1   **Public and pharmacist perceptions regarding counterfeit medicine in Lebanon using focus groups**

2

3   **Introduction**

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5   Counterfeiting is a substantial problem that is growing worldwide and affects both developed and less

6   developed countries (Alfadl et al. 2013). Counterfeit products are illegal, low priced and often of lower quality

7   than their originals (Lai and Zaichkowsky 1999). When it is medicines being counterfeited, this is not only

8   damaging to the pharmaceutical industries but also constitutes a significant threat to public health (Bird 2007).

9   Counterfeiting in general represents around 5–7% of world trade, and around 10-30% of the global medicine

10   supply chain could be counterfeit (UNODC 2006).

11   The incidence of counterfeit medicine (CFM) varies based on each country's regulatory and enforcement

12   system. Poor and developing countries with weak regulatory and enforcement systems have higher percentages

13   of CFM (Chauvé 2008; Alfadl et al. 2013; Rajapandian et al. 2013). Developed countries are less vulnerable

14   to CFM and are considered properly regulated with well-controlled systems, yet several cases have been

15   discovered within their legal pharmaceutical distribution chains (Besançon 2008).

16   The most common factors that encourage counterfeiters to produce CFM are: lack of legislation

17   prohibiting counterfeiting of medicine; weak or minimum enforcement of laws and disciplinary actions; the

18   high cost of branded medicine; and a shortage of medicine supplies (Chauvé 2008; Alfadl et al. 2013;

19   Rajapandian et al. 2013; Al-Worafi 2014).

20   CFMs play a major role in destroying the public's trust in the healthcare team (Newton et al. 2006; Akiny

21   2013) the safety and efficacy of pharmaceutical products (Newton et al. 2006); government and regulatory

22   authorities in controlling the availability of CFM (Akiny 2013; Mdege et al. 2016). Moreover, ignorance of

23   the risks and attributes of CFMs increases the vulnerability towards CFM use, causing lower detection and

24   reporting rates for counterfeits (Akiny 2013).

25   The problem of CFM continues and the crisis of medicine shortages is still present, however, currently the

26   economic, political, governmental and regulatory situations of each country, add to the reasons why CFMs are

27   more readily available in some countries more than others (Chauvé 2008; Alfadl et al. 2013). For example, in

28   Lebanon, a related study (Sholy 2015) explored the availability of CFM in various households in Lebanon and

29   found the extent of CFM to range from 3% in Mount Lebanon (ML) to 12% in the Bekaa and South of Lebanon.

30   This study is part of a bigger research programme based on mixed-methods methodology (Hadi and Closs

31   2016) that included points of interaction between the qualitative (sub-study) and quantitative (bigger study)

32   components, using the explanatory sequential design. The data in this design are gathered sequentially in two

33   phases. Phase one (the bigger study) used quantitative research that collected and analysed data from

34 questionnaires (Sholy 2015; Sholy et al. 2017). Phase two is this study (sub-study) used qualitative research

35 (focus groups) to explain the findings of the questionnaires in phase one (Hadi and Closs 2016).

36   Focus groups (FG) and interviews are both useful qualitative methods (Rabiee 2004; Stewart and

37 Shamdasani 2014). FG allow participants to listen to the opinion of others, gather views of several people

38 simultaneously and understand the issues that would not be possible to generate without the interaction

39 produced from group discussions (Krueger and Casey 2009). FG were used for convenience since they yield a

40 large amount of data in a short period of time, while the one to one interviews would require more time (Rabiee

41 2004; Stewart and Shamdasani 2014).

42   There have been limited studies that used FG to explore perceptions about CFM with the public/

43 pharmacists (Syhakhang et al. 2004). A study in Sudan determined the factors related to CFM purchases using

44 interviews (Alfadl et al. 2013), and another in Lao People's Democratic Republic (PDR) (Syhakhang et al.

45 2004) explored the knowledge and perceptions of medicine quality using interviews and FG. Both concluded

46 that lack of knowledge, high prices and unaffordability of medicines have a major role in increasing the

47 likelihood of the public using counterfeit or low quality medicine.

48   The findings of a related study (Sholy et al, 2017) suggested exploring the experiences, views and
49 beliefs of the pharmacists/Public regarding CFM in Lebanon and how they can be limited/controlled.
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51 **Aim of the study**

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53 To explore the experiences, views and beliefs of the public and pharmacists regarding CFM.

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Method

This study is descriptive and is based on **phase two** of a mixed-methods methodology, using the explanatory sequential design. The study used FG as the qualitative method to explore the general public and pharmacists' experiences, views and beliefs towards CFM. **Phase one** of the study used questionnaires that assessed 849 members of the public (Sholy 2015) and 223 practicing pharmacists on awareness and views towards CFM (Sholy et al. 2017). The results of phase one showed that the questionnaire did not provide sufficient information about the components of people's beliefs and perceptions towards CFM. Therefore, a qualitative research was necessary to explain and build on the findings of phase one (Hadi and Closs 2016).

In order to ensure rigour, trustworthiness, transparency, and integrity of the findings, the methods required the following:

- **Triangulation:** the results of phase two illuminated the different perspectives towards CFM problems identified in phase one (Long and Johnson 2000; Hadi and Closs 2016);

- **Clarification:** the results of the quantitative method (phase one) using a qualitative method (FG) (Long and Johnson 2000; Hadi and Closs 2016);

- **Informed design:** the FG method was based on the findings of the questionnaires, as these provided information from a large sample of the public about their experiences, views and beliefs of CFM (Long and Johnson 2000; Hadi and Closs 2016).

- **Peer debriefing,** the researchers discussed the methodological process with knowledgeable peers on qualitative research on continuous basis (Long and Johnson 2000; Hadi and Closs 2016).

- **Participants' validation,** on completion of the study the findings were checked with participants (pharmacists only, since the public were difficult to trace back), meeting the diachronic reliability requirements of the findings, two years after the completion of the study (Long and Johnson 2000; Hadi and Closs 2016).

The results of phase one were adopted using the explanatory sequential design process for developing the semi-structured guideline questions, for both the public (7 open-ended questions) **(Table 1)** and pharmacists (8 open-ended questions) **(Table 2)**. Follow-up questions were asked to learn more, and probe about topics that participants brought up.

Please insert Table 1 here

Please insert Table 2 here

Sample

This study was conducted in Lebanon using two public FG with participants from different backgrounds, and two FG for pharmacists from different pharmacy settings.

Public recruitment

Two schools in ML were contacted for permission to use their sites. Schools were considered a convenience sampling method (Profetto-McGrath et al 2010) since it offered easy access to members of the public. The convenience sample of participants was chosen based on their visits to the principals' offices. The principals were provided with the following exclusion criteria; any individual who; 1) was younger than 18 years old, 2) was not living in Lebanon, 3) did not approve of audiotaping the meeting, and 4) not willing to sign the consent form. The principals' assistants asked each one if they would be interested in participating in the study. Those willing to participate were asked to register their names on a list with the assistant. Once the date was set, they were contacted and informed of the set times, and those able to attend were present.

Pharmacists' recruitment

The recruitment of pharmacists used the snowball approach since the population was hard to reach, or recruit (Profetto-McGrath et al 2010) due to the sensitivity of the topic, and in order to avoid embarrassing or coercing pharmacists not willing to participate. The inclusion criterion was any pharmacist practicing in Lebanon (Lebanese Order of Pharmacists 1994). The exclusion criteria were pharmacists not living in Lebanon, who did not approve of using the audiotape during the meeting, and who was not willing to sign the consent form. Once the names were available, each pharmacist was contacted by telephone to explain the purpose behind the FG meetings. The call was followed by a confirmation email.

Data collection

The FG took place in the period between April to June 2014. Before starting each meeting, the moderator reviewed the consent form with participants and encouraged questions before signing the form. At the end of the meeting participants were given a demographic questionnaire to complete, and the moderator's contact information for any additional questions.

117   The primary author acted as the moderator for all FG, with the note-taker. Debriefing and observation

118   discussions took place after each meeting between the moderator and note-taker.

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120   **Data analysis**

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122   The discussions of the public and pharmacists' FG were transcribed, read and reviewed for each group. The

123   analysis was performed by the inductive qualitative method followed by a structured process combining

124   description and interpretation of the data (Kitzinger and Barbour 1999; Profetto-McGrath et al 2010) The

125   reflexivity of the researchers was addressed by the objectivity of the results of phase one and the research

126   question, independently of the researcher's background, motives and perspectives. Each FG was analysed

127   separately and then together (Kitzinger and Barbour 1999; Profetto-McGrath et al 2010) The analytical method

128   used was thematic/category analysis as described by Kitzinger and Barbour (Kitzinger and Barbour 1999).

129   With this method a theme is developed based on capturing something important in relation to the researched

130   topic, irrespective of the number of persons who referred to it (Profetto-McGrath et al 2010). The public

131   participants were considered aware of the meaning of CFM, if they said it was not the original, fake, or anything

132   related. For pharmacists, the WHO definition was used as a reference (World Health Organization 2017). From

133   the FG transcripts, meanings were interpreted, grouped and labelled with a code. The codes were compared

134   and formed into themes and subthemes (Kitzinger and Barbour 1999; Long and Johnson 2000; Profetto-

135   McGrath et al 2010; Bellamy et al. 2016). The interpretation of data was based on the "intensity of comments",

136   "specificity of comments", "internal consistency" and the "big ideas" in link with the research question (Rabiee

137   2004). The validity of the interpretation is linked to the triangulation method mentioned above to minimize

138   distortion (Long and Johnson 2000; Profetto-McGrath et al 2010) The relevant quotes were used to support a

139   theme or an observation.

Results

Public FG

The total number of public participants was 23. Their age ranged between 30 and 60, and 21 were female. Slightly more than one third of participants were between 31- 40 years old. The majority had a university degree, and lived in the ML region. Lack of awareness dominated the discussion, mixed with helplessness and mistrust in the system.

Five main themes emerged from the two public FG discussions detailed in **Table 3** with related quotes.

Please insert Table 3 here

Pharmacists FG

The total number of participants was 13. Their age ranged between 26 and 60, 11 were females, and two thirds were between 26-30 years old. Participants were mostly from, and practicing in, ML and Beirut. Five worked with pharmaceutical companies, five in community, two in hospitals and one in both academia and community. They were motivated to discuss and share their concerns about CFM with other colleagues for the first time. Frustration and anger dominated the discussion. These emotions were associated with the perceived financial pressures and lack of professional ethics among pharmacists who deal with CFM.

Five main themes emerged from the two pharmacist FG discussions detailed in **Table 4** with related quotes.

Please insert Table 4 here

The duration of the discussions for the four FG was between 100-120 minutes.

Common themes between the public and pharmacists FG

I. Awareness

The discussions demonstrated a gap in participants' awareness towards CFM: **1) Defining CFM;** the majority of public participants were not able to define or provide a meaning to CFM, and either gave false definitions, or did not know. Pharmacist participants were able to define CFMs and were therefore considered aware of CFM. **2) Identifying CFM;** a few of public participants were slightly knowledgeable and referred to the hologram, due to recent media reports. The majority of pharmacists expressed difficulty in identifying CFM, as they did not rely on the hologram, rather the relied on assessing patients' responses to medicine. **3) CFM reporting System;** No participants were aware of any reporting system, and were not sure how to report suspected CFM. **4) Prevalence and extent**; according to pharmacist participants, CFM were mostly prevalent in the northern and southern parts of the country (away from the capital) and close to the borders where there is less control and implementation of regulations due to the current political situation.

II. Trust

The four FG participants expressed mistrust and lack of faith towards the system and some pharmacists. **1) The system;** all participants believed that the Ministry of Public Health (MoPH) and the Lebanese Order of Pharmacists (OPL) were not carrying out their duties as should be, such as providing safe and effective medicine. Moreover, the public believed that pharmaceutical companies are involved in counterfeiting. According to pharmacist participants, the distribution channels and wholesalers were not well controlled and are not to be trusted. This appeared to originate from an incident in 2010 where CFM were available in some pharmacies through legal channels. Therefore, it would be crucial to control the supply chain. **2) Pharmacists;** a few of the public participants believed that going to their trusted pharmacist would be one way to avoid buying CFM, the others distrusted pharmacists and believed they are all involved in the availability of CFM. The majority of pharmacist participants emphasized how the few pharmacists that were involved in CFM incidents affected their image, and how difficult it would be to regain the people's respect and trust.

III. Corruption

All participants expressed their dissatisfaction, and believed the government and regulatory authorities were manipulating the affairs for private gains. Furthermore, participants stressed the weak implementation and

200   enforcement of the law that in their opinion led to diminished border and customs control. The systems' actions

201   were not for the public's benefit, especially when no measures were taken against offenders. Pharmacists added

202   that working in such conditions was becoming very difficult.

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204   **IV. Overcoming counterfeit medicine**

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206   Participants suggested that responsible authorities should use different methods to discourage and stop

207   counterfeiters and the use by the public of CFM. Five subthemes emerged: **1) Education;** the discussions and

208   exchange of experiences among public participants demonstrated the need to learn and understand more about

209   CFM and the need for authorities to be more transparent. All pharmacists believed in their need to be educated

210   and to educate patients about CFM. Pharmacists emphasized the importance of knowledge, stressing the "know

211   how" that is always missing. The majority of pharmacists raised the concern that physicians should also be

212   aware and educated regarding CFM, as there seemed to be a lack of awareness among physicians. **2) Laws**

213   **and regulations;** all participants agreed on the need for laws and regulations to be implemented and enforced.

214   In addition, there is a need to develop a CFM reporting system and a point of reference where the MoPH and

215   OPL can be available and involved. **3) Responsibility and accountability;** the public participants believed

216   that naturally the MoPH should be responsible for guaranteeing that safe and effective medicine to reach

217   pharmacies. They suggested using different methods to discourage and stop counterfeiters. **4) Central**

218   **laboratory;** all pharmacists highlighted the need for the MoPH to reactivate the national laboratory, to

219   randomly test samples of medicine in the country. **5) Dedicated pharmacists;** the majority of pharmacists

220   believed they could have a major role in controlling the availability of CFM, through organizing and

221   controlling the pharmacy profession, to stop the outliers.

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223   **Uncommon themes**

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225   **V. Locus of control**

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227   This theme reflected the degree that participants' perceived events to be under their control (internal) or under

228   the control of others who are more powerful (external) as the following subthemes: **1) Internal control;**

229   participants' believed that controlling the events and outcomes themselves were dependent on their knowledge.

230   The majority highlighted that people in general lacked enough knowledge about medicine, and thus did not

231   know what to do. **2) External control;** participants' believed they did not have the power to control events or

232   outcomes, rather relying on outside influences or external factors such as other people, government, or fate.

These external factors were subdivided into: **a) Worries;** participants' worries and concerns relating to the outcome of their medicine if counterfeit. **b) Financial concern;** the high cost of medicine was the reason behind the availability of CFM. Patients would unknowingly go for a cheaper medicine if given a choice. **c) Political instability;** the majority of participants seemed overwhelmed with the country's political instability, and did not consider CFM a priority for the government or politicians. Participants considered themselves unworthy of "good" medicine.

VI. Reasons for availability of CFM

The following subthemes emerged while pharmacists' FGs were describing the reasons for CFM availability: **1) Pharmacists;** for the following reasons: **a) Business and profit;** the majority believed that there are some unethical pharmacists who do not care, and each community has pharmacists that deal with CFM, thus contributing to the mistrust of pharmacists. Moreover, some pharmacists illegally discounted the medicine priced by the MoPH to appear more compassionate towards patients, when the discounted medicine may be counterfeit. **b) Professional experience;** participants shared their experiences about being approached and offered CFM. Participants reported how dealers always checked around and offered CFM to those interested, and would target new pharmacies, young graduates or the inexperienced for their tendency to be more vulnerable than others. Older participants stated they were also approached when they opened their pharmacies, and due to their continuous rejections, were no longer approached. **2) Medicine shortages;** the majority believed that counterfeiters took advantage of medicine shortages and offered cheaper alternatives or provided attractive offers for medicine that could only be counterfeit. **3) Demand;** the majority reported in believing that patients end up buying CFM due to the high cost of medicine, and the financial situation caused by the political instability. Participants believed that some members of the public may be aware but do not care and choose the cheaper medicine (CFM), and some lack awareness. **4) Control;** participants reported that their concerns were due to the MoPH's lack of control of available medicine and the supply chain. Pharmacists expressed that they had limited control and were under a lot of pressure.

The structure of the thematic network for the four FG is presented in Fig1.

Please insert Fig 1 here

Discussion

The study explored the views, experiences, and beliefs of the public and pharmacists towards CFM using FG. The study applied the mixed methods methodology using both quantitative and qualitative research. Four common themes emerged among all participants indicating the similar views and beliefs about CFM, reflecting their own perceptions and experiences. The discussions showed a lack of experience and limited awareness regarding CFM among the public, however pharmacists were aware but the level of expertise appeared related to the number of years in practice. The study sample for all groups had an over-representation of females, thus the results might be gender specific, as studies show that males and females do have different views and beliefs (Abbey 1982).

Contributing factors to CFM

No participants were aware of the CFM reporting system, and considered the pharmacy a reasonable place for reporting suspected CFM. One study also expressed pharmacists' need for an official CFM reporting system, and also counselling patients about the system and CFM (Jackson et al. 2012; Sholy et al. 2017). Moreover, pharmacists indicated that CFM were more prevalent in the North, South, and Bekaa in accordance with phase one of the study (Sholy 2015) where the extent of CFM ranged from 3% in ML to 12.1% in the South and the Bekaa. The difficulty expressed by participants in identifying CFM was supported by other studies on how easy it is becoming to counterfeit (Kitzinger and Barbour 1999; Deisingh 2005; Newton et al. 2006; Sholy 2015).

The mistrust towards the MoPH, OPL, pharmacists, regulatory authorities and pharmaceutical companies was probably due to what participants considered lack of transparency and professional misconduct. The findings were in accordance with the WHO which states that counterfeiting is contributing to the damaging of the reputation of pharmaceutical companies by destroying public confidence and trust in medicine, which causes the reluctance of some companies to publicize incidents of their products being counterfeited (Kahn et al. 2012).

The continuous increase in the number of graduating pharmacists' year on year was reported to have decreased pharmacists' minimum wages to $1350/month (Lebanese Order of Pharmacists 2014) which might have contributed to some pharmacists being involved in the reported incidents involving CFM (Sholy et al. 2017). Many studies have documented the impact pharmacists can play in improving patients' health outcome, and decreasing the chances of dispensing CFM (Chauvé 2008; Law and Youmans 2011; Jackson et al. 2012; Alfadl et al. 2013; Rajapandian et al. 2013; Mdege et al. 2016). However, the good or bad headlines do

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influence the perception of the pharmacy profession, therefore, more efforts are required to enhance the reputation of the profession, and improve pharmacists' image to regain the trust of the public (DiPiro 2011).

Trust is an important asset the public can give to healthcare professionals when their work is for furthering social justice and public health (Kass 2001). According to the UK code of ethics, the public need to trust that they are pharmacists' primary concern, and that pharmacists are honest, trustworthy, and protective of patients from any harm by providing safe and effective medicine (General Pharmaceutical Council 2017). To date, there is no known or published code of ethics for pharmacists in Lebanon; consequently, the OPL should consider agreeing on a code that all registered pharmacists must follow (Sholy et al. 2017).

The mistrust theme is related to corruption according to a study that measured the degree of trust in societies around the world, which varied considerably and was strongly correlated with views about crime and corruption (Wike and Holzwart 2008). The 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%). Moreover, the Lebanese and Nigerian's trust was rare due to respondents' reported concern about widespread of political corruption. In fact, in countries where people reported trusting each other, there were less worries about crime or corrupt political leaders (Wike and Holzwart 2008). This study's participants stated the need for clear laws to be implemented and enforced, although they did not believe that their suggestions would be implemented or would change anything, since corruption is so deeply rooted in the culture. Cultures of corruptions will not fade away (Tanzi 1998) and according to participants, this is the case in Lebanon.

Consequently, the belief that corruption had a role in the availability of CFM is also reported in the USA and UK, where corruption among wholesalers and illegal supply chains allowed CFM to enter their legal chain system (Besançon 2008; Mackey et al. 2015). The problem of medicine shortage in Lebanon is also a global concern that counterfeiters take advantage of (Newton et al. 2006) as they use original holograms on counterfeits (Sholy 2015). This would explain why pharmacists reported not relying on holograms. Furthermore, participants stated that shortage of medicine increases the demand for cheaper medicine which are highly likely to be counterfeits, which is supported by a number of studies (Chauvé 2008; Alfadl et al. 2013; Rajapandian et al. 2013; Mdege et al. 2016). In Poland, people who had low monthly income found the low cost of CFM attractive, and consciously bought them due to their availability and low cost, increasing the demand for CFM (Binkowska-Bury et al. 2013).

Overcoming factors to CFM

Participants also emphasised the need for the government to develop legal frameworks and strong legislations

328 regulating medicine, with severe penalties to deter counterfeiters, as supported by several other studies

329 (Syhakhang et al 2004; Chauvé 2008; Alfadl et al. 2013; Al-Worafi 2014; Mdege et al. 2016). Their

330 suggestions were in support of the OPL with pharmacists being positioned at customs and within hospitals.

331 There were also further suggestions to reactivate the national laboratory to test and control supply chain of all

332 medicines in the Lebanese market, to ensure safety (Chauvé 2008; Lebanon Pharmaceuticals and Healthcare

333 2010; Rajapandian et al. 2013; Sholy et al. 2017).

334   All participants indicated that education was key, and considered education the turning point for

335 controlling CFM availability as supported by other studies (Alfadl et al. 2013; El Jardali et al. 2015; Sholy et

336 al. 2017). Participants demonstrated the need to establish a centralized and standardized reporting system, such

337 as Medwatch that encourages voluntary reporting of suspected CFM (U.S. Food and Drug Administration

338 2016). The burden of CFM can then be estimated by costs of hospitalizations or ambulatory settings for treating

339 the consequences of CFM use (Akiny 2013).

340   Identifying the appropriate interventions required for the educational, managerial and regulatory programs

341 may lead to the development of beneficial interventions. Additionally, pharmacists' awareness and CFM

342 education can play a key role in educating and counselling patients about CFM that can empower the public

343 by decreasing their vulnerability towards CFM, improving detection and reporting of CFM, thus reducing their

344 availability/use.

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346 **Limitations**

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348 When approached, not all pharmacists were enthusiastic or willing to participate in the study. The FG were

349 conducted in ML, the region with the lowest incidences of CFM use. There was a bias in the sample of the

350 public participants, as the majority had university degrees, were females and were in the same age group.

Conclusion

This is the first FG study to generate insight on awareness among the public, and pharmacists regarding CFM in Lebanon. The results were consistent with previous studies on the need for changes related to regulations, enforcement of the law, and updating pharmacists' CFM knowledge. Additionally, emphasised the role of high prices and the unaffordability of medicines in increasing vulnerability of the public to using CFM. Finally, there is a need for future mixed methods research to assess and confirm the themes suggested in this study.

357 **Ethics approval**

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359 The School of Pharmacy and Biomolecular Sciences Research Ethics Committee at the University of Brighton

360 approved the study.

361

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