They changed the box."

S3: "They changed the box and the country of origin many times for that one."

S1 (sure): "Yes, but we knew that the box was being changed. They informed us."

S7 (confident, out of experience): "In the hospital setting, when we order new medication, there are always changes. Sometimes the ampoule comes with one head, sometimes there

are two, and that's because they sometimes still have medicine from the old stock which they sell from, so you can't really track all these changes."

Moderator: "So how difficult is it to stay on top of those changes at the hospital? Who is the person responsible?"

S7 (confident, serious): "The head pharmacist eventually will look at the stock, but mainly in the hospital we trust the source of the medicine/where we get our medicine from. But what if the source we deem trustworthy is selling counterfeit medicine? In that case, there is no way we can find out."

S6: "From a regulatory perspective, whenever a manufacturer changes anything in a product, they must provide the Minister of Health and other regulatory authorities in the country must be notified too. It is not a requirement but the agent might also be notified if they're part of the chain."

Moderator: "Why is it not required to notify the agent?"

S6 (hesitant, unsure): "I don't actually know if it's required or not."

Moderator: "So what is the process again?"

S6: "You definitely go to the Lebanese Ministry of Health."

Moderator: "And does the Ministry of Health have to inform everyone else of those changes?"

S5 (jokingly): "No, it doesn't. It's always 'for your information-FYI'"

S6 (also sarcastic): "It's always on an FYI-basis. I don't know why but they like it."

Moderator: "So do you think that the manufacturers don't feel the need to inform someone else since the Ministry is not doing that?"

S6 (unsure, hesitant): "I would say inform the agent, but I don't know if it's legally required to notify them and make the agent pass on the information to the pharmacies."

S5 (confident): "The Ministry should do it, at least let the OPL know and the latter should inform the community pharmacist."

S1 (sure): "If I'm buying something from the agent, I don't check twice, I won't doubt."

S6 (confident): "Yes, because the reference for the community pharmacy is the agent, but the reference for the agent would be the manufacturer and this is why the manufacturers need to inform."

Moderator: "But the agents here are very different from the wholesalers, right? So, if you want to minimize your chances of getting counterfeit medicine, what do you do?"

S3: "We deal with agents mainly."

Moderator: "But are you not dealing with wholesalers?"

S3 (sure): "We are—we are obliged to."

Moderator: "So how do you control that?"

S1 (jokingly, disapprovingly but also sarcastically): "We cannot."

S3 (serious): “We can’t, but we try. Back in the day, we had only the same person per week visiting the pharmacy on behalf of a certain agent. Now we have four different people who come in.”

Moderator: “And is this more of a problem, or is it better?”

S3 (smiling, seems satisfied): “It’s far better.”

Moderator: “Better to have the same four people or different people?”

S3 (sure): “Different people. And they sometimes call to take your order and they serve you on the same day. They deliver the order you place in the morning at noon. So that way you’re sure you have a good agent.”

S1 (confident): “There is a number of meds we don’t buy directly from an agent. I am not sure how much exactly, but I think 30% of the medicine doesn’t come from the agent. Someone might come in asking for something I don’t know. I would call up the drugstore and order it from here as I wouldn’t know the agent. Also, there is one agent who sends a person every day to note down the orders.”

S3 (confident): “That agent has 20% of the local market share of medicine, though.”

S1: “You said you worked in Beirut, right?”

S3: “Right.”

S1: “Well, I’m in Jounieh, I never get my shipments on the same day. I get them in a day and half a day. So sometimes I have to call the drugstore because I can’t wait.”

S6: “Why not move to Beirut?”

S3 (laughing, joking): “No please, easy on the suggestions.”

S1 (serious, shaking head toward the end): “Yesterday, I ordered a shampoo from the drugstore and it was the first time I order. I noticed it was 2000 less than the one sold by the agent. They didn’t look the same although it was from a very well know drug store. I kept it to show it to the agent. Maybe it was an old one, I don’t know.”

Moderator: “Where do you think is the pharmacist in this situation?”

S3: “I think he’s the key.”

Moderator: “Can you stop it at a pharmacy if you want to?”

S3 (sure, serious): “I can stop it in my pharmacy, that’s why people who understand the situation stick to their pharmacy.”

Moderator: “How many pharmacists are aware of the presence of counterfeit medicine?”

S3 (very confident): “Everybody’s aware. They all know.”

S2 (sure, serious): “They might be all aware that there are counterfeit drugs, but many, especially those who don’t deal with them, know nothing about counterfeit drugs, because I’ve asked some and they all said they knew nothing about counterfeit drugs. They know “of” them, but as they had never been visited by anyone nor been in a situation, they knew very little.”

S3 (not satisfied with S2's answer, disagrees, serious): "I think that's cutting it short. No one can work in the field and not know. Because if one doesn't know and suddenly have the counterfeit drugs in their pharmacies, how will they be able to stop it?"

S1: "I think they all know about counterfeit medicine."

S7 (serious): "I think the last campaign done in Lebanon about counterfeit products helped a lot in increasing awareness in the community and among pharmacists."

Moderator: "When was the campaign?"

S3 (serious, shaking head): "Last year, but people forgot all about it 2-3 months afterwards."

Moderator: "Where was the campaign?"

S3: "Everywhere."

S7: "On billboards, on the streets, in the media."

Moderator: "Do you remember anything from what was on the billboards?"

S7: "It was a bullet that kills people."

S3: "It wasn't done especially for medicine. They were talking about many types of counterfeit products."

S7: "Yeah, they were defining counterfeit medicine, saying it's a fake product, "it's not a drug" was the slogan, if I remember correctly. It was very visual for the general population. It was a bullet to the heart."

Moderator: "So where is the pharmacist in this situation?"

S4 (agrees with S3, serious): "As S3 said, I think the pharmacist is the key, for both ends: the patient and the dealer as well, because the dealer needs the pharmacist in order to work, and the patient needs the pharmacist to stay safe, so it's a key on both sides."

S6 (serious, dissatisfied): "I think that the pharmacist has definitely a role, but he's not the most important player, because at the end of the day unfortunately the med is not only found in the pharmacy, it is found everywhere."

Moderator: "Give us some examples: where other than the pharmacy can one find medicine?"

S6 (hesitant): "I don't know, well..."

S2: "Gyms."

S3: "Dispensaries."

S6 (very confident, sure of information): "On the streets, nightclubs, etc, so it's not only found in the pharmacy. It is a national issue, where many political people beginning from the ministry of health going on to the cabinet maybe the opl, everybody who has a political role to play here, the people of the ports, at the airport, they need to take this issue more seriously because it's becoming a problem and I think what's preventing this total "bang" of it is the few remaining pharmacists who are working still within the proper way of doing dtuff, but it should be a collaboration of many different parties. Pharmacists have a limited role now; they can help at their own pharmacies, but the effort should be a national one."

Moderator: “Those few pharmacists you spoke about, how much can they handle?”

S6 (sure, dissatisfied): “Not much, because if your neighbor is selling counterfeit products for peanuts, everyone is going to go buy your drugs at their pharmacy.”

S3 (disagrees, shakes head): “I disagree. I know we said people are aware, but some of them still come to the pharmacy they regularly buy from and they tell us about another party selling them medicine for much cheaper, but explaining the situation to the community helps, too. If all the profit a pharmacy makes is 20%, how can others sell very cheap medicine? People talk among themselves. They would tell each other, otherwise we [pharmacists] wouldn't have survived. We all have “neighbors” in our regions who sell medicine for cheaper prices.

Moderator: “So it is not only happening in the North and the South.”

S3 (sure): “No, it's everywhere, and it's not just counterfeit medicine. But you know, when there's a 20% discount on everything, you start questioning. But how many times have we heard about a pharmacy closing down because of counterfeit? Never. Unless they have a personal issue with the pharmacy.”

S1: “They closed a pharmacy recently in my region because they didn't find the bill for some medication.”

S3: “How long did they close it for?”

S1 (smiling sarcastically): “A month”

S3 (smiling sarcastically, dissatisfied, shaking head): “See? A month and then everything goes back to normal.”

Moderator: “So what does it mean when a pharmacy is closed down when the bill isn't found? What are the accusations?”

S1 (sure): “This is the accusation. Not finding the bill.”

Moderator: “What are they trying to imply when they penalize you for not being able to find the bill?”

S1 (confident): “That you don't know the source of your medicine.”

S3 (builds on S1's intervention, sure and confident): “That you got it illegally. There is a pharmacy in the neighbourhood where I live. It's away from Beirut. They closed it three times. For 3 days, then a week, then a month. Now you can't park there if you want to buy something because it's very busy.”

S6 (smiling sarcastically): “It's also trendy to say that when a pharmacy closes, it's under renovation.”

Moderator: “Do they let them say that?”

S3 (laughing, sarcastic): “And they also say because the pharmacist likes “doing good” to people.”

S6 (still sarcastic): “Yeah. They take it in that perspective so people wouldn't know the real truth behind closing the pharmacy.”

Moderator: “What do you mean doing good to people, could you please elaborate on that?”

S3 (still sarcastic, disapproving): “I mean though discounts. They say this person is very good and they sell cheap medicine because they are. The entire thing turns into publicity for him.”

S2 (dissatisfied): “And this is very common in Lebanon. The pharmacist who does discounts is known to be doing good to patients.”

S7 (serious, confident): “This is the problem: the gap between the pharmacist who knows and the rest of the population who are looking to get medication for cheaper prices, which is their right knowing the financial situation in the country. However, when there’s no education that puts them both on the same level, it becomes very difficult to distinguish. They are always to go against the person against the pharmacist, who they might consider someone who only sells meds.”

S5 (confident, out of experience): “We recently had a new law regarding the pricing of medication. They can profit more than the price of the medication is higher than 300\$. I think they have limited the profit margin to 86\$, so whatever is the price of the pack, the profit margin is 86\$. Nowadays, I think the pharmacies are still doing the discounts, we can now know....”

S3: “Yes, but how many times do you sell this kind of medicine?”

S5: “There are a lot of meds that cost more than 300\$”

S3: “In a community pharmacy you don’t have a lot, unless there are specific pharmacies that sell this medicine.”

S7 (informed, but a little unsure of her information): “I think this law mainly affects hospitals and oncology products. Targeted therapies, and brand products, products supposed to be very good quality, also fall under this law.”

S3 (shrugging shoulders): “It is not very common to have a lot of patients needing that kind of medicine. Like 5 patients a month? When you have this 20% on every single item in your pharmacy that’s too much.”

S7: “Just to add: this law might push pharmacists to find more offers, and turn to generics and more untrustworthy sources to get a little bit of profit that is required.”

Moderator: “What is another path for counter medicine?”

(everyone agrees)

S7: “Yes.”

S6 (shrugging shoulders, shaking head, dissatisfied): “The law was made to help the patient but actually it is not the case because, as S7 said, as a hospital pharmacy where it’s very hard to pay and more restrictions are coming out every single day, one tends to go for the cheaper products and untrustworthy sources. The only thing that was preventing that was the profit hospitals could make, which is using the trusted products, which are usually more expensive. So, I think this is another path that has opened for counterfeit products.”

Moderator: “What’s the status of generics in Lebanon?”

S7 (sure): “There are many generics.”

Moderator: “Is there a law allowing the presence of generics on the market?”

S6 (informed, very confident): “Usually to have generics on the market, you need a bioequivalence study and you need the approval of the Ministry of Health and the authority. You don’t need to have studies involving testing the generic on human, data is not required either. You just need to prove that the generic is the equivalent of another product. The quality of those products and the professionalism of the people producing them come in here. How is this product getting to the patient? How are they transporting it? So, we have so many generics. It is very easy to become a generic on the market nowadays.”

Moderator: “Who carries these generics? Where would you find them?”

S3: “They have agents.”

S5 (corrects S3): “They are agents.”

S2 (informed, confident, sure about what he’s saying): “Concerning the generics in Lebanon: we are a country that doesn’t follow the USA patency law. This might be good, or not good. However, we have thousands of generics. I’ll tell you one thing: we have a product in my industry that is still under patent protection. There are industries in Lebanon producing it legally. I know from medical doctors that when patients get the generic and get the original product, they realize there’s a huge difference. From our perspective as a scientific office, following pharmacovigilance duties to the end, when a patient gets the molecule, which is generic and says this does not have any effect....”

Moderator: “Can I ask you what type of medicine you’re referring to? Oncology? Cardiology?”

S2 (sure, minimal gesturing or nonverbal cues): “Urology. The generic might cause harm if the patient doesn’t see results or is harmed, I need to report that to my company and we need to report the issue globally. The patient is using the generic, but not the official one. If the patient takes counterfeit medicine, I have to report it as well. But my image toward my patient and my physicians would be disrupted.”

S1 (sure of information): “I think we have something called copy here in Lebanon, not generic. There’s a Canadian medication not currently being sold in Canada but is available here, because Lebanon has the right to copy the medicine.”

S2 (confident): “You can do whatever you want. I know of a company, it is a multinational generic company which is part of a well-known multinational company. The patency for Clopedogril has expired, so they recently introduced their generic Clopedogril in Lebanon. The biggest issue they’re facing—because I know the medical representative for this product—is that they’re number 25 among the generics or “copies” present in Lebanon. For Clopedogril, there are 24 other products claiming to be Clopedogril. They are the “real” generics, how can they compete on the market when there are 25 other products.....”

Moderator: “How is the price compared to the original?”

S3: “Much cheaper.”

S5: “They are obliged by the law to sell at a lower price.”

S3: “Than the brand.”

S5: “And lower than the generics, too. There is a certain percentage the price should be lowered by, especially when they need to apply for reimbursement from NSSF, the price needs to be lower.”

S2 (informed, confident): “They are in a similar price perspective, though. They are not sold for much lower. Let’s say you are a real generic company and you belong to a well-known multinational company which sells only brands. You come to a market where an array of products is available, how would you be able to work in such a place? For every molecule you have, there are plenty of generics. Why do we have huge numbers?”

S7 (relaxed, informed, serious): “When I sit with hospital pharmacists, I sense that there’s much opposition toward generic medicine in Lebanon. The majority prefers sticking to the brands, although the generics are supposed to be really good medications as well, at lower prices. I just feel like in Lebanon there is a lot of pressure on the pharmacist within the institution. A company comes up to me and tell me they have generic products. They show me their certificates and all, but to what extent am I able to do my own research? We are supposed to have the governing body that does that for us. The Ministry of Health. I’m not supposed to be doing their work. I should be feeling a little safe that this product has been checked and is safe because it’s been through a safety check process in the country.”

Moderator: “Technically, are there people producing generic medicine going through the Ministry of Health?”

S2 (sarcastic—and few others are too): “They are going, and they are getting approved right away.”

S7 (shrugging shoulders, dissatisfied): “We don’t trust this process yet.”

S6 (sarcastic): “Anyone can get approval for a generic. My small brother can.”

S2 (dissatisfied): “I go back to the example of the Lebanese copies. They *claim* to have bioequivalence.”

Moderator: “When you say Lebanese copies, we are talking about the local manufacturers, right?”

S2: “They claim to have the equivalence, and then when you go to clinical practice, you see that it is not the case.”

Moderator: “Do we do that in Lebanon? Do we have reports in the clinical practice about medicine?”

S2 (dissatisfied with the situation): “They get you a paper that certifies that they have done the bioequivalence and it’s signed by just anyone. In this country, if you have a signature from Europe, or the US, no matter who the person is, they would regard the person as God. This is the situation in Lebanon.”

S5: “On the level of the Ministry of Health, a lot of education is needed, mainly about these products and the importance of some generics and about pharmacovigilance. If people there receive an adverse event from a company or a manufacturer, they don’t know how to read the SIOMs. As we all know, we don’t have a pharmacovigilance unit at the Ministry of Health where all details about reported adverse events can be seen/evaluated. I know of a situation where they once saw in one of the reports “death” and they panicked. We went there and check. The death was not related to the product, but to disease progression. They weren’t able to understand the issue and they judged the product as one that kills people.”

Moderator: “And who are those people reading those reports?”

S5 (laughing, sarcastic): “People in the Ministry of Health.”

Moderator: “Who should be reading those reports?”

S5 (assertive): “Pharmacists.”

S2 (sure): “We faced an issue with one of our drugs. It was for ADHD. After going through the legal details and a lot of clarification, things became clearer for the public. A whole mess was created.”

S6 (confident, serious): “I’d like to talk about pharmacovigilance. It is not our topic right now, but it is extremely important. When one is taking their drug from a certified source, the latter is responsible of following up on the adverse event the product might have. In Lebanon, from a regulatory perspective, there is no requirement to submit an adverse event, unfortunately. If I’m at the Ministry and I receive an adverse event, I am not required to submit it within a specific deadline or penalty if I don’t. There are no timelines. In contrast, in the entire area, there are now specific pharmacovigilance rules and regulations requiring the manufacturer to submit every single adverse event depending on its seriousness.”

S2 (confident, informed): “Within 24 hours if it’s a very serious event, and if it’s not as serious, it needs to be reported within one business day.”

S6: “Exactly. But there should also be specific rules and regulations and consequences if one doesn’t report.”

Moderator (addressing S2): ‘But that’s based on your company’

S2: “Yes”

S5 (serious, confident, assertive): “But regionally, if a company doesn’t report a specific adverse event within the specified deadline, they are in big trouble. It is not the case in Lebanon. If we can reinforce this issue and make it more concrete, it can help limit counterfeit products because when it comes to this area there is no one following up on pharmaco-vigilance or adverse events.”

S2: “But this takes us back to when you asked about how pharmacists can have a role in this process. Well, one point is that we need pharmacists in all the processes and departments.”

Moderator: “Which departments?”

S2 (sure, serious): “Ministry of Health, Ministry of Defence, the airport, the Port of Beirut, or anywhere drugs can be acquired, on the boundaries, etc. I believe we don’t only need any person who studied the discipline; we need pharmacists who are dedicated, with good conscience. There are pharmacists dealing with counterfeit medicine everywhere. We need people with conscience and real dedication to their profession and their patients.”

Moderator: “How many are they?”

S5: “We’re 7.”

Moderator: “Are they a minority in your opinion?”

(everyone agrees: Yes).

Moderator: “I want to go back to something: when I asked about differentiating counterfeit medicine. What is the role of the hologram?”

S1 (assertive): “It’s being copied.”

Moderator: "Are you relying on the hologram?"

S7: "We check if it's there. If it is, what can I do more than that?"

(S2 agrees)

S1: "We need to see the sticker of the agent."

Moderator: "So do you rely on the hologram?"

S3 (assertive): "It mainly makes the people feel safer, if you ask me. It does nothing else."

Moderator: "What about the pharmacist?"

S3: "I am talking about myself here: if they can counterfeit everything, what would stop them from counterfeiting this tiny logo?"

S7: "I also think it a relief for the pharmacist that he is able to take the responsibility off his shoulders."

S2 (jokingly): "This is a placebo effect."

Moderator: "Can they counterfeit a hologram?"

(everyone agrees that yes)

Moderator: "Have you heard of any hologram counterfeiting stories?"

S3: "I haven't read any report, but I'm sure that whoever counterfeits medicine can copy a hologram."

Moderator: "Ok, but have you heard of any incident?"

(Everyone says no)

S5 (assertive, but doesn't sound very sure): "But we know that holograms are being created in Dubai. I don't think they are created in Lebanon. So, we are getting them from Dubai."

Moderator: "Are we talking about the official hologram? That one is created in Dubai?"

S5: "Yes"

Moderator: "Who told you about this?"

S5: "the LPIA, the organization for the agents and suppliers. I think they are printing the holograms in Dubai. "

S2: "Is the hologram the gray one?"

S3: "Silver one."

S2: "Oh ok."

S5: "So that being said, there is a risk you might have a mistake or a hologram which is for a company X goes to another company by mistake, such as a mistake in the delivery of this hologram. We are humans and sometimes we may face some mistakes. Also, some holograms may be delivered to a third party or a dealer."

Moderator: "How many holograms do we have in Lebanon?"

S4 (sure): “Each agent has their hologram.”

(everyone agrees)

S1: “Some medications don’t have a hologram on the box.”

S3: “Yes, they don’t have.”

Moderator: “Which ones?”

S1: “The ones made in Lebanon.”

(people agree)

Moderator: “How do you think the public sees the pharmacists in this situation?”

S3 (assertive, smiling): “They truly trust us.”

S2 (skeptical of S3’s statement, serious): “Well, there are 4 million people in Lebanon, and I believe at least each individual has his or her own picture of the pharmacist.”

Moderator: “OK, but in your opinion, how do they perceive pharmacists in this situation?”

S2: “Some trust, some don’t, and some have a question mark.”

S1: “If they’re our patients, they would trust us. But in general, they assume we are the ones who are selling bad medicine. We are the source.”

S4 (serious, neutral): “As they said, some of them trust you if they are your patients, if you have a certain relation between the patient and the pharmacist in general, but if a person is not your patient and this patient is visiting your pharmacy for the first time, especially if they hear something in the media, they would be hesitant to fully trust the pharmacist, so it depends.”

S5: “I agree. I am not working in a community setting; I am working in a pharmaceutical setting. But I believe that if I worked in a community pharmacy, I would have patients who would have trust in me. So, I can have in my pharmacy whatever medication and they would trust me and take the medication?”

Moderator: “Forgetting about your patients, what is the general atmosphere? How do people view pharmacists in this situation?”

(all assertive)

S3: “As a reference.”

S1: “If there’s an issue with certain meds, they would say it’s the pharmacist’s fault.”

S5: “But I think when there’s publicity or a problem in the media, for example if the minister is making an issue about one product, the customer will come to the community pharmacy and question the product available in the pharmacy; so it’s not only a trust relationship. They might sometimes question the product available at the pharmacy.”

Moderator: “Would they ask you if you have counterfeit medicine at the pharmacy?”

(all assertive)

S5: “Yes, they might.”

S2: "I find this very ridiculous."

S1: "I don't think they would ask, but I do think that the pharmacist is always the first person to blame."

S2: "No, I think they would. I have visited many pharmacies and come across patients who ask pharmacists if they have the original product or not. What would the pharmacist do in this case? They would have to say yes, of course the products are all original."

S3: "But they [pharmacist] need to make the patient feel comfortable, make them feel like they know what they are doing and they know what products they have at their own pharmacy. I personally do believe that they trust us."

S7: "I think the fact they're asking shows they trust us. They rely on our answer and they think we know exactly what it is and we can track it and we can help them."

S3 (smiling, compassionate): "How many times they don't go to the doctor, but instead ask us about their health, the most precious thing one has?"

S7 (serious): "And this is the most dangerous part: that they trust us and sometimes they might be putting their trust in the wrong hands."

S6: "I think that as a global status of the pharmacist, we are still kind of respected, but I also think that many view us today as markets and mini-markets."

Moderator: "And what's your role in the mini-market?"

S6 (confident, serious): "That would be to sell as many products as I can per day and not care about anything else. This comes back to another important point: I think we are at risk of losing our status because the difference between how the pharmacist is perceived here versus how he is perceived abroad, you cannot really feel it except if you go experience working abroad, which is something I think most of us have done. Thing is, if we don't really go back and think about reorganizing this profession, we are at risk of losing our status. Today, the number of pharmacist graduating from different schools is huge. It's very hard to find a decent job. People working at community pharmacies have increasing competition. We are becoming like gas stations, every 10 meters there's a pharmacy. This also opens doors for counterfeit medicine. If you don't have some organization for the profession then you have more people having the chance to do whatever they want, and they are actually happy because those good pharmacists who work in their pharmacy decently have built up the status for us today. So the corrupt pharmacist is taking this advantage. We need to organize this profession because today we are still important in the chain."

Moderator: "Do you think organizations might help solve the problems? We have this situation and we are thinking of ways to combat it. What comes to mind? Could organizations have an impact on the profession?"

S6: "Of course. If the number of graduates is limited and how many pharmacies can be found in a specific area..."

S1 (interrupts, assertives): "You cannot."

S6: "you are not going to have so many people trying to be in this profession for the business part of it."

Moderator: "So once organized, what else can we do?"

S2: "First, we need a well-established political system..."

S6 (interrupts, says jokingly): “First we need a president!”

S2 (serious, assertive, confident): “So this minimizes a lot the access to whatever there is in this whole world. Second, there are people working now who are not updated and do not have the adequate competencies to fulfill their roles adequately, so these positions need to be renovated. Third, we need to organize the profession by limiting the number of pharmacists who graduate, so let’s say there are 300 pharmacists graduating every year, and we always hear news about new schools of pharmacies willing to open; this would increase the number of graduates to at least 500 or 600. The pharmacists graduating with loads of loans and all the effort they did to graduate, these people need to have a future and I believe the need is the mother of creativity, they want to build their future. They might go to counterfeit medicine, opening pharmacies with illegal competition, etc..”

S5: “Dispensaries, too.”

S2: “We also need to regulate the dispensaries.”

Moderator: “Are we talking about drogueries or dispensaries?”

S2 (dissatisfied, shaking head): “Dispensaries—I participated in the 20th Pharmacists’ Day and I think they said we had about a thousand or more dispensaries in Lebanon and only 16 have proved they have pharmacists in them.”

S3 (sarcastic): “And that goes up during elections. You have more dispensaries open during elections.”

S5 (assertive with a little sarcasm): “It’s a way to help people be president, and I think the majority of the products available in dispensaries also are fake and they are all coming through donations. We have many organizations present here in Lebanon and they do get medications. I think we don’t know from where they are getting these medications, only to help poor people and as donations and they are available everywhere. Yes, they are available everywhere, at the majority of dispensaries.”

S2: “There’s one more issue. Now if you’re a pharmacist you can get a license to get any product, and I remember one week ago on the news, they said we have at least 600 companies bringing in products to Lebanon and the total amount of products entering Lebanon (the market) is around 1 million USD. Does this population afford 600 companies and this number of products and this amount of 1 billion dollars?”

S1: “And there are other sources, too. These are only the reported ones.”

Mr. Farah: “If we want to go to the trust issue; You are probably aware of the poll in the US where they asked people to rank pharmacists between an MD, a nurse, a dietician, etc. Where do you think in Lebanon pharmacists rank? Give me the top 3 please.”

S7 (a little hesitant though): “I would say MD would be the first. I think we are right after the MDs here.”

S6: “Today, I think nutritionists are growing a bit because the issue about diet and good health and shape and wellness. I don’t think they rank one, but they are growing.”

S2: “They are on their way.”

(S6 agrees with S2)

S6 (sarcastic): “Now they understand really everything. So they can tell you yes take that and don’t take that. They tell you which drug to take.”

S2: "They can prescribe drugs because they have clinics."

(some participants are perplexed, they ask if nutritionists can really prescribe now)

S1 (sure, assertive): "No, they can't. But some of them prescribe because they were supposed to become MDs and then they stopped studying for it."

S5: "They do prescribe. For diabetes, for example."

S3: "They do prescribe but they don't sign; they don't stamp. I have papers from dietitians, but they don't sign. They don't rank. They're not in the top 3."

S6: "They're not on the radar yet, but they are coming. In terms of trust and information, I think I agree with S7. I think we are number 2."

S7: "I'd like to add something since you said you agree with me. I think we also have herbal medicine. I think they come before us. Everything traditional."

S2: "But they're not much available."

S7: "I think we are together if you want."

S6: "You know if you have a person that can be on a mountain and go directly to the sea on a horse, I would trust this guy."

S5: "I think we are number 2. MDs, pharmacists, and then nurses."

S4: "I think we are number 2. MDs definitely come before us."

S3 (confident, speaks out of experience): "Practically the same, but sometimes I don't know if I can that, but sometimes I do feel that people trust us as they trust their MDs. They say we can encounter more than 100 patients a day and we know about many different things and medicine, but the doctors, each one is specialized in his own branch, and we are here to see all of them. We can see what the patient is encountering and the medicine and we see what happens after the medicine. That's why I believe they do trust and if they don't see that their problem is as major, they come and trust us and we give them their medicine instead of going to the doctor."

S2 (very confident): "My personal opinion, we are number 1 for two reasons. One because we are the easiest accessible healthcare professionals; they don't have to pay us for consultation. Second, because now I see that many people or patients see their doctors are traders, especially when they don't get the benefit from the first time and they visit multiple doctors and doctors nowadays don't have as much time for their patients as they used to have, so these two factors would help us be ranked as number 1."

S5 (serious): "People who are working in a community pharmacy and having their patients, I think they will rank them as number 1 because they have maybe daily contact with them. They can call them any time and pass by them any time and get the needed answer."

S3 (confident): "Even if they are not our direct patients. There are people I haven't seen ever. They walk in and they tell me they don't want to go to a doctor. They say they want to ask me questions because I know better."

S5: "Because you are in a community pharmacy, you are accessible. But for me, I am the first one for my colleagues maybe, for my friends, for my family. They do trust me as number 1, but if I want to compare myself to you, having a community pharmacy, of

course you will have more people who are trusting you and considering you as a reference.”

Moderator: “Although she ranked.”

S3: “It’s because I don’t want to say 1. I’m hesitating between 1 and 2. If I personally have a problem, I go to the MD. You know, after consulting my father, my mother and my brother: they are all pharmacists in the family (sarcastic). But I definitely do like to see a specialist in every single thing, but since we are talking about how people rank us, I believe they rank as number 1.”

S6 (serious, confident): “I also want to add something: I think if you put in the same room with people in it and two people on a stage. You can’t know whose who, but you know that one of them is a physician and the other is a pharmacist; If the pharmacist says “OK, I recommend that you take drug A, in so and so way”; and then the MD comes and recommends another drug, I think most people would go with the MD.”

S3: “No, I disagree.”

Moderator: “Would it be based on their personal experience with doctors you mean? Because S3 automatically said no.”

S3 (assertive): “I said no because many patients come after having got a prescription from the MD, and they say if you don’t say yes, I won’t take it.”

Moderator: “OK, but based on what?”

S3: “Based on their previous experience because whenever they come and we dispense them medicine and they are directly better off, this is by experience. You build this trust by experience.”

S1 (assertive, smiles when she mentions dermatologists): “But doctors are being trusted less, especially dermatologists. Big time.”

S2 (serious): “As a pharmacist in a community pharmacy, we have selling skills and good communication skills, and this is very important. Convincing the patient to trust us more than the MD. I believe it believe a high role, and especially in Lebanon. Abroad, let’s say in the US, our role in communicating and the ways we should work would limit those skills. But, in a country where you can do whatever you want and you can even prescribe as a pharmacist a drug, this is very important, crucial. Creating a trust relationship with the patient and letting them trust you more than the MD.”

S7: “I think the problem with trust here is that it’s not an educational judgment. It’s based on who’s more available....”

S2: “It’s also based on emotions..”

S3: “Experience and emotions..”

S1: “But MDs nowadays are becoming dealers.”

Moderator: “What about pharmacists? Are they known to be the same way?”

S3 (sarcastically, laughing): “No, they’re not.”

S1 (serious, assertive): “No, they can’t go that far; they cannot do that much.”

Moderator: “Pharmacists don’t do that?”

S6: "I mean they do."

S1: "They are doctors who are known for being dealers. I know them."

Moderator: "What is your opinion of pharmacists who deal with CFM?"

S3 " ... this is the most dangerous part, that they trust us and sometimes they might be putting their trust in the wrong hands." and all agreed.

Moderator: "Are you aware of other pharmacists who deal with/dispense CFM?"

Majority nodded, "yes..."

S1 (sure, confident): "Yes, many times I have had patients coming from the North and getting boxes I have never seen."

Moderator: "So we have counterfeit medicine. Who should be responsible? A patient ends up with counter. Who is the first person who comes to mind in the patient's perspective?"

S6 (jokingly): "The president."

S5: "The Ministry of Health, people at the airport, etc."

Moderator: "I'm not asking about what you personally think; what do you think goes through the patient's head?"

(everyone agrees that patients think of pharmacists first.)

S7: "The person who sold it to them. Pharmacist."

Moderator: "Who should be screening counterfeit medicine?"

(everyone agrees that the Ministry and the OPL)

S5: "They have people present on the field."

Moderator: "What is the role of the LPIA?"

S3 (assertive): "They are doing their best, I think, because they are the first people to be harmed."

Moderator: "So you're saying the Ministry of Health followed by OPL or in parallel to, or before?"

(everyone says in parallel)

S3: "Because the main concern of the OPL is the respect of the pharmacist. If our image in the country is not good, they are the first people to be held responsible."

S5: "They should talk to the Ministry of Health."

S2: "Their role is to protect..."

S3: "I'm not in close contact with the people in the OPL but from what I see, they are trying to do their best in the area where they can go [referring to geographic area]."

Moderator: "So there are areas they are not allowed to access. So they are trying to play their role, but what is it?"

S3: "For me, it's to protect the pharmacist and to keep the image in shape."

Moderator: "How can they do that?"

(all assertive answers)

S1: "They have to screen the dispensaries, pharmacies, drug stores."

S7: "They OPL have an educational role as well."

S5: "They have to punish, not only screen."

S3: "It's not only about punishment. You can't punish everything every time. You have to build the positive side of the thing. This is what we cannot see in Lebanon."

S5: "But it's too late now."

S3: "When we are as pharmacists always in a negative relationship with any institution, we won't cooperate. When I don't have anything false and negative in my pharmacy and people still come in trying to find something they have never found before, I ask myself do they not have anything more important to do?"

Moderator: "Have you ever told them?"

S3 (assertive, confident, smiling a little): "Yes, I have. At my sister's pharmacy, they came more than once in the same month. They said there must be something wrong with your pharmacy, that's why. After we spoke to them, they never came back. What happened that led them to come three times in the same month I don't know."

S1: "The neighbour told them."

S3: "Probably. That's why they said we must crack down."

S5: "The neighbour is well connected."

(S3 laughing)

S7 (serious): "I think if this was happening in a more homogenous way, we wouldn't feel that attacked."

S1 (serious, dissatisfied): "We would still feel attacked when we know there's nothing here and they are still coming to check."

S5 (serious, confident): "I wouldn't personally mind if I had my own pharmacy. Where I work at the hospital, they are coming to see us also. They came like three times, but if they are coming on the contrary I would feel protected when I know I have nothing. But when I know they are not going everywhere else, I would feel weird."

S3: "But you won't feel protected when you're busy working and they come in and they want to open your purse."

Moderator: "They open the purse, too?"

S3 (gesturing, dissatisfied): "Yes, it happened with Zeina. They wanted to check the contents of the purse."

S1 (assertive, dissatisfied): "They have the right to open everything."

S3: "They do, but there's a way."

Moderator: "Do you get inspected from the Ministry of Health too? What do they do?"

S3 (confident): “Yes, they come one time a year. They check for psychotics.”

Moderator: “Only?”

S3: “Yes.”

S6: “It’s their responsibility.”

Moderator: “So the OPL is the only entity responsible for counterfeit medicine?”

S6 (confident, sure): “This is again my idea that you need to have more clear rules and regulations. I don’t know if we have those. There are some maybe small sentences that talk about this issue, but are they really new and up-to-date rules and regulations? It’s a governmental issue as well.”

Moderator: “Do we have a law against counterfeit medicine in Lebanon?”

(they are all hesitant, unsure of the presence of a law or what it is)

S2: “We don’t.”

S6: “I’m not really sure.”

S3: “There must be, but who applies it?”

“... but who would apply it ... only the weakest link is identified in dealing with CFM.”

S6: “Exactly.”

S3: “We’ve heard of a hospital selling false oncology medicine few years ago, right? Did they close the hospital? What happened to the patients (rhetorical?)”

Moderator: “Who was involved in this case? Do you know?”

S6 (sarcastically): “We cannot say, because we don’t know.”

Moderator: “Who do you think would be involved in counterfeit medicine scandals? Is it the pharmacist, the employee? Who?”

S2 (dissatisfied, shaking head): “The weakest person in this game would be the one who’s known. You wouldn’t know who’s really behind it.”

Moderator: “What is the patient’s situation in this case? How do you think the patient is feeling at the moment when they know they have counterfeit medicine, and they have to go to pharmacies and these counterfeits can harm them, can be of no use, or whatever it is?”

S1 (confident): “There are two kinds. The ones who know about counterfeits and are educated and know where to go and who to trust; and the others who are ready to take whatever, mostly because of the price. Those are the patients that are less educated. They care less, and they don’t really know what is the result of counterfeit.”

Moderator: “So do you think people are aware about counterfeit medicine?”

(assertive, rather neutral tones here)

S1: “Very few.”

S3: “They are aware, but because of their many other issues, I think they sometimes they try to ignore just for the price of the medicine. I think that’s it.”

Moderator: “So you do believe they are aware?”

S2: “To a certain extent.”

S3: “Of course, because we talk in all the media. There is no way they don’t know, but sometimes when there are so many financial problems, they try to ignore. They say no it won’t happen to me.”

S2 (sure, a little sarcastic at some point): “I believe in this country, we have only a general culture. We have big headlines like: Be aware of counterfeit drugs. Ok, I will be aware. But how? We don’t have the how? This is the issue with counterfeit drugs and other issues. We do campaigns: be aware of counterfeit drugs. That’s great, but how would I as a patient or as a pharmacist know? Many pharmacists don’t know anything about counterfeit drugs. There are general guidelines that those people are protected, etc. This is our case.”

Moderator: “So how would you tell them?”

S2 (assertive, sure, informed): “We need to have not just laws, because we might have laws saying vague sentences like there should be a pharmacist in the Ministry of Health, but what is the role of the pharmacist in the Ministry of Health? We do not have an agreement on the roles. Who should be responsible? The OPL, the Ministry and the LPIA let’s say should be responsible. But how should each institution be responsible? In what ways? And we mainly get to learn these techniques when we get to university, especially universities of high caliber of education and when we get into institutions or workplaces that are mainly related to multinational companies. So now let’s say in my experience at my job, I know understand how to formulate a sentence, how to formulate an objective. Or let’s say from my university experience: I know how to formulate an objective, but the general population, they know nothing. They just say vague terms.”

S3 (sarcastic but genuinely bothered and dissatisfied): “Even pharmacists. I’m trying to recruit two people. I’ve seen all kinds. Truly. And they’re pharmacists.”

S2 (very unhappy with the situation, dissatisfied): “I’d like to come back to my example of the urology products. I saw the physician’s office, where people sit. There are brochures from local companies producing drugs. In the brochures, there is “research has proven ...”; we as a company who have made the drugs and done the studies, don’t have that. Literally. So I took a picture and I sent the picture to the company and took all the brochures.

Moderator: “Where was that? At a clinic?”

S2 (still dissatisfied): “Yes. And even at hospital. People wouldn’t notice. They wouldn’t pay attention. They would see those brochures and believe them most of the time. I am serious, I took all the brochures that day and threw them out, and I sent a copy to the company, maybe they can do something.”

Moderator: “Do you think they can do anything?”

(people sigh, expressing disapproval)

S2 (dissatisfied): “In Lebanon? Because the company is Lebanese, they cannot do anything. But should the company be multinational, we would have done a lot of things.”

S1 (confused): “Why, though? What’s the different between local and multinational when it comes to taking acting?”

S5: “Because they have rules. They are more organized.”

S1: “Oh, okay.”

S2: “There was an multinational company that worked on a program that wasn’t ethical and put in on the Lebanese market. We took action and we stopped their program. We can do it because it’s a multinational company. You can refer back to their headquarters.”

Moderator: “They were not allowed to do that?”

S2 (angry): “No, they weren’t, and the program was stopped right away, because it wasn’t logical; it wasn’t ethical. We are not selling potatoes here.”

(people laugh)

Moderator: “I have a hypothesis or a scenario here: Let’s say you have a counterfeit medicine or you were provided with a counterfeit medicine that has the correct amount of the active ingredient and is cheaper than the original. Would you be willing to give it to a patient that cannot afford the original?”

S3 (assertive, vehement): “Of course not.”

S6 (sarcastic): “If I have a brochure like number 2’s, maybe.”

Moderator: “Let’s suppose it has the right amount of active ingredient and everything. What would you do?”

S3: “And bio-availability studies and all? It might come in, it might come out.”

Moderator: “It is counterfeit, it has the exact amount of the active ingredient.”

S3 (perplexed): “Are you sure? What if they say that but it’s not true?”

Moderator: “They tested it; it has the active ingredient; it is counterfeit medicine and it is cheaper than the original; would you give it to someone?”

S7 (assertive, confident): “If it’s parenteral, it’s a no-no for me because you have the manufacturing and the sterility and so on. So it doesn’t matter if you have the active ingredient. I wouldn’t do it as to sell myself. It’s a responsibility.”

S6 (confident): “I would. This is an issue: when you talk about a counterfeit product, it could be a product which is not functional or has a problem in it. It could also be the good product which is coming in illegally or through parallel importation.”

S3 (assertive): “Parallel importation is not counterfeit.”

S6: “Yes, but it’s counterfeit vis-à-vis the law because it didn’t enter the country legally.”

S3: “But parallel import is legal.”

S5: “Parallel import is legal, but there are a lot of people who smuggle medicine in, unregistered products.”

S3 (hesitant, concerned): “How can you be sure how the medicine arrived to you? In the sun? It is a medicinal product. How could you have the responsibility to do it?”

S5: “Well, if I’m a hospital and I have a patient who needs it...” (he didn’t continue his idea, was interrupted by S3).

S3: “I think if you really want to help someone who truly is unable to pay for medicine, there are so many ways.”

S2: “Charity or you pay for the medicine yourself.”

S3 (very assertive, gesturing): “Yes, or whatever. But it’s wrong to give out counterfeit medicine if the person doesn’t have the money. There is my image which might be affected and I’m responsible for the patient’s health. If something happens to them I would be held accountable.”

S6 (sarcastic): “I just said yes to have a discussion.”

S7: “The patient might get confused, too. They might ask themselves why am I taking this medicine and why is it OK to take that medicine but not the other one?”

S3: “I think if you explain the situation to him in a different way, he would be more respectful. If he doesn’t truly have the money, you can just call the agent whenever he’s here and ask him for help. The agent would be more than happy to help, instead of shifting him to any other medicine.”

Moderator: “Have you encountered a case?”

S3 (confident, out of experience): “Yes, it happens. Lately the Diamicon was out of stock because they were changing agents. And the person who does not find the Diamicon, a medicine for diabetes, he would just call his MD and be shifted to another one, normally. However, I asked an agent to find a way. They gave me samples of 10 tables. Within these 10 days, the new agent, Fattal, was going to have medicine. And that’s what they did.”

Moderator: “But how would you know this medicine is good, the one given by the agent?”

S3: “It is from the agent; it’s a medical sample. Instead of giving it to the MD, they gave it to us and we solved the issue. And the people were happy instead of calling and getting shifted to another type.”

S7: “The sample were being sold?”

S3: “Of course not. Medical samples, ten tablets.”

Moderator: “And the need here was not related to cost; the medicine was out of stock. What if you have someone coming to you with a cost issue?”

S3 (sure, confident): “I sometimes need to shift to another one. It doesn’t happen very often, but whenever you have a problem, you have so many solutions except the counterfeit.”

S2 (assertive): “You can find many ways. You can pay for your product.”

S3 (eyebrows raised): “That you will never do in a pharmacy.”

(people agree)

S5: “I agree—never do it.”

S2: “It depends. Somebody who’s willing to pay.”

S3 (sarcastically): “But the order will come directly to you. You cannot do charity work in the pharmacy. It’s impossible. Never. You go there, you give him the medicine as a gift, that’s another story. But you cannot put on your computer that you sold X item and put in 0. You cannot do it.”

S1 (a little hesitant though): “I think fully for free is different than discount. I know of a pharmacist who didn’t take any money from someone just so that he doesn’t do a discount.”

S3: “I have never heard of this, but I know if they see 0 down, it’s bad: straight to the disciplinary board.

S2: “You can pay for it yourself, or even call the MDs, switch to other products.”

S3: “Yes, there are many ways.”

S2: “There is one important thing. You can look at the issue from two perspectives. Either you pay the money now and you save later, or you will be paying the money throughout. Let’s say I’m paying for a product X dollars each and every month, and I can pay 20 or 30% less. On the long run, I would be paying part of my health considering safety and efficacy. If it’s a diabetes medicine that’s not as effective then you would suffer at the end and you would pay more for diabetes complications.”

S5: “This information and complications can be shared with a physician to convince them, but I don’t think with the patient you would succeed.”

S2: “Depends on the IQ.”

S5: “I don’t think talking about cost effectiveness and survival benefit would pay off.”

Moderator: “Why do you think this wouldn’t work?”

S5 (assertive): “Few people are educated and would be able to understand. The majority I don’t think they can understand.”

Moderator: “Can there be any other way to approach those people?”

(all answers assertive)

S3: “Yes, according to their own level.”

S2: “Right. If a person has diabetes, you would ask him if they would rather pay now or have their leg amputated in the future. What would their answer be?”

S5: “They would say they don’t have the means.”

S2: “But that’s only one of the solutions. You can send him to a charity.”

Moderator: “Is there anything you would like to add to the topic that would be something we did not address that you think is important?”

S3 (confident, smiling): “I think counterfeit is a big issue not only in Lebanon but in every single country even in the European and the us but the third-world countries, whenever things are shaken up, we have too many problems and I think that counterfeit is a big area. So, your topic is directly in place with our situation.”

S7 (serious, confused, but unsure): “I wanted to add something also. When we have counterfeit products and we discover they are counterfeit because we bought them. What do we do? Who do we call? Would the product be paid back?”

Moderator: “Do you know anything about the process?”

S3: “If you want to go a long way, you can start the report thing and file it.”

Moderator: "Is there a system? Were you informed of a reporting system?"

S3: "I think the best thing would be showing it to your agent because you're sure he's the only one who can do something about it."

Moderator: "Let me rephrase the question: were you as pharmacists at some point informed of a way to report counterfeit medicine if you encounter it?"

S3: "No, no, of course not."

(people agree, shake their heads)

S7 (confident): "I think that also encourages the pharmacists that do not want to go the long way. They would just sell it."

S1 (dissatisfied, shrugging shoulders): "I once called the OPL to report a prescription and the answer was that they didn't want to have problems with the physician. I called the physician. He told me that he knows that his stamp is stolen and he doesn't care."

Moderator: "So it was a prescription with a stolen stamp?"

S1 (dissatisfied): "Yes, and I was having the same prescription two and three times a week. At the end of the month, when we were trying to do the inventory, I called the OPL and they say they couldn't do anything and they didn't want to get into an argument with the physician."

S2: "There is a conflict between the Syndicate of Medical Doctors and the Syndicate of Pharmacists."

Moderator: "Do we have malpractice in Lebanon?"

S3 (smiling bitterly): "Plenty."

S5: "The medical issues in Lebanon are very weak."

Moderator: "Anybody to deal with these cases?"

S3 (sadly, sarcastically): "No one is interested."

S2 (assertive): "Perhaps if you have a "wasta."

S6 (sarcastic): "The president."

S2: "If you have connections, you might be able to get what you want. If you don't, then it's impossible."

S1 (assertive, confident): "There are many things that could go better. When I ask people in the OPL why they wouldn't divide the country into parts and specify the number of pharmacies that can open up in each part, they say it's political. They cannot tell how many Christians and how many Muslims are there, and that's why they cannot divide. So basically pharmacies can do anything basically. They can give discounts, and people would appreciate that, thinking the people there are good people because they give high salaries and help the community them afford their medicine."

S2: "True."

S5: "Yeah."

Moderator: “Thank you so much for your time. I appreciate your coming here on a Saturday. If you would like to add or send me anything, you are more welcome to get in touch with me on my University of Brighton e-mail or my personal one.”

-----End of focus group-----

B. Transcript: Pharmacist Focus Group: LAU-FG2-061414

Moderator: “How do pharmacists define counterfeit medicine?”

(answers to first question were all given in a serious tone, confidently, focused manner etc, the ice hadn't been broken yet)

S6: “Counterfeit medicine is any medicine that doesn't conform to what it should be. So it might be different maybe in the physical appearance or in the content and this might lead to a different efficacy or a different action and could affect the pharmacodynamics and pharmacokinetic properties of the medication.”

S5: “Counterfeit medication is any medication that I'm not sure of. Any medication where I cannot tell 100% what laboratory, what land of origin, which industry, laboratory, and which agent brought it to Lebanon. This is the most important thing here. You have well-known agents and then you have anything in this country.”

S4: “We can define them as fake drugs also. So, any drugs that do not contain the specific amount of active ingredient or at least the exact active ingredient that can lead to dangerous effect to patients sometimes. That can also lead to no effect. And we don't know how they are being distributed and delivered. And also manufactured.”

S3: “In one word I would say they are fake products, medications that are manufactured in an attempt to comply with the original. They are not generic products. And we don't know the exact concentration (the amount of active ingredient) or any other excipient added to the product. Also, even there could be in some cases some excipients that are added to the drug itself which is not available in the original product. They are meant to be out on the market to copy the original.”

S2: “Counterfeit medications here in Lebanon, I see them in two ways: according to the Ministry of Health and our Order: it's any medication that doesn't have the name of the agent that brought it here. It didn't go through normal... all the taxations and all these things. There are medications, however, that don't go through this regiment but they are good products. You can get any product from abroad, from reputable pharmacies or whatever, just because they are not available here in the country, yet they are seen by our Minister of Health that they are counterfeit. I also look at other medications that have stamps, entered to Lebanon through normal “channels”, yet they are counterfeit because either they have what is written on their pack is not really what they are, or even the originator is not the correct country or even the quantity which is written on the box is not the one found in the pills. So what number 5 defined counterfeit are the fake medications that don't have the correct either ingredients or the quantities less or more or excipient. All of those are counterfeit regardless if they are seen by our country as fake or counterfeit or not.”

Moderator: “I'm going to ask you about the other products in a minute.”

S1 (sure, confident, serious): “They are products that don't provide quality assurance at any level of their production of their pill from the moment of selection of raw material to the moment of delivery passing by the SOP according to which it was produced, the quality, the quantity, and the identification of the raw material that has been put in it, plus moving into storage, delivery, etc. Sometimes, these are sub-standard kinds of medication that wouldn't provide safety and efficacy they are supposed to provide and we have seen counterfeit meds that have been produced in high-quality labs meaning those are production facilities to produce other kinds of chemicals and we have seen products polluted by other kinds of chemicals, toxic ones that are not supposed to be there.”

Moderator: "When we say sub-standard, do we consider all sub-standard counterfeit?"

S1 (hesitant at first, then confident): "All sub-standard are counterfeit, no. All counterfeit are sub-standard, yes. But not the opposite."

Moderator: "You said you have products that are coming from the well-known sources and you know that these are products that are of proper or adequate qualities, but they're coming in and the country is considering them counterfeit. Are we talking about the parallels?"

(everyone says no)

S2: "There are some medications in Lebanon that aren't found here."

Moderator: "How do they get into the country?"

(people are a little hesitant on this; they are not sure)

S2: "Some pharmacists or some people...."

S5: "There are known pharmacists that get them."

(S2 agrees)

S5: "And doctors know about this, and actually, if I have let's say medication that is for my own use without a hologram on it, but I forgot it on the shelf in the pharmacy I might be penalized."

(people agree)

S5: "because it's like I'm having counterfeit drugs."

Moderator: "Why wouldn't you have a hologram?"

S2: "If you bought it from abroad, from any other country."

S5: "Something that is not available in Lebanon and that you get in your pharmacy. This one pharmacy has it and all doctors know about it."

Moderator: "But she has these products with no hologram on it."

S3 (confident, dissatisfied): "Actually, I know how she's getting the products. The patient brings a prescription from the doctor and a copy of the identity card and then she will send them to Europe. She will buy the product as if it is under the patient name."

S5: "But we cannot do it here."

S3: "But she can."

Moderator: "Why can't you?"

S5 (slightly angry, dissatisfied): "We would be penalized."

S2 (dissatisfied): "Because this would be considered according to our Ministry of Health as counterfeit medication, although this medication..."

Moderator: "But who's allowing this person to get these medications?"

(some say they don't know)

S3: "They have privileges."

S5: "They are above the law."

S1: "The Ministry."

Moderator: "So is it the Ministry of Health?"

(everyone nods, agrees, says yes.)

S5: "I wish we had all the products that aren't available in Lebanon, for their own sake."

Moderator: "Would you refer your patients to go to this pharmacy?"

S5 (not happy that she's obliged to do that, frowning): "I have before. We have to. We are obliged."

S2: "We have to."

S3 (sorry): "At the end the patient needs to take it."

S6 (dissatisfied): "It's like a monopoly for certain medications."

S5 (dissatisfied, bitter): "And they are overly charged. 4-5 times what they're worth. You sense the bitterness in all of our voices."

Moderator: "This is what I want to sense. This is what I want to know from you. What is the extent as far as you know of counterfeit medicine in Lebanon? Do you have a percentage? Do you know how much of the products that are available are counterfeit?"

S5 (serious): "I can tell you in points. When I started practicing pharmacy, people on vespas would come in and ask me if I was interested in buying Xanax off the books at much lower price and I would kick them out, so they eventually did not come anymore, but this is one side. They would visit the pharmacy and ask the pharmacist if he's interested in putting counterfeit products in their establishment."

Moderator: "So this has been going on for long?"

S5 (serious, confident): "Yes, of course."

S2: "Of course, long ago. When it was war times. It was very bad."

S5: "Then another aspect depends on the location of the pharmacy and this is really important. When a pharmacy is in Tripoli or in Bekaa, which is the north and the south and on the border with Syria, you have medications in Lebanon that you have never heard of."

(people laugh)

S2: "Exactly"

S5: "With chemicals that have been banned for years."

(people show they agree by nodding)

S5: "But they do exist."

Moderator: "Do you see them more in the north and south?"

S5 (sounds sure of information): "In the rural areas and Syrian border."

Moderator: "And in Beirut?"

S5: "More and more now with the Syrian conflict. People are asking for those medications who aren't in any book, that don't have pharmacopeia."

S1: "But the reach of counterfeit medication to the Lebanese market has been developed now. So it's not only through the motorcycle; it's through even sometimes they penetrate legally through containers with... I don't know how. Like somebody just lets them in; they hit the market and then they discover they're counterfeit."

Moderator: "Could you elaborate on that?"

S1: "On a large scale, not only the small bag medications where they come on bikes saying we have this, are you interested? Now we have seen more. One of the medication has been distributed through legal channels and then discovered as being counterfeit medicine."

S5: "Plavix is one of them."

Moderator: "This was few years ago?"

(answers to this question were given in serious, confident tones. Not many nonverbal cues except for the occasional dissatisfaction, sarcasm, and bitterness).

S5: "Yes and it was through a Chinese mafia."

S1: "So it's large-scale mafia stuff"

S5: "And it was worldwide actually, not just in Lebanon."

S2: "And pharmacists were the ones who paid the penalty, and they're the one who didn't have any idea about it."

S1: "They asked us how come you bought counterfeit medicine. We said how were we supposed to know it's counterfeit? We got it from a legal source."

S5: "This is why I emphasized in my definition going to the agent."

S2: "But also, I need to add something: there are even some medications that have their own brand name. Unlike Augmentin and Plavix and copies. They have their own name and yet they are counterfeit. And they went into Lebanon through also normal channels and through wholesalers who got this name from nowhere. Just got it and the boxes you can find on them that they are made in UK and this medication is not even found in the UK and after like years of selling them on the market...."

Moderator: "They have a hologram?"

S2 (confident): "They have a specific wholesalers who's getting them, yet what they found later is that all the tests done were fake tests and that these medications are generics more than they are brands. It is not a copy. It is a generic by itself but they're counterfeit. They don't have what is written on the box. What they claim on the box. This is the real change of counterfeit in Lebanon. Since I open my pharmacy in 2000, counterfeit medicine were through these people selling them in bags and this man that you can know from a distance that he sells counterfeit medicine. Now counterfeit is coming through legal channels."

Moderator: "Those channels look like they're legal or is it really through legal channels?"

(more than one person say it is through legal channels)

S2 (serious, sure, confident): “It is legal. It is not a mafia. Nothing. It’s really a legal channel. Went through Lebanon, sold for many months and even years, and by chance one of the labs which is also a university saw somebody in the Ministry and told them ‘Oh, I haven’t been receiving medications to check for many months.’ He was told that the Ministry had got a certificate just a month prior for a medication from your laboratory. And by chance they knew that it’s a whole family. It’s Omeprazole, Metformin, etc. Generics in of themselves, not copies, but products that have nothing to do with what is claimed on the box. Event he manufacturing country, even what is written, the ingredients, all are fake.”

S3: “They are also getting some meds from India and China and they are packaging them in Lebanon in Lebanese facilities and they are registering the product as if it’s coming from Lebanon, as if Lebanon is the originator. It is only secondary packaging while they’re getting them from other countries, and it’s known.”

S2: “Or even they say the meds are made in USA while they come from China with ingredients that are banned. As S5 has said. They are withdrawn from the whole world many years before, and they are written as Made in USA while they are Chinese and everyone knows, yet they are common.”

Moderator: “When you say everybody, who do you mean?”

S2: “From the pharmacist, to the Ministry, to the people who are even taking the medications and many universities are checking the ingredients and they are finding out but no one is doing anything. What they are doing is that they bring a big shipment like 1000 or 2000 items. They bring them, sell them, then they are making them to stop selling them. But it’s already sold and it has been taken. And then they would change the name and the packaging. The same thing is happening.”

S5: “I’ll have to ask you about that later.”

Moderator: “Would you like to ask her now?”

S5. “What are they?”

S2: “Easy Slim for example.”

S1: “Chinese pills.”

S5: “I have never heard of it. It depends also on the region.”

S1: “At a certain period of time, there were people coming back with major side effects like night sweats, tachycardia. And this is what triggered the Ministry to investigate.”

Moderator: “So side effects were reported?”

S1 (dissatisfied): “Yes, but not officially of course. There is no official reporting system of side effects in Lebanon. There is no regulatory agency that takes feedback from the market.”

S6 (dissatisfied): “There is no pharmaco vigilance center.”

S1: “When you’re working with an agent, usually the agent or the scientific laboratory are interested in collecting data from the market.”

S5: “Absolutely.”

S1: “Because they have to give it back to the FDA.”

S2: "If they are reputable agents, but there are some agents that aren't."

S5: "So we're talking about the ones who bring products from Argentina?"

S1: "Not necessarily. More than this distributor specifically. They just put in on the market to be sold. That's it."

Moderator: "If you're talking about this incident, how many importers were involved in this?"

S2: "One importer."

(people agree)

S2: "But very famous."

Moderator: "There were three different names under the name of this importer?"

S2: "Yes."

Moderator: "What happened to them?"

S2: "They are still there and even the medications that were withdrawn are back again."

S1: "In a different name, though."

S2: "Some of them are I think are the same."

S6: "Different package."

S1: "Yeah, refined package."

Moderator: "What happened to them? Did they send a memo to withdraw these products from the market?"

S2: "Yes and they sent their salesman to withdraw."

Moderator: "Where did they put them?"

S4: "They said they had to change something."

S2: "But they were sold in rural areas, of course."

Moderator: "When they usually collect these products, what is supposed to happen to these products?"

S2: "It's the Ministry's role. They have to destroy them."

S1: "That's something important that needs to be noted. These products aren't registered under medications in Lebanon. They are registered under food supplements. This is why it is easier for them because they don't fall under the medication laws."

S2: "There are products that fall under medication; they went through normal channels and they were re-distributed."

S1: "That's true"

S2: "But you're right, all diet products are under food supplements. But I want to say something also that not all counterfeit meds are only sold in pharmacies, there are many

other places, such as dispensaries or even you know, gyms where they sell proteins, hormones that are banned.”

Moderator: “And hormones go to gyms through pharmacists?”

S2: “No, trainer.”

S5: “But the trainer has to get those from a pharmacy, right?”

S2: “No, not necessarily.”

S1: “No, not really.”

S2: “What they sell is something we don’t sell in our pharmacies. It’s not only the products we sell. Those are products not found in our pharmacies and they’re also illegal.”

S5: “They have their proper channels.”

S2: “Yes, some of them bring them through Iran. Many of these.”

Moderator: “So if we want to give a percentage, how much do we have?”

S5: “We have no clue. For a number, to give you a number, no clue...”

S2: “but as I’ve seen lately, in pharmacies, the normal counterfeit we used to identify and know is decreasing dramatically.”

S5: “Yes, because of the OPL.”

Moderator: “What is the one you used to know? What do you know?”

S2: “We used to have Xenical, Plavix, Xanax, all of those were copies. Now I don’t know if I’m not seeing them because people don’t offer to sell them to me, but I believe that their sources are being stopped. I don’t know...”

S5: “With major exceptions. I don’t know if the inspectors can reach all the areas. They’re not welcome in certain areas.”

Moderator: “So inspectors aren’t going all over the country?”

S2 (dissatisfied, sorry, matter-of-factly): “They can’t reach. You know there are places you cannot reach.”

Moderator: “The OPL cannot reach some parts; how about the Ministry of Health?”

S1 (dissatisfied): “It’s worse.” “Inspectors should inspect all, not specific areas,... the approach should be standardized and with appropriate approach.”

S2 (hopeful): “Our order is much better. They treat most of the pharmacists equally. The Ministry have political issues.”

S5 (sure, hopeful): “I’d trust the OPL much more than the Ministry.”

S2: “And the OPL is the one making the major changes in pharmacies. We aren’t talking about places OPL cannot go through, but where they can, they are doing work.”

S5: “I’ve seen the OPL work better than any of the ministers. Dr. Hassouna is doing a great job. I don’t think he’s sleeping this guy.”

Moderator (addressing S6): “Coming from your area of practice, which is at the hospital, what’s your experience with counterfeit medicine?”

S6 (sure, very confident, serious and informed): “Well, fortunately, throughout my three years of experience I didn’t see any counterfeit medications going into the hospital. I’m working at a hospital. We might have a channel or a policy that could prevent these things, for example starting from supplier evaluation. We go through a very strict procedure to do supplier evaluation. To put first-line suppliers. I won’t hide that sometimes we fall into shortage. One supplier tells us they can’t give us this medicine, so we go to our second-line supplier, but what we are doing is a regular evaluation of these suppliers and second thing also: once we receive the products, we do a very strict checking starting from the physical appearance of the medication and also to the content. And then if any medication or mainly the generic ones, because they are the ones that could be counterfeit medications rather than the brand ones, we go through another process. We put the med on a probation period. Throughout this period, we will ask the physicians and nurses to report any unusual response from the patient and we will keep this into our files.”

Moderator: “Because you got it from another channel?”

S6: “Because it was either through a second-line supplier or because we haven’t got meds from the company previously. But we want to make sure that the company has something called ‘bureau scientifique’ or “scientific office” because if we want to report any unusual thing, any pharmaco vigilance issue, we want a source to be reporting to. Again another thing we have is another form filled by the nurses for any product that is present at the hospital called the Nonconformity Form, and there’s the Adverse Drug Reaction form. I think all of those give us an idea whether the medicine is doing the job or not. Beyond that, I don’t know if there’s more things we can do, but fortunately until now, we haven’t faced any discrepancies, expect for some batches that came and didn’t do the required efficacy and fortunately we have a recall system, so we can give back all the lot to the company and then re-evaluate the supplier.”

Moderator: “So you actually had the system working.”

S6: “Yes we have everything documented.”

Moderator: “So how do you test the content?”

S6: “We test the product physically. Products containing solutions with changed colours with particulate matter that is sedimenting so all of these can be suspicious and we can resend the products to the supplier. We don’t accept such discrepancies.”

S5: “So you are doing the job of the Ministry.”

S6: “Yes, because to be honest, I receive the specification studies, the bioequivalence, I will see them and see the stamps, but I cannot believe everything I’m seeing.”

Moderator: “Why is that?”

S6 (perplexed): “Because every now and then I find products with all the required documents, but I still don’t know if it’s logical to go through all these studies as it should be and in a short time. I don’t trust them. So I prefer to be more suspicious in every product that will be accepted. That’s why all the companies know that it’s very hard for me to accept a new product unless I’m 100% sure.”

S1 (sure): “If I can add something to this, because I had a lengthy experience in formulary access in several hospitals in Lebanon. The major university hospitals have their own

checking system and these are less than 5 hospitals in Lebanon, and all other hospitals. For vials and injections, you can tell from the physical appearance there is something bad.”

S6: “But for the tablets, you can’t.”

S1 (dissatisfied for the most part): “For the tablets, it’s the patient trying the medicine so it’s the patient who’s being the guinea pig. It’s unfortunate because we don’t have a national lab, there’s no trust in our legislative system and MOH needs to make sure that the right quality of meds is entering the market. But the majority of hospitals don’t have any kind of assessment. It’s all about price. Give me your lowest net price, I will use your product and it’ll be the exclusive in the hospital. It’s a price fight.”

S6: “And you can conclude that from the surprise of the med rep in front of you. You need all these documents to be accepted, they ask? I’m giving you the best offer, you have a history with our company, we are reputable, and they get surprised once I ask all these questions. I even have a checklist: I must see that it went through the Ministry, etc.”

S1 (confused): “What about the FDA and EMA?”

S6: “Yes, but I’m facing some difficulties with that, actually, with some generic products. Some of them don’t have those types of approval, so I either don’t accept or I put them on an extended probation period, for example 6 months or one year, as much as I can.”

Moderator: “So when you put them on probation, you wait for the reports on them?”

S6 (confident): “Yes, and I follow them closely. There are different forms. One for physicians and the other for nurses. The latter will report on a daily basis and the physicians gives his feedback at the end of the period but the nurse doesn’t know how to analyze the response of the patient. It could be an ADR to the medicine but the nurse defines it as trivial or normal reaction, so the pharmacist has to have an input regarding the responses of the patient, especially with very important medications such as antibiotics. I would rely very much on a the turf level for example. If I see a t.level of 2 after 6 doses of vancomycin, then it’s not working.”

Moderator: “How do you differentiate counterfeit medicine from the original?”

S4 (confident): “Actually, I can do that through physical appearance. The package, or the pill itself, the tablet itself. That’s’ from a community pharmacist point of view.”

Moderator: “So you actually open the pack?”

S4: “If you can, yes. There’s also the 3D hologram on the package and we check for different printing or different shape of the box.”

Moderator: “Do you do that with every package you receive?”

S4: “Yes.”

S2: “You cannot. You cannot.”

Moderator: “Are you able to differentiate all the time?”

(they are confused, serious, not sure of how to differentiate)

S2: “Not always.”

S3: “Not always.”

S5: “It’s usually through the patient’s response.” (All nodded their heads in agreement)

S3: "It's becoming difficult."

S1: "Yes, it's because they are professionals now."

(S3 laughs, agrees)

S4: "We can prevent that from happening by ordering from the agent."

S3: "Exactly, this is the only way."

S2: "Exactly."

Moderator: "When you say agent, are we including wholesalers?"

S2: "Agent is the agent, the direct one."

Moderator: "But do you have to use the wholesaler, too?"

S5: "Yes, sometimes, but less and less nowadays."

S2: "Even the agents are making us use less the wholesalers, because they aren't distributing to them but directly to the pharmacies."

S5: "And we have a quicker system now, with an online network. We order everything online."

Moderator: "Can you explain that for me?"

S5: "It's an Internet system where you connect to different major wholesalers and at the end of the day...."

S1: "They are through the agent."

S5: "So you enter whatever quantity you want on the computer. It will send it to different agents and you get pretty fast the order that you put in."

S2: "Even faster than if you order it over the phone. And you can do it over the night after finishing all the work."

S6 (asks): "Is this applicable only to community pharmacies?"

S2: "I think to hospitals too."

S1: "But all products are available through this system."

S5: "Only the major ones."

S2: "Yes, only the very major ones."

S6: "So you enter the list and then the wholesaler responds? It will be redirected?"

S2: "Yes."

S5: "Yes, the system, PharmaNet, you only have to enter what you need. You don't need to divide them...."

S2: "The system will divide them and send them to different agents."

S5: "And it will tell you at the end, you have 5-6 agents. And it will give you the amount as well."

S6: "Of the purchase order?"

S5: "I'm not sure."

S2: "If you do it by agent."

S5: "The good thing is that it also has the offers, 10+1, it will show up on the system. It's a good one."

S4: "Yes, and it's updated on a daily basis."

S5: "For years, we had Atroxin out of the market before Eutyroid which is another generic was on the market, and a good laboratory in Lebanon packaged a 100mg and started selling on the market. For years, we used it because it was out of stock of like, 7 years. I was very suspicious. I went to an Endocrinologist and she asked me to switch because the medicine wasn't good. Finally, years later, everybody screamed, and they finally did a bioavailability study that showed that only 5% was being absorbed. There was 100 mg of Tyroxine and only 5% was absorbed."

Moderator: "What about the patients?"

S2: "Many patients had to take it and didn't see results."

S1: "They had to take it because there was nothing else."

S2: "My mom was one of them."

S5 (dissatisfied, disapproving, frowning): "I want to add something: a hospital, a very well known hospital, I'm not going to mention any name, kept on using it because it had a big stock for at least another year, and I was outraged."

(people disapprove, shake heads, frown)

Moderator: "Did they ask for the product to be withdrawn back then?"

(people say yes)

Moderator: "But despite that, the hospital kept on using this product. Who follows up on these things? So I actually ask for the product to be withdrawn and here's where my job ends?"

S2: "The Ministry of Health should follow up on withdrawn products."

S6: "I didn't see anyone following up after withdrawals."

S2: "It's only the agent who does it and it shouldn't be that way, because the agent wants to get rid of the products sometimes."

S1: "Yes, because recalling products is a loss for agents."

S2: "We discovered suddenly that they have been stopped from the manufacturing company, and they are still found on our markets."

S5: "Like Di-Antalvic and Lagaflex."

Moderator: "Is Di-Antalvic still available?"

S2: "Yes, but under a different name. And for Lagaflex, they said sell the stock and then we stop getting it."

S5: “But do you know how many people are addicted to it? It was a major problem. It was like Xanax was out of the market or Lexotanil.”

Moderator: “When you have shortages, do you get people coming to offer you alternatives?”

S2: “Sometimes. But usually people would come when there’s shortage and they would remind us about the generics that can be used as a substitute.”

Moderator: “Would these alternatives be legitimate medication?”

S2: “Yes, they’re registered.”

Moderator: “Have you heard the story about Phenytoin?”

(some say yes)

S4: “Yes, it’s still not in shortage. We can only get it from the famous pharmacy in Byblos.”

S5: “Yes, and at an exorbitant price, but they’re sometimes switching to something else, but usually the other medicine is much more expensive, and not everybody can afford it, or they can get it for 2 Euros from France.”

S2: “Exactly, but if you get it from France and put it in your pharmacy, we are not allowed, and it is considered counterfeit.”

S1: “We have seen pharmacists doing that.”

Moderator: “What about that pharmacist you guys were talking about?”

(people laugh bitterly, shake heads disapprovingly)

S2 (outraged): “She puts it in her pharmacy and she gives you a receipt.”

Moderator: “Is it on her shelf?”

(S2 and S5 say yes, vehemently)

S3 (sarcastic): “It’s on her shelf, but in the basement.”

S5 (sarcastic): “She’s called the Goddess of Pharmacy. I’m very jealous.”

(everyone laughs)

S1: “But we have seen pharmacists doing it.”

S3: “Out of curiosity, I worked there for one month just to know how she is selling these meds. Because my father was diagnosed with cancer and he needed one product and she was selling me the pill for 10\$. He needed 8 pills per day, because it’s based on body surface. Every day I need 8 pills, 80 dollars, for 6 months. So I bought the product from Cyprus for 100 euros. The full pack.”

S5: “How many tablets?”

S3: “It was 120.”

S5 (dissatisfied): “I’m telling you. It’s a business.”

S3: “I had to do it.”

S5: “But it has nothing to do with counterfeit products. And that pharmacist has 4 kids. On Sundays she’s at the pharmacy. She’s a workaholic.”

S1: “She’s a businesswoman.”

S5 (dissatisfied, disapprovingly): “And she has a dermatology section now.”

S3 (disapprovingly): “She doesn’t treat the patient as a patient.”

S1 (disapprovingly): “It’s a number. She’s a businesswoman.”

S6 (sorry to say): “But you know, practically speaking, most of the time, she’s our savior, our last resort.”

S5: “Let’s face it.”

S1: “Again, I think this takes us back to the legislation issue where you know there are certain molecules that are flooding the market with different names and other molecules that are just not available. So, I do believe for example, and correct me if I’m wrong, diclofenac: how many names are there under diclofenac? Do we really need more diclofenac and metformin on the market? So, I think instead of giving more approvals for the same molecule....”

S2: “120 generics for omneprazole. Why? Why do we need all this?”

Moderator: “Who controls what generics are available?”

S2: “Ministry of Health through the registration,. But there is no law or anything that says that if we have, for example, 5 generics of the same medicine, it’s enough on the market, or 10.”

S1: “And there is no prioritization of molecules less available of other molecules, so it’s really first-come-first-served, you get there first, you get more.”

Moderator: “Do you guys at the hospital use more generics than trade?”

S6: “At our hospital, in every hospital, the trend is towards getting only the brands to get the best quality but practically speaking you cannot do so. At my hospital, and maybe that’s a strategy I shouldn’t be talking about, but we’re usually going with the trend toward having brand and at least one or two generics. Why? Because in the hospital it’s different than the community. In the latter you can say to the patient you don’t have the med and ask them to go to another pharmacy. At a hospital when there are critically ill patients, you cannot say I don’t have the medication, so you always have to have alternatives, so we try to choose the best generics but we try to have always at our stock or always deals with companies to get the medications as fast as possible. So, yes, we have brands and generics.”

Moderator: “How reliable is the hologram?”

S5: “It depends on the agent. So it’s not the hologram that will make the pharmacies comfortable with the medication.”

S2: “It is the sources.”

S5: “It is the sources, the lab that the agent is
ing from.”

S2: “Even, it’s better, you know, for instance vaccines, these things that need refrigerator, if the medication has a hologram yet is not being put in specific storage for places, it will lose its efficacy, so according to me and my strategies, I only get these that need special storage from direct agents.”

S5: “They bring them through cooled vans.”

S2: “There are some drugstores that have the same strategy but not all of them and I feel that even the drivers make a difference, if they are educated. They know what they are dealing with, more than the motorcycle with all the sun around them, not really very... they know what they are handling. It is very important for these people who don’t have to be pharmacist but aware that they are handling things that would affect the medication and its efficacy.”

S5 (confused, genuine): “I have something to say. How do we proceed to destroy vaccines that have not been used? I have a stock of vaccines since... it’s been in my pharmacy... I called the Ministry, they said get rid of it. I said how do I get rid of injections with viruses or attenuated viruses? There is no system.”

Moderator: “The WHO doesn’t have a recommendation?”

S2 (disapprovingly, dissatisfied): “Here in Lebanon, there’s nothing.”

S5: “Nothing, and people ask us. Let’s say expired medications: can we bring them to you to destroy them? And I say, oh my God, they say we are not going to flush them down the toilet because it’s going to go to the sea and pollute it; they have a point. Some of the people are educated, not all, but it makes you realize that throwing an expired box in the garbage is very common. Throwing injections that drug addicts can use later on, use the syringe and stuff, they’d be perfect. We have no system.”

S2 (sure, confident): “I’ll tell you why also; I once asked a reputable agent: MERSACO. I told them there’s something wrong with your system. They were sending duplicates of orders and sometimes the meds were so expensive and they refused to return them it was their mistake. They told me that according to their agent outside Lebanon, they have a certain system: once the medication is out, it cannot come back, because they have system whereby they bring it packed and whatever. I said how come? He said you cannot know how much place we’re using for expired medications. It is an extra expense for us because neither the Ministry is letting them destroy in a way, nor they can destroy, so they are keeping all expired medications and paying rent for places to keep them.”

Moderator: “The expired medications they still have in stock or the ones returned from pharmacies?”

S2: “Both.”

Moderator: “Why don’t they recall the expired vaccines?”

S2: “We sometimes forget to return them, and sometimes things that need fridge, they refuse to return them.”

S5: “Yes, those are non-returnable, non-refundable.”

S4: “Even vaccines.”

S5: “Yes.”

S1: “Anything in the fridge.”

S6: "I don't know if it's the same in community pharmacies but in a hospital setting the Ministry asked us to do lists of all expired medications that are present in our pharmacies."

S2: "We're not supposed to have expired in pharmacies."

S6: "We did lists, we put 5 employees for 2 days doing the list hoping that there will be certain procedure after that for discarding the medications, but the Ministry came by, took the lists, and there was nothing, so now we're not doing the lists anymore."

S1: "If I can comment on something: awareness in the market is not at all the case. I think the OPL a few years back played the role on increasing awareness that cheap medication is cheap and this was the highly the peek time of you know the market being flooded with counterfeit, substandard medication, everything coming from Syrian war. There were some things given as donations to Iraq then snuck back into Lebanon in weird ways."

S2 (laughing sarcastically): "Medications from our country to Iraq, but they were sneaked back."

S1 (confident): "At that time, people used to think that these medications are cheap just because there are no taxes added to them, and patients used to go to pharmacies selling the best prices, not aware that for example a certain medication cost LBP 100.000 and we need to sell it for LBP 120.000; The same medication if it's counterfeit is being delivered for LBP 100.000 and then sold at the cost of 80.000, so it's less than the cost of the original medication, but the patient is paying less and then coming to the pharmacists who don't get these medications and saying we are robbing them. We explain and say that there's something fishy. They started the campaign of cheap is cheap and that started creating a little awareness."

S5: "There are patients refusing to get an alternative to Augmentin. They insist they want the original, even if they have to pay a dollar after a dollar."

Moderator: "Why do you think?"

(answers were said in sure, confident tones)

S5: "Because they're aware of their health and they don't want to...."

S2: "Some, not everyone."

S1: "Some, yes."

S5: "But more and more are like this."

S6: "Depends on the area."

S1: "Culture, too."

S5: "Just one more thing: Marvil is on the market and other names for osteoporosis and it was selling like hell because it's half the price from the original medication. Less than half (agreeing with S2 who said that). And so many doctors were prescribing it. It has the hologram and was approved. I had a patient who had osteopenia who was taking it and the medicine was for osteoporosis. So anyone who asked me 'should I go for the generic?' I said no."

S1: "As I said before, all counterfeit are substandard but not all substandard are counterfeit. This is a typical example."

S2: "But I believe this is counterfeit."

S1: “No, it is available in Argentina and it is registered in Argentina so it’s not counterfeit, but it’s low-quality medicine.”

S2: “But how does it come here?”

S1: “If you go to the Ministry, there’s no file for Marvil. It doesn’t exist.”

Moderator: “What do you mean it doesn’t exist?”

S1 (shrugging, smiling sarcastically): “It’s not there. They registered overnight and it hit the market and is reimbursed by the Social Security. Nobody knows how.”

S5: “Another worst case scenario because Marvil you can follow year after year. Plaxiv and Nefazan. How can you measure the bad effect? Unless you have a stroke.”

S2: “But even Marvil, I know many of my patients who have went into a hip fracture from the use of Marvil.”

S5: “Because the doctor told them to do that. Because they trusted the Ministry of Health.”

S1 (laughing): “No, because they have been flying back and forth to Prague.”

(everyone laughs)

S2 (laughing): “Exactly. Because every 3 months they have a trip.”

S5 (sarcastic, laughing): “A family trip.”

S3 (confident): “I still have one thing to mention that another type or way that counterfeit products are reaching the patient is through doctors themselves, so basically dermatologists and plastic surgeons and the use of fillers and Botox. Some of those are counterfeit. Many physicians are using Chinese products but they are putting vials in other packages.”

S1: “I’ve seen personally Viagra counterfeit being put in the original box.”

Moderator: “The sachet you mean?”

S5: “The pharmacist does that?”

S1 (smiling bitterly, sarcastically): “Yes, because usually here they sell it by pill, they don’t sell the full box, so once the original box is empty, they bring the counterfeit and put in it.”

S4: “Doctors are also doing it, because directly the company sells the physicians....”

Moderator: “Is it legal to do that? This is being done against the law? The physicians are doing it?”

S5 (dissatisfied): “I can give you a simple example. I have my pharmacy and I have my kids. Polio vaccine, it would have cost me LBP 5.000 to vaccinate my kids, but I said no, it has to be done by a paediatrician because I’m following the book here. I went to the doctor and he’s a friend and he had the same drug; I paid USD 80, and my kid was traumatized because it’s an injection. I could have done it.”

S1: “And it’s illegal actually to give vaccines, it’s not legal to give vaccines to the physicians and the latter selling it. No one should sell vaccines except the pharmacist.”

S6: “But this is not happening.”

S2: “It’s not happening.”

S5: "HPV. Gardasil is directly sold to the..."

S2: "No, not the doctor; let me tell you..."

S1: "No, they bill it to the pharmacy first."

S2: "Exactly. They have two or three pharmacies all over Lebanon. They will bill it to the pharmacy but the latter will never see it, and deliver it directly to the doctor. This pharmacy will take 3% to pay his taxes and get some for themselves and that's all."

S5: "And there is an offer of 3 plus 1 that the pharmacist isn't taking advantage of."

S2: "We are not selling any vaccines because of this."

S1: "I had one patient who asked me to bring Gardasil. This was 3 + 1 but the 1 I'm going to throw it out, the dose is 3."

S2: "But ask for the Botox you were talking about. It's not counterfeit, there is Chinese Botox on the market."

S3: "But there are not registered. I'm sure. I know because I work in the company."

S2: "Ah really? And how are they selling it?"

S3: "But we are facing this dirty competition."

S2: "But I hear they're giving a receipt with the drug. How are they selling it with a receipt if it's not registered?"

S3 (sarcastically): "I don't know; I'm not the brand manager. But that's what I knew last week at the company."

Moderator: "What is your company doing with respect to this?"

S3 (unsure, confused): "I actually don't know a lot of details about this, but I know that we are facing dirty competition at all levels on the market because the physician would prefer to buy this Chinese product and would sell it for more."

Moderator: "Is it doing what it's supposed to?"

S6 (disapprovingly): "Sometimes you have damages."

S2 (sorry, dissatisfied): "They don't care."

S5: "I've been doing Botox, and my dermatologist once used the generic on me saying it's as effective as others. And I can tell you that it didn't work. I told him and realized and decided never to use it ever again."

S2: "He's a good one."

S1: "He's one of the few honest ones."

S3: "The Korean currency isn't registered in Lebanon, and we have Korean products in Lebanon. How can this be?"

(Indistinguishable chatter)

S2: "We were saying that Botox is reimbursed."

S1 (shocked): "Really?"

S2: "It has other uses."

S3: "They are indicators for Hyperhidrosis"

S5 (sure): "Oh yeah."

S2: "Also urologists use it."

Moderator: "What is the role of the pharmacist? What can you do?"

S5: "The role is major. Our concern as community pharmacists is the community. We don't really care about the Ministry of Health, who's gaining more money, losing more money, etc. Our concern, and I think I talk in the name of all of you is our patient's health. If we're not sure about a generic or any medication, our role is tell the patient. Like the Marvil. Should I switch to the Marvil from Fozamax? No, Mrs., you should not. Should I take that or this?"

Moderator: "Would you tell them why?"

S5: "Tavanic is USD 30 a box. There was before Lomax at USD 1. It's Indian and I refused to even have it in the pharmacy. I mean USD 1 for something so expensive and valuable, it's better to flush it down the toilet."

S1: "And you're contributing to resist."

S5: "Exactly. So it is our role and thankfully, they know that we're not after the money. And we tell them, if you can't pay it now, pay it later. You can pay half the amount, pay half of it, but do not take the other one."

S4: "I think also the Ministry of Public Health should have a central lab to test drugs. Our role lies in refusing to buy or get some drugs from wholesalers."

S2: "But it depends on your situation. In a hospital pharmacy, it's easier. There is no contact with patients. People don't always trust you. Second, it's our job and we are getting our income from it. There are medications I know we shouldn't sell. It doesn't have any calibre, yet I have been asked for. I cannot stop selling or even the diet products. Let's face it. I'm telling you the truth. According to me, if you ask me a question, I will tell you the truth but I must say there's a business part to it, we need to continue our life."

S5: "This is where I tell you our role is to make the patient aware."

S1: "But it's his decision."

S5: "If they want the product, take it. We as his pharmacists need to help him understand."

S6: "I think in a hospital setting..."

S1: "It's easy..."

S6 (disagrees): "No, it's not easy at all. It's hard. I'll tell you why. It's a multi-disciplinary approach because not only do you have to give a safe option for a patient; you also need to give a safe option for physicians and a cost effective approach for administrators. You have to give also a safe option for the nurses because the nurses will be hearing all the nagging and seeing all the adverse effects happening. The doctor might have some conflict of interest with the company. You have to please the doctor but also preserve the good quality of the product. We are seeing it in our PNT committees where we have the financial, medical and nursing parts. So, I think it's even harder and you have to also preserve not only the safety of the patient but your credibility of a pharmacist. Because

faced with any major dangerous effect or discrepancies the physician will come and blame you.”

Moderator: “How does the public perceive the role of the pharmacist?”

(people laugh)

S5: “It depends on the setting of the pharmacy. If it’s a community pharmacy in a living area, there is a channel of trust that is build. If it’s a highway pharmacy, it’s different.”

S2 (sorry, disapprovingly): “Pharmacists are seen like supermarket. But yet, I have to say something: it’s the pharmacist himself that makes a difference, yet as I have been saying since one month or three weeks when this decree has been written for the decrease of our income, I told them ‘You know when some of my patients know that I teach at a university, they say oh really?’ You feel like they think I’m not qualified. Let’s forget if I teach or not. I have the same doctorate degree as my colleagues who teach. Maybe as community pharmacists, perhaps because we talk to them, they feel like we are businessmen. They have in their brain the concept that we are there to make profit.”

S5 (sure, confident): “Maybe the first time, then we make them change their mind.”

S1: “Not always.”

S5: “We are the ones they call when they have an emergency because the doctor isn’t answering.”

S2 (dissatisfied): “Exactly. But why do they go to the doctor’s and wait 1.5 hours to go inside to sit there for 10 mins and they have many questions they were afraid to ask the doctor and then they will come, if they have just two before them, they will nag saying ‘I have my car outside.’”

S5 (sorry): “This is the Lebanese mentality.”

S2: “Exactly. Because they don’t put us on the same standard. This is the thing. Why would they prefer sitting there and not nag and at our pharmacy they ask us 10 questions they should have asked their physicians for free while they would have paid their physician a lot of money.”

S5: “And then they ask for a discount.”

S2: “With all this, and they also need to take some of our profit, which is very little in comparison to all the other business.”

S1: “But this is of us too.”

S3: “Because of some pharmacists.”

S5: “I’ve been a pharmacist for 20 years in Lebanon; it is just this year that I put the ‘pharmacy sign up because I’m finally proud that someone is representing me, because I was ashamed before to be like the other pharmacists.”

S2: “You’re right. The OPL these days are working hard, different than all mentalities that passed before.”

S5: “They’re still way behind.”

S2: “And now our Ministry is making our life difficult...”

S4: “As S2 said, being in a residential area, having your regular patients, you know them and they get to know you, they will call again every time they need a question answered before they go to their physician and after for any counselling tips after buying or dispensing the medicine. This is a major role, and procuring services like blood pressure or blood sugar measurement.”

S3: “Being ‘out of the community’, I know a lot consider pharmacies a supermarket. That’s my major concern if I ever decide to open up a pharmacy. Some pharmacies are driving the profession in that direction.”

S4: “This was a major challenge for me before opening my pharmacy but the way you interact, present the pharmacy, the whole setting, allocation of products, medications, etc would make a different.”

S3 (hopeful): “You have to do the effort to change the perception. It exists but we have to change it. Working in the business development department, we make sure to bring new products that are from reputable sources, starting from the companies where they are based. We don’t deal with companies from Argentina, China, or India. Never. Only European or American products and that’s it. That’s how we try to stay loyal and trustful.”

S1 (confident): “I think an issue that should be dealt with is the level of awareness of the physician about the harm that substandard medication can do, especially nowadays that we see major American and EU companies, major brands going for manufacturing in India, China and these less costly products in terms of manpower. What the physician do not differentiate is that having a major company produce their drugs somewhere less costly is not the same as having products directly from those countries.”

S2 (sure): “What if it’s controlled? Under license means controlled.”

S1: “But if they go and investigate, they will know that there is supervision by WHO, it’s under license, it’s under control, etc, they would know that the final product is rarely from India. They go and they put the packaging from Europe most of the time, from UK, France, Italy, etc. And the physician needs to understand that this is a product that has been done under close specifications and supervision. Other medications produced there might not be under any supervision whatsoever, though. This is what the general community, the lay community do not understand.”

S3: “I have one point to add. Now when you want to register a product in the MENA region, the Gulf, mainly Saudi Arabia, UAE, etc.. They ask to go to the site itself and see where the product is being produced and how they are producing it, they go from the SFDA, they go there and inspect.”

S6: “The SFDA is much harder on them than the FDA sometimes.”

S2: “Some medications in the Gulf are much more reliable than medication in this country.”

S1 (sarcastically): “We have no reliability at all, actually.”

S2 (laughing): “Exactly.”

Moderator: “If I want you to rank 1-2-3, where does the pharmacist fall? Physicians, pharmacists, nurses, nutritionists, etc?”

(people ask in terms of what)

Moderator: “Trust.”

S2 (confident): “We are trustworthy.”

S4: “I’d say we’re still 2.”

(The majority agrees they’re at number 2)

S5: “I’d say 1 because otherwise they wouldn’t be coming again.”

S3: “They have to come.”

S2: “They are some people trust as number 1. There are 10% who might rank us first but the 90% rank us second. A lot of people go get a prescription and check with the pharmacist. A lot do not trust what the pharmacist says, when we offer to call the physician and check. Very few are the ones who do.”

Moderator: “Would you call the physician anyway?”

S2: “Yes, sometimes I do.”

Moderator: “When they ask you not to call, you call anyway?”

S2 (disapprovingly): “I do, but it happened many times with me, the physician was not willing to change anything, and he was giving two highly interacting medications. They would say no it’s not that much of an interaction. I would say there is a study on that and offer to send it by e-mail, but they wouldn’t listen to me.”

S6 (dissatisfied): “They always hide behind the fact that they are seeing a patient and diagnosing them instead of the pharmacists who treat the patients theoretically. However, with the evolving role of pharmacists, as clinical pharmacists, the physician is seeing that the pharmacist is even present as him with the patient and the pharmacist is not only seeing numbers or theoretical interaction. They have the clinical input or analysis too.”

S1: “In the community 90% of the time the physician doesn’t acknowledge a mistake in a prescription.”

S5 (sarcastic): “But if we’re talking about ranking, how they see us, definitely number 1. Physicians might see us number 6 or 7.”

(People laugh)

Moderator: “What is the role of trust? Is there trust?”

S2: “For patients to come and buy their meds many need to trust.”

Moderator: “Is there trust in your practice for you as pharmacists?”

S5: “As long as we’re dealing with reputable companies and good agents. We base the relationship on trust.”

S2 and S6: “It depends.”

S5: “Not all pharmacists are like the ones sitting here.”

Moderator: “What is the situation for the other pharmacists out there?”

S5 (sorry): “Unfortunately, a lot of those pharmacists should not be called pharmacists.”

Moderator: “How many of those are there?”

S1: “Majority.”

S5: "A lot."

Moderator: "If you are in the city of Ashrafieh, surrounding you, how many practice like you and how many don't?"

S5: "A lot are not pharmacists."

S1: "The majority aren't pharmacists everywhere."

S5: "A lot of pharmacies don't have the owner supervising, so they have employees that could have a degree or not and who really don't care what is happening."

S6: "Sometimes the patients trust those people more than the pharmacist, because they are there all the time."

S5: "Someone brought it up, that it's the pharmacists' mistake to begin with. If we are seen badly by the community today, it's because of mistakes that have been made in the past."

(S1 and S2 agree, people nod)

S2: "The scandals are destroying the image of pharmacists. The problem is it does not highlight the source of CFM, or drug supply chain, but only accuses pharmacists ..."

Moderator: "Who should be responsible for screening counterfeit medicine?"

S5 (shrugging): "MoPH should be responsible for screening counterfeit medicine, but that's non-existent."

S6: "There should be competent people judging whether the products are good or not."

S2: "Because it'd never be fair to judge some people and some other aren't judged. This thing would be unfair for the ones who, although they're making mistakes, but it's unfair. Even we're fair to everyone, or let it be like it is."

Moderator: "If the patient ends up with counterfeit, who is to blame?"

S5: "The pharmacist."

S2: "Legally, it's the pharmacist."

S1: "It happened in one of the hospitals here. There were counterfeit medications and even though the pharmacist had the proof she was not the one giving the final approval of buying the medication but once the med had been found at the hospital, she was the one brought before justice. Fortunately, the owner of the hospital took the responsibility."

S6: "Meds are always billed under the name of the pharmacy."

S2: "By putting somebody in your pharmacy even if they're pharmacists and they're the ones buying and it happened to be counterfeit medication, it's the owner of the community pharmacy who would be punished not anyone else."

Moderator: "So what should you do in this case?"

S6: "Be more aware and supervise."

S2: "Check what's entering your pharmacy."

(people agree)

Moderator: "So can you or can you not stop counterfeit medicine?"

S1: "In your own pharmacy you can stop CFM"

S5: "I have my pharmacist that I trust and let's say I go away for a week. This person can during this week sell whatever they want off the record in my pharmacy."

S2: "You don't even one week. Two hours are enough."

S1: "If you have a stock on the system, you need more than that."

S5: "No, no, he or she will put it in their pockets."

S1: "We've seen pharmacists put counterfeit medication in their cars and waiting for certain patients to come by so that they can give it to them."

(people nod, shake heads, disapprovingly)

S2: "It can happen and it's not very easy to be aware of everything happening in your pharmacy."

Moderator: "What you're saying here is that someone can put something in their pockets and sell it in your pharmacy."

S5: "This could happen anywhere."

S2: "Yes, black markets are found anywhere."

S5: "We have a major problem in problem where too much responsibility is given to a pharmacist. We are practically doctors (jokingly)."

S1: "And not enough rights."

S5 (dissatisfied): "You know, so many newly OTC drugs in the US have been over the counter for years in Lebanon just because people cannot access a physician very easily. They don't have the money to pay a consultation for a gird or ulcer or whatever, but unfortunately, you have pharmacists who don't know their limits and go on prescribing medications."

S1: "If something happens to the patient, there is nothing that can be done. Nobody. Let's say a hypertensive comes to the pharmacy. He doesn't know he's hypertensive; the pharmacist prescribes something based on blood pressure measurement. For a reason or the other, they trust the pharmacist and the prescribed medicine causes side effects and something happens to the patient, there's no responsibility on anyone."

Moderator: "Even if the pharmacist gives him the medication?"

S2: "Unless his family complains about something. I know some pharmacists who dispensed medications that are on prescription, yet they sued them."

S6: "Are you sure? Wasn't it the physician who was sued?"

S2: "No, because the pharmacist said that he switched the medication by mistake."

S1: "But there's a proof here."

S2: "Because this pharmacist doesn't have connections."

S5 (disapproving, not happy): "Another anecdotal story: a man comes into my pharmacy with a scribbling of the doctor of something With +. I read it Concord + to the husband and I asked if the wife was hypertensive. He said he guessed so. He didn't know. Still, I

took the extra step of trying to reach the doctor on his personal phone, he didn't answer. So I said I wasn't over God, so I dispensed the medicine and sent him home with the medication. Then finally the doctor calls me. I asked him, he said it's a vitamin called Genesis plus, and I was screaming over the phone. So I ran to the woman with my blood pressure machine and I took it away from her, and I checked. She had already taken a dose. But also, there should be better channels of communication between doctor and pharmacist."

S2: "I agree with you 100%. I always say we have to have to have prescriptions typed. We are not here as someone whose job is to try to understand. Patients ask us if we take courses to learn how to read physicians' handwriting. It is not our job to read those. Let them print them."

S5: "Usually you guess by the combination. It's guesswork. And they never answer you."

Moderator: "So you think the Ministry of Health is handling this well?"

(everyone says no, not at all)

S5 (sarcastic): "It is actually a danger to people's health."

S3: "They are trying, the OPL."

S2 (happy, satisfied): "OPL is doing a great job especially these days, but in a country in a mess, it's not easy."

Moderator: "What about pharmaceutical companies?"

S5 (agreeing): "They're doing a great job, the major ones."

S2 + S1: "Yes, the respectable ones."

Moderator: "What are they doing?"

S6 (confident): "They are setting the ethical standards for their companies."

Moderator: "Do they have this ME code of ethics posted on their website?"

S1: "It's actually distributed to the different orders and all employees in companies. Every single employee needs to sign on it as a commitment that they need to abide. I'm not sure if it's available to the public."

S6: "On conference invites it's written we are abiding by the code of ethics. You cannot bring your spouse, etc."

S1: "So they're limiting bribery attempts."

Moderator: "When they approach physicians, is it the same approach as when they approach pharmacists?"

S5: "Never."

S2: "Travelling, yes, pharmacists do."

S6: "I don't think it's like physicians."

S5: "I have never had a travel invite. I've never been invited."

Moderator: "What do the packages they offer include?"

S2: "For example, you have to buy for USD 5.000, with the extra bonus you get, you get a trip."

Moderator: "A conference trip or a trip?"

S2: "A trip."

S1 (shocked): "MSD? No way."

S2: "Well, yes, they will have a conference in the trip, but it's still a trip."

S1 (assertive): "But there's a scientific agenda."

Moderator: "Let's say the conference is for two days. Is the trip for two days or five?"

S1: "For 2 days."

S2: "Three days."

S1: "One day before, one day after, according to flight availability."

S3: "It depends on the company."

S2: "Exactly."

S5: "This is a small-scale thing I think. Usually doctors are the ones who receive these offers."

S6: "Doctors get furniture for their clinics... from local companies, not multinational."

S5: "Is it local or Italian furniture?"

(Everyone laughs)

Moderator: "You said the Ministry is responsible for screening. How is this counterfeit getting into the country? Who is bringing it into the country?"

S4: "Sea, air and land."

Moderator: "So you see it coming through different channels?"

(people agree)

Moderator: "Easier channels than others?"

(people agree it's land)

Moderator: "Which country most medicine comes from?"

S1: "Directly from Syria."

S5: "China."

S2: "Iran, Iraq, which makes it worse by the way because if it has any active ingredient, by the time it gets here, bye bye."

S1: "Actually I know from trusted sources that when they used to come from Iraq, they used to be put in big trucks, under the trucks. That was before the Syrian conflict. They used to unload the truck, put in a whole in the ground, then put it back in the truck after security officials are gone."

S2 (sarcastically): “Which makes it very effective.”

(people laugh; disapprove)

Moderator: “Let’s say a patient comes to you and says I’m not responding to this kind of medication, and you discover that that is most probably it’s counterfeit, what would you do?”

S5: “First, call the doctor to inform them.”

Moderator: “I’m sorry, is there a process you must follow?”

S5 (dissatisfied, serious): “Not at all (there is no process). We do it on our own. You can be an employee in a pharmacy and say I don’t care, go check with your doctor. As a responsible doctor, you’d first call the primary doctor, then you would check where the medicine came from, from a distributor or an agent. If it’s from an agent, I would call them and talk with the scientific bureau and let them know about this. If it’s from a distributor, I would still call the agent and tell them I got this from a distributor and this is what is happening. Beside Marvil I’ve never experienced anything else.”

S2: “But you know, sometimes you might think the person is not being compliant to the treatment. There are many other ideas that you would think.”

S5: “Given that he has been compliant.”

S2: “Sometimes I would think some medicine is not being effective not because they’re counterfeit but maybe it’s a case-by-case basis where it’s not effective on this particular patient.”

Moderator: “Might they develop some side effects that might have never had before?”

S5: “Yes, sure.”

S2: “It’s not always because the medicine is counterfeit.”

Moderator: “So, if I’m concluding right, it’s not always easy to conclude that this is related to that, right?”

S2: “Exactly and it’s not the first thing we’d think of. If I already know the source, the origin, etc, I might not know, but with Marvil I wasn’t shocked when I learned it was counterfeit.”

S5: “But didn’t you call the doctor back then to report side effects?”

S2: “I did, but many patients already were....”

S1: “You know what the doctors used to say? They would say it depends on whether they measured it on the same machine or not, on the patient too, there are different bodies, etc.”

Moderator: “At this point we’re talking about Marvil, if this is the case and we’re suspicious and you contact those people. What happens next?”

S5: “Some people say we cannot afford it, and they did, and they kept on taking Marvil. I told them don’t take it because it’s like wasting LBP 24.000.”

S2: “I used to tell them to take Calcium instead of taking Marvil.”

S5: “This is our input. This is not working. This is not the medication for you.”

Moderator: "So you knew it was counterfeit or you had a hunch it was counterfeit?"

S5: "At first we didn't know."

Moderator: "What about the package?"

S5: "The package had all the information on it, said that it was reimbursed, approved, etc..."

S2: "They would never give them Nefazan first; they would prescribe something and then switch them to Nefazan if that didn't work. They knew it wasn't that good. And this happened from the first day Nefazan was on the market. Everybody was suspicious."

S5: "Other generics are now competing with Nefazan."

Moderator: "Is the Canadian competitor of better quality?"

S1: "Canada is more of a trusted source than Argentina."

Moderator: "Do we have respect for patency in Lebanon?"

(people say no)

Moderator: "So local manufacturers can produce generic products? Does this create a problem for you as practicing pharmacists?"

S2: "It doesn't but it creates suspicion. When the product is being manufactured after 20 years of the original brand, I feel it's normal to have generics that are less expensive. But when you have this brand that has been on the market for less than 1 year and then you start having many..."

Moderator: "Within one year you have generics coming out?"

S2: "Yes."

Moderator: "Who tests those generic products?"

S1: "Certificate of analysis is what's required."

S2: "They are asking for CE, though, aren't they?"

S6: "They also ask for specification studies, but it's just paperwork, not more."

S1: "Yes, just paperwork."

Moderator: "Do you know where those studies are done?"

S6: "Depends. Sometimes you have a certification from a certain country; sometimes you have a company that did its own certification. So, it depends."

S2: "It is the company because we've been looking for something to import. They only ask you for the CE which can be done by the company itself."

S6: "I always ask for the GMP as well for the company. And it's sometimes surprising for the med rep."

Moderator: "Do they have it?"

S6 (assertive): "They should have, otherwise their file wouldn't be accepted."

Moderator: "Is it easy to get?"

S6: "It is very easy to get if it's available."

S2: "Some companies don't have it."

Moderator: "What if they don't have it? Is it easy to have it available?"

S6: "They should if they want to meet the standards."

S2: "But some companies outside don't have it because as I said I was trying to import and when I asked some manufacturer in Spain for example, they didn't have it, and I learned it wasn't easy to get."

Moderator: "So the company in Spain that doesn't have it, what kind of product are they providing you?"

S2: "Most of them are OTC drugs. Hygiene for females products, etc."

Moderator: "Do they have products that are just to be shipped out of the country?"

S2: "Yes, there are, but I didn't deal with those much."

S6: "And they have new molecules also. There's a new molecule that's not available anywhere. The raw material is from Spain."

S2: "Now Spain is taking control. It's easy to get Spanish products because they have this crisis."

S6: "They also have a big rise in publications and studies. All conferences are happening there."

S1 (confident, informed): "This doesn't really fall under the regulations of counterfeit, but there are certain European generics available on the market before the creation of the European Union. They didn't have the EMA. Who would go through the hassle of creating that for a product that's already available in three of 5 countries in Europe. For these companies, they used to have GMP, but they never knew. So, check if they have an old GMP. There is no way they are available on the market if they didn't have a GMP at the moment of accessing the market, but they probably want to save some money. They don't renew. So you should ask them to renew all the GMPs. It's a lengthy and costly process. For a product to reach one of the big five European countries, they cannot hit the market in Europe if they don't have all the documentation needed at the moment of the registration of the products. A lot of their companies don't renew it after they get the first one, though."

S2: "But some don't have CE, I think."

Moderator: "I have two more questions. This is a hypothetical situation. If you have a counterfeit medicine that you were told has the active ingredient and is cheaper and your patient really needs this medication, would you give it to your patient?"

S6 (enquiring): "No other availability of other medication?"

S1 (suspicious): "Are you sure they have the exact active ingredient? They claim..."

S2: "Once we were in the situation when Xanax was out of stock and many patients needed it and there were plenty of counterfeits on the market."

S1: "They were parallel import no?"

S2: "They were counterfeit."

Moderator: "If they were effective, would you give them?"

S1: "But there's the issue of side effects, too."

S5: "Just a second: do we still have parallel import?"

S1: "No, it's not legal anymore."

S6: "Why do you mean by parallel import?"

Moderator: "This brings me back to my question. I want to know your feedback. How do you feel toward parallel imports?"

S5: "It's outrageous in Lebanon to have parallel import."

Moderator: "When you think of parallel, what is the major....?"

S5: "Who's the agent who's going to bring me...?"

S2: "There were two agents bringing parallel import. One is now legalized bringing their own..."

S5: "Which is offered. Do we agree?"

Moderator: "Isn't this the same company that was....?"

S2: "Yes it is the same company that was... that brought all these medications with all the testing not done."

Moderator: "So they are parallel import?"

S2: "They used to. Now they are still but in a different way. Now they are getting Nexium from Omnipharm as they are saying, but they are selling it with the stamp of the real.... But the net price would be less so purchase price would be better."

S5: "I didn't know about that."

Moderator: "Is this parallel or counterfeit?"

S2: "Neither parallel nor counterfeit. What they're saying is that they're buying big quantities which makes them have big offers and sell them at better prices. Scientific offers."

Moderator: "How do you know this is not counterfeit?"

S2: "That's why I'm not buying it, because the difference is very minimal."

Moderator: "Is price really the indicator now? If it's cheaper, should I be suspicious? Could they sell it to you at higher prices so that you become more comfortable buying it?"

S2: "Could be, could be."

S5 (assertive): "In the past Augmentin was LBP 40.000, Curam was LBP 20.000. At that time, because it was a good lab and a good supplier, I used to recommend it with no problem."

S2: "But now we're talking about the same brand, it's Nexium with the same logo, hologram, everything. It's not parallel import...."

S5 (enquiring): “So they’re doing the same work as a droguerie?”

S1 and S2: “Exactly.”

S1 (assertive, informed): “Usually there are subdealers in Europe. This is not parallel. It used to be called parallel import. It is now illegal secondary sourcing of products. We remember sporadic cases maybe happening in Lebanon about patient not responding to Marvil, or patients on Nefazan having a second stroke, etc. However, I personally read a lot of data about substandard and counterfeit meds all over the world. That was a report published by the WHO and this is why I would not give counterfeit medicine to a patient who might face danger of death or a stroke because I would be increasing his chances. A lot of reports, but one that stuck to my mind which was about Panadol syrup for children. There was report about it being sold, a batch was to be sold in the Middle East and eventually it reached I guess India or I don’t remember where. And a product polluted by the anti-gel you put in the car and three children died because of renal blockage so even if they claim whatever they want to claim on the box. The active ingredient was there and the excipient was there too but it was polluted by something else that wasn’t supposed to be there are so many things that could go wrong. I’d rather not give him the medication than giving him the counterfeit and taking the risk.”

(people agree)

Moderator: “Do you think that all pharmacists in Lebanon are aware?”

S1 and S6: “They are aware but they don’t care.”

S2: “No, not all are aware. Some are not, some don’t care.”

S1: “I think this should be taught in university.”

S5: “Teaching matters.”

Moderator: “When the counterfeiters approach pharmacists, as some of you mentioned, that they came to you and offered and either never came back or tried later, do you think the new pharmacies that open or the new graduates are a target?”

(everyone says yes)

S2: “Really a target. Once I opened, you cannot believe how many used to come and sell me these things and as you have been saying, you are not that much aware, even whether it’s legal or not. At first you’re not aware but when you are older and more mature and these people know that you’re not buying they wouldn’t come anymore.”

S5: “It has to be taught in my opinion.”

Moderator: “As a practicing pharmacist, is it possible to have counterfeit medicine and you not being able to detect it?”

(everyone says yes, it’s possible)

Moderator: “What could be a solution for counterfeit medicine in Lebanon?”

S6: “A strict legal decision and action plan.”

Moderator: “At which level?”

S6: “Starting from the analysis of all medication that reach Lebanon until the process and channel of distribution to the community pharmacists and hospital and ending with a source for pharmacists to let them know if they faced any complications. A

pharmacovigilance centre for example. And then from the centre, a certain relation with the manufacturing company abroad. So, it should be a whole channel that is closed where everybody knows their own responsibilities.”

S1 (laughing, sarcastically): “Without political interference, though.”

S6: “Yes, without that.”

S2: “But I believe the entrance of medications should be controlled do because the pharmacists aren’t always the source of medicine. There are dispensaries and other places too. Even if the OPL are checking and inspecting on the pharmacist, it’s not the only place where you can find counterfeit. You have to stop it from entering the country. This is what I believe.”

Moderator: “So you stopped but it leaked through. How does it leak through?”

S6: “It leaks through the system by certain people inside the MOH with different political affiliations.”

S2: “Leakage is in two ways: proper channel way where no testing is done, or leaving products that everybody knows that they are counterfeit. Leaving them to enter.”

S5: “So the tip of the iceberg is the Ministry of Health.”

S2: “But even the borders. A lot of things enter the country without passing through the Ministry of Health.”

S5: “Let’s say that because of the war and whatever we have, the geopolitical situation, we cannot impervious borders.”

S6 (dissatisfied): “The Ministry is not acting as a reference.”

S5 (assertive): “They have the money, they should do it. They should have investigators raiding the pharmacies.”

S2: “Which cannot be really done, with the political situation.”

S6: “Also, we want a reference, someone to get back to if we face any problem, so now she’s doing her own way in detecting the ADR. We should have a well-defined, standardized system between all of us.”

(People agree)

S5: “Right. This is OPL’s work.”

From both 6 & 5 “...OPL should have a well-defined, standardized system for detecting the ADR between all of us (pharmacists)”

S1: “But again, OPL has the power to install the system, but people need to listen. They have no legislative power.”

S5 (dissatisfied, eyebrows furrowed): “A supposedly doctor was giving us prescriptions with like 5 anti-inflammatory and cortisone for arthritic pain. I called and he said I want this to be delivered to the patient and mind your own business. He wanted me to dispense all these medications to the patient. I called the Order of Physicians, they said we never heard about this doctor. He’s not registered. So the next step, I called OPL and they took note and I called the Ministry of Health and they also took note and I kept on getting for years prescriptions from this doctor.”

Moderator: "Is he still practicing?"

S5: "Yes, as we speak. I think I must have called the Ministry 5 times."

S2: "Does he have a certain clinic? Maybe he's doing his prescriptions from the house."

Moderator: "Does he have a name?"

S5: "Yes, and at the end, I sent a few of the prescriptions to the Ministry of Health and I made copies."

S1: "Nobody cares."

Moderator: "You've hit all these doors, what's next?"

S5: "I refuse to dispense and I tell the patient, I try to tell them and explain. Instead of taking all this, take only this or this."

S1: "When you add meds, you don't add efficacy, you add side effects."

S2: "Now patients come and ask Rivo, they have a nickname for it. They're friends, they know the nickname."

S1: "And if we sell one of these meds without a prescription, we are faced with jail. What about the doctor who's prescribing and knows it's for addiction?"

S5: "I have a patient who used to take Xanax from my pharmacy from half a tablet at bedtime, she went to 6 tablets a day, and then I find out from her chauffeur that she was having different prescriptions in different pharmacies and this patient was a lovely lady. And yes, it is a controlled substance. What she did one night is swallow the whole month's supplement with two bottles of whiskey. She choked on her sleep and she died. She wanted to die. Who's responsible? Am I not responsible?"

S2: "No you're not."

S1: "You delivered a product, a prescription, you're not supposed to know."

S5: "I feel responsible, morally."

S1: "You should have checked on her background? No. You feel responsible but you couldn't have..."

S5: "Legally I'm not, but morally, I knew she was depressed and she was going to commit suicide. I used to call her everyday to check on her."

S1: "What could you have done differently to reach a different outcome?"

S5: "Refuse to dispense."

S1: "She would have taken it from somewhere else. Your role is not..."

Moderator: "You gave her the emotional support as you were checking on her."

S5 (smiling, jokingly): "She's the same one with the Concord + by the way."

(people laugh)

Moderator: "How difficult is it to be a pharmacist in Lebanon?"

(everyone says it's difficult, challenging)

S2 (confident, a little sorry to say, but genuine): “Open eyes all the times. I used to say I would never work as a medical rep. Now I find it the best thing to do because you don’t have anything that you need to care about. In a community pharmacy, you have to care about your patients, your legal papers, you have to care the insurance papers, your taxes, Ministry of Finance come by, drug addicts come to your pharmacy, etc. You have many legal things to think about. On top of that is the fact that you need to live from this. You have your conscience, you have to give them the good products, now we are checking every invoice to check that there’s nothing because sometimes you’re having some drugs from places where drugs are improper or counterfeit. It’s completely messy because you are just being responsible for everything. As a pharmacist in charge, you have all these responsibilities. Especially when you have a community pharmacy. It is where you get your income. You need to live and all that. It’s very difficult.”

S5 (bitter, embarrassed and dissatisfied): “Do you remember SARS when there was.... I went to Hotel Dieu, it’s a French hospital, where there was a conference about SARS. Because you know we are the first ones patients go to. There was a huge conference with all the medication residents and doctors. I was not invited but I went there out of curiosity, I wanted to know. At the end, the doctor Dr. N asked if anyone had questions. No one had questions. I didn’t want to ask at first because I ‘m a pharmacist. I said I’m sorry I’m not invited, but I’m a community pharmacist and I am concerned about SARS. What do we do if we have a SARS case? Are we supposed to have masks all the time? He said you know what you should do? Never sell medications without prescription. This way they wouldn’t come to you first. This was his stupid answer. And everybody started clapping and I was feeling so small. That’s the physician. To tell you how physicians look at pharmacies. Then I took the microphone again and I said you’re right, but maybe you should have a way for yourself to be more accessible to the patient and make yourself more affordable and this is a scientific question. This is not a personal question. He started apologizing and I said if I was not concerned I would not be here in a place where I’m not supposed to be. Give me some credit, I mean.”

S1: “He has an anti-social personality, by the way.”

S5: “He did regret it, though, and the proof is that he called my pharmacy to apologize again. This shows you the way they look at us and how much we are alone in this work.”

S2: “We are.”

Moderator: “Do you think the way you approached or the way you answered had an impact on how he behaved later?”

S5: “Yes, of course. But back then it felt awful. I just wanted to drop off the face of the earth, with all this applause around me. I was in tears when I replied to him and I said you should appreciate the fact that your patients in the community have a pharmacist who’s concerned.”

Moderator: “Yeah, don’t dispense without a prescription.”

S5: “And he’s right, in the absolute figure.”

S2: “I don’t think the perception would change if we sell by prescription.”

Moderator: “If this is how people see you, where is this coming from?”

S2: “Physicians.”

S5: “The practice of some pharmacists.”

Moderator: “Are there many that actually take the time to communicate with the patient? If you go randomly to pharmacies...”

S1 (dissatisfied, sorry): “The bigger the pharmacy, the less available is the pharmacist.”

S5: “And you have airheads who would go to bigger pharmacies for the name, for the prestige, etc.”

Moderator: “On a final note, anything you would like to add I didn’t touch on that you think is important for me to consider and think about?”

S2: “I think we’ve covered most of the issues.”

S5: “Thanks for giving us the opportunity to whine.”

Moderator: “Thank you for coming and I really appreciate what you’ve told me, your feedback and your experience, and I hope we can make an impact.”

S1 + S2: “We hope so.”

Moderator: “And it’s not just in Lebanon, it’s all over the world.”

S5: “It is.”

Moderator: “And we can see how the other countries that are at least doing something about it. By the way, do you know of any punishment? Is there a law that punishes?”

S2 (assertive, informed): “Yes, there is punishment. There’s payment and a huge amount of money.”

S1 (shocked): “Really?”

S2: “I know someone who was imprisoned.”

Moderator: “We’re talking about last year, the importer? Is this the guy?”

S2 (laughing bitterly): “You know that the importer was not imprisoned? It was a pharmacist whose name was on the diploma who went to prison.”

Moderator: “But in the reports, they say the importer was imprisoned.”

S2 (confident—sorry on second part of answer): “That’s not true at all. You know once I kept calling this salesman from a company I bought medicine from. He didn’t answer for 2 or 3 months, after which he came to see me. I noticed he was depressed, and when I asked him what was wrong, he said he was jailed because he sold 2 boxes of Xanax or Viagra or something to a friend of his who said his neighbor needed the products. He went to sell him, it turned out to be an ambush. He was jailed for a long time. Thing is, they jailed him and he’s someone who has 10 boxes only. He told the authorities where he had gotten the medicine. They made him USD 30,000.”

Moderator: “So what’s the punishment? What is the law?”

S1: “But the law is not for counterfeit. It’s for selling controlled medication without a prescription. That guy might have been taken to jail for selling Xanax not Viagra.”

Moderator: “But is there a law?”

S2: “I can get you if you want the law.”

S5: “The first prescription that was required was when Viagra was on the market, and I went nuts and I had an interview where I was saying why? I mean, ok, a prescription for Viagra, but what about other medicine? What about Xanax, Lexotanil? That was when you were still students at school I guess.”

Moderator: “The rest of you, do you know anything about the law about counterfeit medicine?”

(people say no, no idea)

S1 (laughing, sarcastic): “ No idea...Because usually the people who deal with counterfeit medicine are above the law.”

Moderator: “Is this one of the limitations?”

S1 (bitter): “I guess—I mean, look at the people who are bringing this kind of medication. They are all backed up by a politician or somewhere higher up. It’s always like that. And by the way, without naming the company, the company that was bringing counterfeit medication is a money laundering company.”

S5 (smiling bitterly): “We have money laundering universities, too.”

(people laugh)

S2: “We are now stuck with 11. Mabrouk (congrats).”

Moderator: “Thank you so much.”

S5: “So I guess as pharmacists, our role is very important on a day-to-day basis. We are solo workers. No one is backing us up.”

Moderator: “You back up yourself—thank you so very much. I appreciate everything you’ve shared.

-----End of focus group-----

Appendices 8.I – 8.V.

أقر مجلس النواب،
وينشر رئيس الجمهورية القانون التالي
نصه:

مادة وحيدة:

أولاً: يلغى نص المادة ٩٢ من القانون
رقم ٣٦٧ تاريخ ١/٨/١٩٩٤، مزاولة مهنة
الصيدلة، ويستعاض عنه بالنص التالي:

«المادة ٩٢ الجديدة»

يعاقب بالسجن خمس سنوات على الأقل،
وبالغرامة من مائة مليون إلى مائة وخمسين
مليون ليرة لبنانية، بالإضافة إلى تلف الأدوية
على نفقته، كل من يرتكب الغش في المواد
الصيدلانية، أو يبيع، يصنع، يستورد، يوزع،
أو بشكل عام، يقوم بأي عمل يتناول أدوية
مزورة، مهزبة، منتهية الصلاحية، غير
مسجلة أو ممنوع التداول بها.

يمنع من حق مزاولة مهنة الصيدلة مدى
الحياة كل صيدلي يحكم عليه بجناية أو
يرتكب الغش في المواد الصيدلانية، يبيع
أدوية سرية أو مخدرات أو من أجل مزاولة
مهنة الطب بصورة غير قانونية».

ثانياً: يعمل بهذا القانون فور نشره في
الجريدة الرسمية.

يعيداً في ٢٦ حزيران ٢٠١٠

الامضاء: ميشال سليمان

صدر عن رئيس الجمهورية

رئيس مجلس الوزراء

الامضاء: سعد الدين الحريري

رئيس مجلس الوزراء

للذين نجحوا في المباراة التي أعلنت نتائجها
النهائية في ٢٤/٢/٢٠٠٧ ولم تتم ترقيتهم.

- تتولى السلطة المختصة وضع هذا
القانون موضع التنفيذ وإصدار مراسيم منح
قدم ووضع على جدول الترقية والترقية فيما
يتعلق بالمفتشين الممتازين وما فوق
المذكورين في الفقرة الأولى وعلى أن
تستثنى هذه الدورة من القوانين والأنظمة
التي ترعى مواء الترقية إلى رتبة ملازم أو
عديدهم في ملاك المديرية العامة للأمن
العام.

- يعمل بهذا القانون فور نشره في الجريدة
الرسمية.

يعيداً في ٢٦ حزيران ٢٠١٠

الامضاء: ميشال سليمان

صدر عن رئيس الجمهورية

رئيس مجلس الوزراء

الامضاء: سعد الدين الحريري

رئيس مجلس الوزراء

الامضاء: سعد الدين الحريري

قانون رقم ١١٧

تعديل المادة ٩٢

من القانون رقم ٣٦٧

تاريخ ١/٨/١٩٩٤

مزاولة مهنة الصيدلة

(تشديد العقوبات على كل فعل

يتناول الأدوية المزورة، المهزبة،

Appendix 8.II.

Definitions of the common terms that may be used and/or confused with counterfeit medicine, and whether they should be or not.

Term	Definition and Verdict
Generic medicine	Generic medicines are the same as the original brand name medicine, are legitimately produced and contain the same active ingredient(s). However, they are mostly, not made by the company that first developed, marketed and often patented the medicine. A generic medicine is in general not patent-protected but it will have the same effect as the patented brand name medicine, and also has a trade name that is different than the original brand name. Generic medicines are in general, cheaper than patented medicines, as a result, are more accessible and affordable to people especially in developing regions, where people tremendously rely on quality generics (Rosenthal, 1998; Mackey and Liang, 2011). Therefore, generic medicines must not be considered CFM, just because they are cheaper.
Substandard Medicines	Substandard Medicines (Majid, 2008) are “Genuine medicines produced by legitimate manufacturers, however, do not meet the minimum quality requirements that the producer declares they meet. For example, they may contain less (or more) active ingredient than written on the package or label, or they were not stored properly. The intention may not be to cheat, but maybe due to problems with the manufacturing process or storage. These medicines are referred to as “low quality medicines” and must not be considered CFM (Majid, 2008). However, if dishonest people knowingly used substandard medicine with the intention to be sold as the original, manipulating the packaging or the contents to hide their low quality then, should be considered CFM (Majid, 2008).
Degraded Medicines	Degraded medicine “may result from exposure of good-quality medicines to light, heat, and humidity. It can be difficult to distinguish degraded medicines from those that left the factory as substandard, but the distinction is important as the causes and remedies are different” (Majid, 2008). These medicines must not be considered CFM, unless they have been re-packaged, or used as is to deceive the users then, should be considered CFM.
Misbranded medicines	A medicine is considered to be misbranded if it has: false or misleading information about the identity or ingredients of the contained medicine, lack of required information, conspicuousness and readability of required information, misleading packaging, improper packaging and labelling of colour additives, and deficiencies where the Poison Prevention Packaging Act requires special packaging (Bahjat, 2008). False labelled statements about the identity or ingredients of the contained medicine, should be considered CFM, for the intention was to deceive.
Pirated medicines	According to Merriam-Webster dictionary pirated is “to reproduce without authorization especially in infringement of copyright (World Health Organization, 2012a). The same can apply to medicine, if there has been an infringement of copyright and if the aim is to deceive then, these medicines should be considered CFM. According to Phau (World Health Organization, 2012a), and Zaichkowsky (Traynor, 2007), counterfeiting and piracy are in term the same since they are both the reproduction of identical copies of the genuine product.

Continue Appendix 8.II.

Definitions of the common terms that may be used and/or confused with counterfeit medicine, and whether they should be or not.

Term	Definition
Adulterated medicines	An adulterated medicine differs in strength, quality or purity from the original product. Can be tempered with it's content or can be substituted with another substance. According to the FDA, (Bahjat, 2008) a medicine can be considered adulterated if: it bears or contains any poisonous or deleterious substance which may render it injurious to users, if it consists in whole or in part of any filthy, putrid, or decomposed substance, if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health, if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.” (Bahjat, 2008 Mackey and Liang, 2011). This should be considered CFM since it would be unsafe.
Out-dated medicines	Out-dated medicines are genuine medicines produced by legitimate manufacturers that meet the quality specifications that the producer says they meet, however, have passed the expiry date. These medicines must not be considered CFM, unless they have been re-packaged, and/or sold as valid medicines with a new expiry date by extending their expiry date. Then, should be considered CFM since their aim was to deceive.
Parallel medicines	The practice of parallel trade of pharmaceuticals is also referred to as the “grey-market”. With parallel imports, a licensed pharmaceutical distributor can, after obtaining proper authorization, import any medicines produced genuinely under the protection of a trademark, patent, or copyright, as long as the medicine that is being imported is identical to the medicine that is locally sourced, that it contains the same active ingredient and is produced by the same manufacturer. The intended medicine will be available in market, and then imported by an intermediary into a second market without the authorization of the local owner of the intellectual property. Parallel trade exists when there are significant price differences between countries, making this trade attractive. This is legal in the European Union (UN), where prices of medicines are not governed by free competition laws, but are fixed by the government (World Health Organization, 2008; UNODC, 2015) These medicines should not be considered CFM.
Smuggled medicines	Based on Merriam-Webster dictionary, smuggling is ” to import or export secretly against the law and without paying duties imposed by law.” (World Health Organization, 2012a). Smuggled Products or medicines maybe more attractive to the public since the cost excludes taxes, customs and any legal fees that are normally due. Therefore, any smuggled medicine will be in violation of customs laws, and therefore, illegal and should be considered CFM for the means of transportation and storage would be questionable.

Appendix 8.III.

The role of pharmacists in controlling counterfeit medicine

Pharmacists should safeguard their practice and protect their patients; therefore, pharmacists should do the following:

1. Abide by the adopted Code of Ethics as a guideline for pharmacy practice.
2. Update their knowledge and information about CFM to be aware of what is new in this area. Such as through: continuing education, workshop, conferences, etc ...
3. Commit to controlling and stopping the availability of CFM, by being responsible and vigilant in choosing the most reputable and reliable source in the supply chain.
4. Check regularly the integrity of wholesalers/Agents (medicine suppliers) (Wala, 2005):
 - a. Ask medicine suppliers to provide a written description of the product sources and their anti-counterfeiting measures.
 - b. Check regularly the MoPH site for information regarding problems with medicine suppliers & dispensaries.
 - c. Use Dispensaries (secondary distributors/wholesalers) only if they provide written verification from MoPH, and verify by checking the Ministry's official site.
5. Establish procedures to regularly check packaging, condition of packaging, labels, print, medicine appearance, smell, etc....
6. Report to the CFM reporting system any suspected CFM case(s), after the proper investigation. Additionally, patients should be encouraged to check the CFM reporting system's website, for CFM updates.
7. Contact the MoPH or the CFM reporting system, if suspecting a CFM.
8. Report other colleagues, healthcare professionals or anyone who is dealing with CFM. Whistleblowers can protect the public from the harm of using CFM.
9. Educate patients by counselling them on CFM and the importance of buying their medicine from reliable sources (pharmacies).
10. Interact more with patients by providing effective participation and counselling in issues related to their health and medicine.
11. Alert and educate patients about the use of Internet pharmacies, and the risks of buying counterfeits medicine and products.
12. Refer patients to OPL and MoPH for information about registered pharmacies and pharmacists.
13. Encourage patients to report to pharmacists, any problems with their medicine.
14. Document and report, complaints, unusual side effects, or unusual medicine responses that could be due to CFM, and investigate them promptly.
15. Commit to buying medicine only from registered importers/agents/distributors.
16. Abide by the MoPH price list.
17. Participate in the educational campaigns to control the availability of CFM, by involving the patients who are the primary targets or victims.
18. Assume responsibilities in the delivery of safe and effective medicine along every point of the medicines supply chain.
19. Beware of risks pertaining to improper information and dispensing and the threat such practices pose to patient safety.
20. Ensure accurate and ethical information are conveyed to patients, using the Code of Ethics as a guideline to be followed and applied properly.

Appendix 8.IV.

The role of the Ministry of Public Health in controlling the availability of counterfeit medicine

The patient is the victim, the liability of the company is increasing and the credibility of the government is threatened, therefore, the author would recommend that the MoPH, perform the following:

1. Describe on the official website, the role of pharmacists, and other healthcare professionals.
2. Involve and support pharmacists in preventing the spread and promotion of CFM
3. Establish reliable information sites related to CFM, to inform people of related cases and reports.
4. Collaborate with HCP, OPL, and OML to create CFM awareness and education of patients.
5. Create incentives to devote sufficient resources to regulate and monitor the medicines market.
6. Encourage political commitment and will to control the availability of CFM
7. Create coordination with international organizations and authorities such as; WHO, FDA, EMEA, ...
8. Establish an independent medicine control laboratory, to regularly and randomly test the medicines that enter the country and those already available on the market.
9. Create an entity independent from the cabinet to be responsible for supervising medicine, and to be involved in the development of a clear and precise national medicine policy.
10. Develop a national medicine policy (Ehrlich, 1985).
11. Enforce tighter controls at the five commercial harbors (Beirut, Tripoli, Jounieh, Sidon, and Tyre), the Rafic Hariri International Airport, and three land border-crossing checkpoints with Syria at Masnaa', Abboudiyeh, and Qaa'.
12. Enforce constant inspections of customs.
13. Track down reported discrepancies.
14. Prosecute counterfeiters for criminal offense, not only for IP violation
15. Define clearly, all law enforcement processes (World Health Organization, 2009b).
16. Define clearly, the roles and power of officials and committees to enforce the law (World Health Organization, 2009b).
17. Illustrate or classify all laws and regulations, to be made easily accessible to the public (World Health Organization, 2009b).
18. Control and regulate medicine purchases over the Internet (Since the sources are difficult to trace, and manufacturers are unknown, making the safety and effectiveness of these medicines suspicious and questionable) (Chambliss et al, 2012).
19. Devote more resources to search for CFM at the borders, and for strict enforcement of laws.
20. Dispose all confiscated CFM, by officials; either to re-export or destroy them, to avoid recirculation in the market, to be witnessed by minimum 3 members of "CFM-Alert" (Grossman and Shapiro, 1988).
21. Agree on CFM definition for the country to go by, to facilitate the work of regulators.
22. Encourage the development of healthcare distribution management association to check integrity of the pharmaceutical system, and to provide guidelines for pharmacists to follow.

Continue Appendix 8.IV.

23. Mandate and instruct all registered wholesalers to provide a written description of anti-counterfeiting measures that they should comply with, and the guidelines for pharmaceutical system integrity, and product sources should be printed on purchase agreement.
24. Authorize registered dispensaries only, to dispense medicines, provided these medicines are directly provided by MoPH, or purchased from registered good standing distributors; wholesalers/Agents (medicine suppliers). In addition, to provide complete sales histories of the purchased medicine to MoPH, and written verification to pharmacies.
25. Monitor and inspect, regularly, wholesalers/Agents (medicine suppliers) and dispensaries, and post on its website any relevant information or problems.
26. Post on MoPH website, an updated list of registered wholesalers/Agents (medicine suppliers) and dispensaries
27. Identify CFM by randomly testing the medicines imported into the country at ports of entry and as needed for inspection.
28. Require and necessitate the presence of pharmacists at each port of entry for identifying and checking for CFM
29. Provide pharmacists with the authority to administratively detain medicines believed to be CFM.
30. Intervene and develop a collaboration strategy to achieve a common understanding of the impact of CFM on public health by:
 - Conducting regular joint meetings with the security forces and the law enforcement judiciary system to promote collaborations,
 - Identifying gaps in regulations (Hosseini et al, 2011).
31. Alert all stakeholders. Once MoPH receives a confirmed report of CFM, it would be their responsibility for deciding when and how to alert all stakeholders (police, trade, customs authorities, public, and other countries that may be affected and Interpol).
32. Inform pharmacists of changes in the packaging of certain medicines in the market, as reported by manufacturers, to avoid identifying them as CFM.
33. Prosecute, implement and enforce the law against all offenders dealing with CFM.

Appendix 8.V.

The initiation and role of an external institution/body

The external bodies could have an influence over medicine control policy, in addition to the MoPH (Ehrlich, 1985) and their role would be to control the availability of CFM. This body could be named “**CFM-Alert**”. The aim would be to:

1. Seek and develop local and international legislation and regulations, and assure enforcement.
2. Invite members from diverse backgrounds, however, the main members should be academicians from prominent universities in Lebanon, in addition to other professionals and members of the public.
3. Exchange information among members to share valuable experiences to help better control the problem
4. Educate all stakeholders to become aware of the safety and economic risks, to help avoid unintentional buying of CFM (Ehrlich, 1985).

The role of CFM-Alert:

1. Develop a uniform **definition of CFM** since different definitions can hinder the communication and exchange of information.
2. Develop an interactive website for exchange of information between “**CFM-Alert**” and stakeholders
3. Classify and organize communication with stakeholders, i.e., an icon for each; public, pharmacists, physicians, educators, etc ... for better communication
4. Establish a CFM reporting system
5. Screen contacts to avoid pranks
6. Keep identity of contacts confidential to protect anonymity
7. Report incidents or cases related to CFM availability or use
8. Follow up by investigation, trace and track source of CFM
9. Follow up by attempt to prevent further production, if source was found
10. Enforce actions against counterfeiters, by original manufacturer, or MoPH.
(Each of the above steps would rely on the previous one to be successful. Keep in mind that by the time the case against counterfeiters is pursued, the counterfeiters may be long gone (Ehrlich, 1985)).
11. Establish a database to record and documented all cases of CFM, and develop a list of most counterfeited medicine. The list should be continuously updated to alert HCP, regulatory authorities and patients.
12. Establish an Alert link that would provide up to date news, safety measures and alerts
13. Send awareness messages using mobile phones, similar to the Cotonou study (Abdoulaye et al, 2006a) that reported 90% of participants received messages prohibiting the purchase and the consumption of medicine from the street.
14. Initiate awareness campaigns in collaboration with MoPH and OPL such as workshops, and interactive programs with questions and answers (Q&A) for students, HCP, and the public.
15. Establish a hotline for Q&A related to CFM.