

Falsified Medicines: Literature review

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In order to understand the global phenomenon of falsified medicines, this literature review is conducted as a pilot study to identify knowledge gaps and deliver insights for further research. The emergence and prevalence of falsified medicines take on different forms between developing and developed nations due to political, economic, social and cultural factors, yet studies from social, historical, cultural and ethical perspectives are rare. Empirical studies on consumers' healthcare seeking behaviours and coping strategies such as the purchase of medicines from unknown, informal or extralegal sources, as well as on if/how healthcare professionals follow up patients who experience unusual lack of medical efficacy, are lacking. Inter-disciplinary research is urgently needed.

Keywords: falsified medicines, healthcare, global pandemic, literature review

Förfalskade läkemedel. En litteraturöversikt: Förfalskade läkemedel är ett globalt och ökande fenomen som dock är föga känt. För att identifiera kunskapsluckor och ge insikter för vidare forskning om fenomenet, har denna litteraturstudie genomförts i form av en pilotstudie. Framväxten och förekomsten av förfalskade läkemedel tar sig olika uttryck mellan utvecklingsländer och i-länder på grund av politiska, ekonomiska, sociala, historiska och kulturella faktorer. Det är därför nödvändigt med studier som angriper problematiken utifrån sociala, kulturella och etiska perspektiv. Sådana studier är emellertid sällsynta. Det råder brist på empiriska studier som undersöker människors attityder till hälso- och sjukvårdskonsumtion och eventuella coping strategier som till exempel inköp av mediciner från okända, informella och olagliga källor. Det behövs även studier som granskar om/hur sjukvårdspersonal följer upp patienter som upplever ovanliga omfattande behov tvärvetenskaplig forskning.

Nyckelord: förfalskade läkemedel, hälso- och sjukvård, global pandemi, litteratursökning

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ABSTRACT

Background

Falsified medicine is a pharmaceutical product that pretends to be genuine and combat diseases. It may be ineffective or harmful, which usually leads to devastating consequences both for individuals and society. International collaborations against the global spread of falsified medicines are urgently needed and called for within and beyond academia. In order to understand such a pandemic phenomenon, this literature review is conducted as a pilot study to identify knowledge gaps and insights for further research.

Methodology

With coded keywords, a thorough search for academic journals published between 2000 and 2015 within all the databases Lund University subscribes on the EBSCOhost database platform was conducted. Thematic analysis was then used to categorize and analyse selected articles in order to delineate discourses on falsified medicines.

Results

Lack of universally accepted definitions on various forms of illegal medicines remains the most obvious obstacle for stakeholders in taking effective actions to address the phenomenon of falsified medicines. The actual scale of the problem is difficult to depict given the limited and poor-quality data collected. The emergence and prevalence of falsified medicines takes on different forms between developing and developed nations due to political, economic and social factors. In addition the flourishing e-commerce opens up a virtual market where falsified medicines can infiltrate legitimate supply chain and reach directly to the consumers whose awareness of this issue is still rather low. Among healthcare professionals, knowledge of falsified medicines is also alarmingly limited.

Conclusions

Literature shows that the problem of falsified medicines has been widely recognized, but far from being well defined or clearly addressed. The number of studies from social, cultural and ethical perspectives is small. Empirical data regarding consumers' healthcare seeking behaviours and coping strategies are lacking. What is more, studies on healthcare professionals' perception of falsified medicines and how they can play a preventative role in this battle are needed.

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1. INTRODUCTION

1.1 General information & Objectives

Falsified medicine is a pharmaceutical product that pretends to be genuine and combat diseases. Falsified medicines may be ineffective or harmful. Sales through e-commerce is ever increasing in Sweden, Europe and the rest of the world. The consequences are usually devastating both for individuals as well as for society. Even in the poorer parts of the world where life-threatening diseases such as malaria, AIDS and tuberculosis rife, counterfeit drugs is a growing problem.

Falsified medicines pose a serious threat to both individual health and public health in general. They may contain wrong dosage of ingredients, wrong ingredients, or ingredients of low quality, the consumption of which may, at best, fails to help improve patients' condition, and at worst, cause avoidable mortality and morbidity. In some cases, it also leads to drug resistance, which will impair patients' response to future medication. Besides the direct harm to patients, falsified medicines may also result in financial loss to the pharmaceutical industry and eroding public confidence in genuine medicines and their trust in national healthcare system.

The literature review has been funded with the support of LU Innovation System, Innovation Office South, with the intention to stimulate early development in collaboration with companies and organizations. The literature review has been conducted by researchers from the department of Arts and Cultural Sciences, Lund University, in collaboration with the Swedish National Council on Medical Ethics.

1.2 Methodology

In order to do a search for literature on falsified medicines, we searched a number of different databases. The databases were chosen to cover literature published from 2000 until 2015 on falsified medicines from a range of perspectives even though the main focus was on articles from academic journals. The searches were performed and compiled by Aron Lindhagen at the Humanities and Theology libraries at Lund University.

The search was the same in all databases, with some minor alterations, and based on key words provided by the members of the project. Web of Science, PubMed and all the databases Lund University subscribes on the EBSCOhost database platform were searched. Some of them were removed after the original search because they either retrieved no hits or the hits were irrelevant to the project.

Keywords were coded as a combination of "drug" or "drugs" or "medicine" or "medicines" or "medication" or "pharmaceutical" or "pharmaceuticals" with the

following words “counterfeit, fake, faked, false, falsified, substandard, degraded, illicit, illegal”.¹

¹ We are indebted to Michael Deats for him having made us aware of the literature search could also have included the term *spurious*. This term is not in our current search.

2. RESULTS

2.1 Falsified medicines – a serious threat to public health

In the literature there is an international consensus that falsified medicines pose a serious threat to both individual health and public health in general. They may contain wrong dosage of ingredients, wrong ingredients, or ingredients of low quality, the consumption of which may, at best, fails to help improve patients' condition, and at worst, cause avoidable mortality and morbidity (Newton, Green, Fernández, Day, & White, 2006). In some cases, it also leads to drug resistance, which will impair patients' response to future medication (Dégardin, Roggo, & Margot, 2014). Besides the direct harm to patients, falsified medicines may also result in financial loss to the pharmaceutical industry and eroding public confidence in genuine medicines and their trust in national healthcare system (Ratanawijitrasin & Phanouvong, 2014). Some researchers even argue that this problem is not only a health emergency, but a “macroeconomic pandemic in the making” in that major workforce could be too ill to work and healthcare sectors would then carry too much burden in handling the situation if the problem continues growing (Wertheimer & Norris, 2009). Furthermore, there is literature indicating that terrorist organizations are also involved in this medicine falsification business to raise fund for their terrorist activities (Cannon, 2015).

The most heavily affected areas are Southeast Asia and sub-Saharan Africa where infective diseases are widespread. Anti-malarial medicines, together with antibiotics, are particularly attractive to falsifiers (Delepierre, Gayot, & Carpentier, 2012; Newton, et al., 2006). Now this pharmaceutical crime becomes more sophisticated and widespread, and falsified medicines are found to have infiltrated into the legitimate supply chains in developed countries where security and regulations are supposed to be more stringent (Attaran, Bate, & Kendall, 2011). In addition, as the flourishing internet pharmacies have transformed the conventional way of medicine distribution, it further facilitates the expanding of falsified medicines. This problem is increasingly recognized and classified as a global pandemic, and actions are needed to stop it.

2.2 Poor-quality medicines – how to define it?

Despite the increasing awareness among governments, pharmaceutical industry and international organizations on the dangers of the “fraudulent drug epidemic” (G. M. L. Nayyar et al., 2015), no universally accepted definitions exist to differentiate various types of legitimate and illegitimate medicines (Attaran et al., 2012; G. M. Nayyar, Breman, Newton, & Herrington, 2012; G. M. L. Nayyar et al., 2015), which leads to difficulties in taking effective and strategic actions to address the problem (Clift, 2010). The lack of clarity is widely recognised in the literature as the “heart of the problem” (Gostin, Buckley, & Kelley, 2013; Newton

et al., 2011), and consequently ignites heated debates within and beyond academia.

For legitimate medicines, it is relatively clear that there are two types in the market: proprietary medicines and generic medicines. Due to lower levels of Research And Development (R&D) investment, generics are normally much cheaper than the proprietary ones and thus have larger market share in developing countries (Oxfam, 2011). But both types are produced under good manufacturing practices (GMP) and properly regulated for quality, despite price differences.

For the illegitimate medicines, however, the situation is rather complex. In the literature, there are different terms used to refer to poor-quality medicines, such as counterfeit, substandard, falsified, spurious, degraded, fake, and falsely-labelled. Among them, the term “counterfeit” appears to be especially controversial. On one hand, World Health Organization (WHO)’s definition of “counterfeit” formulated in the 1990s remains to be the worldwide reference (Dégardin et al., 2014), stating that counterfeit medicines are those which are “deliberately and fraudulently mislabelled with respect to identity and/or source”². On the other hand, “counterfeit” has now been largely associated and legally defined within intellectual property (IP) legislation, which adds another layer to the connotation of this term. Some stakeholders therefore fear that the enforcement of IP issue on counterfeit medicines would empower big pharmaceuticals with branded medicines and hinder the generics industry, which would ultimately deny patients’ access to legitimate and more affordable generic medicines (Attaran, Bate, & Kendall, 2011). As a result, what comes to the fore is which aspect of “medicine counterfeiting”, the public health or the IP infringement, is represented, and whose interest, big pharmaceutical companies or generic pharmaceuticals, is addressed when it comes to defining the problem.

Facing criticisms and pressure from stakeholders, WHO now chooses to use a very general term “substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products³” to cover all the illegitimate medicines and keeps clarifying its standpoints on SSFFC medical products to emphasize its interest in maintaining public health (Lieberman, 2012). In addition, the term “substandard” also receives criticism, because it was originally defined as genuine medicines of lower-than-standard quality but manufactured by legal companies. This definition was criticized as self-contradictory (Clift, 2010). Therefore, WHO had to revise its definition and the latest provisional version defines substandard medicines as “pharmaceutical products that do not meet their quality standards and specifications”⁴ (Clift, 2010). Whereas for European Medicines Agency, in order

² <http://www.who.int/medicines/regulation/ssffc/definitions/en/> (Accessed on 29th Oct., 2015)

³ <http://www.who.int/medicines/regulation/ssffc/definitions/en/> (Accessed on 29th Oct., 2015)

⁴ <http://www.who.int/medicines/services/expertcommittees/pharmprep/14052010NewDefinitionSubstandardMeds-QAS10-344Rev1.pdf> (Accessed on 29th Oct., 2015)

to clear the confusion, the term “falsified medicines” is employed to define “fake medicines that pass themselves off as real, authorised medicines”⁵ to particularly distance from “counterfeit medicines”; substandard medicines are listed under the umbrella term of falsified medicines.

In the literature there is still much confusion. A majority of the articles do not separate clearly the various types of poor-quality medicines. In this report, we are using the term “falsified medicine” to refer to poor-quality medicines.

2.3 Scale of the problem

Literature shows the problem is growing, but its size remains unclear. The lack of reliable data has been widely acknowledged among international organizations and academia. It is estimated in an International Medical Products Anti-Counterfeiting Taskforce (IMPACT) report (2008) that over 30% of medicines in many African countries and some part of Asia are falsified. In areas which are heavily affected by infective diseases such as malaria, tuberculosis and HIV/AIDS, this figure goes even beyond 50% (Cockburn, Newton, Agyarko, Akunyili, & White, 2005; Newton et al., 2006). In developed countries where regulations are more stringent, the figure looks less daunting, with less than 1% of poor-quality medicines circulating in the market (IMPACT, 2008). What was once considered as a problem in developing nations has now been spread to developed countries. What’s more, according to IMPACT (2008), any kind of medical product, even medical devices, can be and have been counterfeited. Moreover, the emergence and increasing use of Internet contributes to the already serious situation by opening up one more distribution channel in addition to the conventional ones for falsified medicines. It is estimated that over 50% of medicines bought from illegal sites that conceal their physical address are falsified (IMPACT, 2008). In the summer 2015, during the Interpol operation Pangea VIII⁶, 20.7 million falsified medicines of an estimated total value of \$81 million were seized in just one week (Lundin, 2015). A survey done by America’s National Association of Boards of Pharmacy (NABP) found that over 99% of online pharmacies did not comply with NABP patient safety and pharmacy practice standards (Clark, 2015). The Medical Product Agency of Sweden also conducted a population-based web survey on internet purchase of prescription-only medicines, whose result shows that in the past year 1% of respondents have purchased prescription-only medicines without prescriptions and 40% would consider doing so in the future (Sveriges Läkemedelsverket, 2015). This report also points out that the number of people purchasing medicine from internet

⁵http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000186.jsp (Accessed on 29th Oct., 2015)

⁶<http://www.interpol.int/fr/Crime-areas/Pharmaceutical-crime/Operations/Operation-Pangea> (Accessed on 29th Oct., 2015)

pharmacies in Sweden has rapidly increased from 3% in 2007 to 20% in 2010 (Sveriges Läkemedelsverket, 2015).

Regarding the origins of falsified medicines, China and India are considered to be two biggest manufacturers and exporters (Delepierre, Gayot, & Carpentier, 2012). Russia is reported to have joined this international crime recently (Clark, 2015). And Middle East and Switzerland are assumed to be major transit hubs of falsified medicines (Dégardin et al., 2014).

Beyond those estimated figures, two points are highlighted in the literature, which are the lack of reports from certain parts of the world and the underestimation of the actual size of the problem.

First, in spite of the increasing reports of detection of various falsified medicines around the world, reports from middle- or high-income countries quantifying the scale of the problem are few (G. M. L. Nayyar et al., 2015). The majority of studies were conducted in low-income or lower middle-income areas, especially countries in South-east Asia and sub-Saharan Africa (Almuzaini, Choonara, & Sammons, 2013). Literature from Middle-east and Eastern Europe is especially rare. To the best of our knowledge, two articles are identified, in Poland and Romania respectively, presenting the public awareness of the danger and the scale of falsified medicines (Binkowska-Bury et al., 2013; Pál, S. (1) et al., 2015). While regarding research from Middle-east, there is just one report from Iran showing the prevalence of falsified medicines on a national scale (Hosseini, Sh, Tehrani Banihashemi, Naseri, & Dinarvand, 2011).

Second, the actual prevalence is highly likely to be more serious than the collected data has shown, due to various factors. One reason is the technical barriers, such as inconsistencies in drug sampling methods (Almuzaini, Choonara, & Sammons, 2013). Another one is the difficulty in detecting and tracking falsified medicines. The act of producing and trading falsified medicines is conducted in the grey zone, so it is impossible to know how many falsifiers go undetected (Harris, Stevens & Morris, 2009). Plus, at the end of the distribution chain, healthcare workers and patients rarely question the quality of the medications if expected relief is not experienced; even if they do, the pills might already have been metabolized in the body and the packaging might be thrown away. This leads to a situation where no one suspects or tells, and no evidence is kept for forensic investigations (Liang, 2006). One more reason why the data fails to depict the size of the problem is that in many countries the data of incidences caused by falsified medicine is hidden in public health statistics (Cockburn et al., 2005). Last but not least, the industry and governmental agencies are reluctant to share critical information with the public and researchers, which is referred to as unpublished “grey literature” (Taberner et al., 2014). The industry fears that publicity will damage the sales and reputation of their products while some governments are accused of being corrupted and even involved in medicine

falsification activities (Cockburn et al., 2005), therefore the inaccessibility of important data hampers the measuring.

Besides disproportionate levels of falsified medicine prevalence in different areas of the world, the types of targeted medicines show divergence between developed and developing countries. In developing countries, especially in tropical areas, the majority of falsified medicines are anti-infective medications, with anti-malarial medicines being particularly targeted by falsifiers (Newton et al., 2006). While in developed countries, falsifiers mostly target the so-called “lifestyle” medicines, such as those for weight management and erectile dysfunction. However, lately, falsified life-saving medicines are also found in developed countries, from over-the-counter medicines to cancer drugs (Liang, 2006). In addition, what’s worth mentioning is that according to the only report we found from Middle East, it is falsified health supplements that occupies the falsified medicine market in Iran (Hosseini et al., 2011).

2.4 Why so prevalent?

Reasons for the emergence and prevalence of falsified medicines differ from country to country and from region to region, due to a variety of political, economic, social and cultural factors. The most obvious difference is between rich countries and poor countries. In impoverished nations like Nigeria, the demand for affordable essential medicines is strong, but meanwhile we have to bear in mind that this is also a country where over 70% of medicines rely on importation and people have to live with chaotic distribution networks (Erhun, Babalola & Erhun, 2001). Nearly all kinds of medicines, Over-the-Counter (OCT) or prescription-only (POM), good-quality or poor-quality, are mixed together and can be found in open market, street vendors, public and private hospitals, and hawkers on motorcycles (Erhun, Babalola & Erhun, 2001). The strong demand together with lax regulations open the door for falsified medicines. Whereas in developed nations such as European countries and the US, drug distribution is highly regulated, but the less-regulated online pharmacies rise to be a more prominent issue.

However certain phenomena are recognized as exist worldwide that eventually escalate this problem to a global alarm. Much literature has contributed to pinpointing limitations in current legislation framework, showcasing the challenges in fighting against falsified medicines, as well as providing suggestions on how to move forward in this battle. Thus, the following sections aim to present and delineate some of the main factors that assist the expanding of this pandemic.

2.4.1 Deficiencies in legislation and enforcement

Being one mostly criticized topic in the literature, deficiencies in nationwide and worldwide legislation and enforcement are considered as a major hurdle in

battling against the issue of falsified medicines (Lamy & Liverani, 2015). Medicine falsification is financially rewarding, whose profit can compare with the manufacturing of narcotic drugs. Nevertheless, the penalty for this kind of pharmaceutical crime is light (Liang, 2006). In some countries, producing falsified medicines does not even counted as a crime, while in some countries like Norway, imprisonment of possessing falsified medicines without legal reasons is maximum 4 months (Attaran et al., 2011; Liang, 2006). In addition, as medicine falsification activity becomes more organized, even highly globalized, the lack of international law and inconsistent definitions of this crime among different nations unfortunately make it difficult to extradite and prosecute falsifiers (Attaran et al., 2011) and thus “translate into impunity to medical criminals”(Newton et al., 2014). In response to this problem, Attaran (2015) proposes a “Model Law on Medicine Crime” aiming to strengthen the current legal framework and enforcement, providing suggestions including the punishing principles, prohibitions against manufacturing, trafficking and distributing poor quality medicines. This paper also suggests that this Model Law can be flexibly implemented into the current national laws and lessons from tobacco control can be learned (Attaran, 2015). Nonetheless, one practical obstacle to detect and regulate falsified medicines is the lack of human and financial resources of Medicine Regulatory Authorities (MRA) (Delepierre et al., 2012). This has been reported in both developed and developing countries. For example, Food and Drug Associates of the United States is “chronically underfunded” (Liang, 2006). It once admitted at a Congressional hearing that the agency did not have enough resources to ensure the safety of imported drugs (PEW, 2011). Developing countries encounter similar problems, but in a more resource-limited setting, in a way that even maintaining a fully functioned MRA might have to compete with other national priorities (Caudron et al., 2008). Last but not least, the booming yet loosely regulated internet pharmacies pose a potential threat to consumers, in that the public with rather low awareness of the danger of falsified drugs are exposed to a large quantity of illicit online pharmacies. Even worse, when prescription-only medicines can be purchased without prescriptions, drug misuse may happen and drug quality cannot be ensured. To some extent, online pharmacies also accelerate the global movement of goods including falsified pharmaceutical product, yet regulations on this cyberspace are lacking (Mackey & Liang, 2013). Further discussion on Internet pharmacies is carried on in subsequent sections.

2.4.2 Vulnerable supply chain

Falsified medicines do not only circulate in unauthorised pharmacies and street markets, as traditionally described in developing nations, but have also penetrated into the legitimate supply chain and flowed directly to hospitals, doctors and authorised pharmacists, or even go straight to the end users – patients – through

internet sales. The latter is particularly identified in the literature from developed countries. For example, in 2011 fake Avastin®, a drug for cancer treatment, was found to have entered the legitimate supply chain in the US. Shockingly enough, the supplier was a licensed wholesale company and they sold directly to doctors (Weaver & Whalen, 2012). This infiltration magnifies the vulnerability of the porous supply chains, even in countries with stringent laws like the United States. The routes of medical products from the manufacturers to the end users can be long and circuitous. Numerous secondary wholesalers, retailers and re-packagers constitute the extra layers in the distribution network, which means each transaction would potentially be an entry point for falsified medicines (Chaudhry & Stumpf, 2013).

Several authors believe that in Europe, medicine falsification issues are largely related to pharmaceutical “parallel trade” between European countries due to price differences in each country and the policy of free movement of goods and service (Dégardin et al., 2014; Liang, 2006; Lybecker, 2008). Whereas in the U.S, the major weakness in the supply chain is believed to be the (re)importation of medicines. Importation means bringing goods in one country from another country for sale, however, as Liang (2006) points out that products for export are not subject to the local safety laws, which means imported medicines’ quality is not guaranteed. As for re-importation, according to Dégardin et al. (2014), it means product for export might be brought back to the domestic markets, which opens the door for medicine falsifiers. Moreover, globalization of the financial market and global mobility of goods are also challenging the strength of supply chain. With increased outsourcing of medical production, from the procurement of key ingredients to the final stage of manufacturing and to distribution, this process takes on a transnational nature; any weakness or negligence during this process could potentially be capitalized by falsifiers (PEW, 2011).

2.4.3 Double quality standard, double quality assurance practices

It is worth mentioning that the production of poor-quality drugs are not limited to medicine falsifiers who illegally and intentionally manufacture falsified medicines, legitimate pharmaceuticals could also be involved in producing and distributing the so-called substandard medicines, possibly due to unintentional manufacturing negligence and inappropriate handling during transport and storage. However, according to Caudron et al. (2008), medicines manufactured for export from developed countries to developing countries do not often follow the same GMP standard as those for domestic use. Their observations show that there are “parallel production” in the same GMP-compliance facilities, which are of high standard, intermediate standard and lower standard, respectively for strictly regulated markets, middle-income countries and poorly regulated markets (Caudron et al., 2008). Besides the hierarchy of medicine quality during

manufacturing, what also underlines this problem is that products from developed countries for export are often subject to fewer controls than those for domestic consumption (Dégardin et al., 2014). Subsequently, this burden is placed on the recipient countries, which is nearly impractical for poorer countries because their MRAs' capacity is already limited in evaluating medicine quality. Bate (2007) extends this argument and points out that not only the pharmaceutical companies are to blame, but some international aid agencies should also bear the criticism, in that some international donors fail to test the quality before they sanction the drug to countries that are in desperate need of medicines (Bate, 2007). And what needs to be emphasized now is not the access to medicines, but the access to good quality medicines (Newton et al., 2014); and it is not only quality control, but quality assurance (Caudron et al., 2008).

2.4.4 Internet pharmacies

Shopping medicines online is an alternative to conventional way of buying medicines, however, despite the obvious benefits, medicines bought from the internet can also put consumers' health at risk, one major reason being that falsified medicines can find their path to reach the end users directly and cause harm. Rogue online pharmacies sell from "life-style" medicines to "life-saving" medicines, as well as nutrition supplements (Lavorgna, 2015). Most of them market their service with such conveniences as fast delivery, lower-than-market price and, most disturbingly, "no prescription required" (Dussart, Mazenot, & Grelaud, 2011; Mackey & Liang, 2013). When people do self-diagnose and then order prescription-only medicines online without a proper prescription from the doctor, it means patients remove themselves from the protection of medical professionals. The real health problem that leads to the physical discomfort may however be neglected and the chances of being exposed to poor-quality medicines may increase (EAASM, 2008). Apart from the open Internet, the "darknet", an overlay network that can only be accessed with certain software or configurations, has increasingly become a popular virtual marketplace for falsified medicines (Bloomberg Business (2015)⁷.

Nonetheless, regulations regarding pharmaceutical trade in cyberspace are weak, as previously mentioned. In addition what makes it even more difficult to tackle rogue online pharmacies is that they are more resilient to national legislations and more difficult to track than conventional pharmaceutical crimes, given their evanescent, transnational and anonymised nature (Fittler, Bosze, & Botz, 2013; Mackey & Liang, 2013). In a long-term follow-up evaluation of 136 online pharmacies, the result shows that only half of them remain active by the end of the four-year observation and many of them only run temporarily (Fittler et

⁷ <http://www.bloomberg.com/news/features/2015-10-21/darknet-drug-trade-lures-big-pharma-tor> (Accessed on 29th Oct., 2015)

al., 2013). This article further introduces that a certain amount of online pharmacies are found revive after temporarily disappear, possibly because they tend to avoid legal troubles at times. Plus, more than half of them do not display contact information on their websites, while, among those that do, the majority however show a discordant registration domain (IP address). This study also opposes researchers' initial hypothesis and indicates that rogue online pharmacies tend to have greater longevity (Fittler et al., 2013).

2.5 Which disciplines are presented in the literature?

Comparing to the large amount of literature that come from law, medicine, criminology and political science debating on a macro-level around the phenomenon of falsified medicines, empirical studies on the micro level only account for a small portion. Within the limited amount of empirical researches, most of them are conducted from medical perspectives, testing medicine quality and quantifying the scale of poor quality medicines in a particular region or country. Literature from social and cultural analytical perspectives is scarce. Although rare, these current studies are able to go behind those technical discussions and unfold the reality that ordinary people, including consumers of pharmaceutical product, healthcare workers, drug dealers and physicians, face in their daily life. What is presented through these studies is how stakeholders with conflict interests negotiate, how the phenomenon of falsified medicines is perceived and handled online and offline, and finally how buying and selling medicines from “unknown” (probably known from the consumers' opinion) sources constitute the legitimate part of everyday life.

2.5.1 Working with the “ambiguity”

As presented in previous chapters the definitions on various forms of illegitimate medicines are ambiguous and vague. The controversial term “counterfeit” blurs the agenda for public health with that for commercial interests. While many researchers suggest a narrower and more specific term to frame the problem, Hornberger and Cossa (2012) however provide another perspective. They argue that it is exactly the “ambiguity” of the overlapping usage of the term counterfeit that paves a common ground and attracts different parties with conflict interests to participate in the collaboration against falsified medicines. It allows stakeholders to “hold their interest in balance” and to be able to seek and secure what they need such as financial support and partnership (Hornberget and Cossa, 2012), and yet these two authors also clearly point out that this kind of collaboration bears an unsolvable tension. By conducting ethnography, they suggest that state resources are “instrumentalised” and forcibly directed to work towards private interests. Their observation also shows that the market is restructured by big, financially

capable pharmaceuticals who take advantage of the shift from “drug safety” to “drug security” and covertly police the market (Hornberger and Cossa, 2012).

2.5.2 Victims or perpetrators?

Patients or medical consumers do not often appear in the literature, but when they do, they are often counted as the victims of this battle, while unauthorised drug dealers are often depicted as the devils who illegally traffic falsified medicines. This portrayal can certainly fit in certain settings, for instance, when vulnerable children are poisoned by falsified teething mixture (Bonati, 2009), or in situations where falsified medications infiltrate legitimate supply chain and are distributed through such legitimate channels as hospitals and legal pharmacies, and consumed unknowingly by patients (The contamination of Lipitor, a drug for cancer treatment, is such an example⁸). Nevertheless, some researchers seek to show another side of the story that patients actively seek healthcare and make rational judgement when it comes to where and from whom to buy medicines, whereas unauthorised drug dealers are justifiable in some way as decent businessmen. For example, Hornberger and Cossa (2012)’s research in Johannesburg, South Africa observes that migrants are often excluded from the formal healthcare system, so they have to seek informal healthcare practices. What is interesting is that a form of trust has been developed between migrant buyers and drug sellers in the neighbourhood, and this kind of trust to some extent guarantees medicine quality. Comparing with the formal healthcare system, Hornberger and Cossa (2012) argue that the informal purchasing, though potentially dangerous, appear attractive in that it offers flexibility (consumers are offered a spectrum of medicines to choose from) and even social counselling. Nordstrom (2007) adds another scenario in Angola where local people do not consider clinic drugs and street medicines differ much in quality. Street vendors carefully and diligently run their business and believe that they are capable of telling good drugs from the bad ones. They are also proud of their work because essential medicines are actually made affordable and more accessible for community members via their “unauthorised” trade (Nordstrom, 2007). As Nordstrom (2007) comments: “Like most any businesspeople, he (referring to the drug seller) seeks the respect of his community” (p. 133). In another African country, Sudan, unaffordability of genuine medicines is also accounted as the major reason why people buy falsified ones (Alfadl, Hassali, & Ibrahim, 2013). Data collected from in-depth interviews with policy makers and pharmacists shows that poverty and high price of genuine medicines leave patients no choice but to seek cheaper, most likely falsified, alternatives. This paper also argues that motivations of buying falsified medicines or buying from non-legitimate sources differ between developed countries where people can afford genuine medicines but choose to purchase illegitimate ones and

⁸ <https://www.pfizer.com/files/products/LipitorUSRecall.pdf> (Accessed on 29th Oct., 2015)

developing countries where genuine medicines are generally not available or affordable for ordinary people (Alfadl et al., 2013). From the above illustrations, it is clear that patients in precarious conditions do suffer and fall victims from inaccessibility and unaffordability of legitimate medicines, but they also take initiatives in seeking alternative healthcare and the goodwill, hopefully and possibly, of street vendors are able to satisfy their need. These articles indicate that patients are neither ignorant nor passive, not all unauthorised drug sellers are unethical (or bad in a more straightforward way). “Risk is an intrinsic part of life in informal spaces” (Hornberger and Cossa, 2012); in seeking and providing alternative medicines, patients and informal drug sellers might be involved in the mobilization of falsified medicines, but they both choose to take the risk. And this can somehow turns victims into perpetrators in this war on drugs⁹.

2.5.3 The line between legality and illegality

Quite many researchers argue from legal perspectives that an international treaty is needed to combat against international pharmaceutical crime. One way of doing this is to classify the most severe case of medicine falsification as crimes against humanity (Attaran et al., 2011), but first it needs to differentiate whether the poor-quality medicine is manufactured with a criminal intention or merely out of structural negligence, and then treat them differently (Attaran et al., 2012). This argument is refuted by some researchers as they argue that, first, telling if there is criminal intent behind the manufacturing is often impossible, and, second, consequences of poor-quality medicines caused by either practice can be severe and are equally unacceptable (Dorlo, Ravinetto, Beijnen, & Boelaert, 2012). While the above debate centres around defining the line between legality and illegality as well as on how to protect within the border of legal space, Nordstrom (2007) in her book discusses various forms of border crossings between legal and illegal space, including smuggling of falsified medicines and the myth that all medicines produced by legal companies are safe. Rather than defining what is legal and what is not, her ethnography unfolds how the two seemingly distinct spaces get blurred and eventually tie into the mundane life of people working along the shore. Legality simply becomes a fluid concept (Nordstrom, 2007).

For consumers, (il)legality does not seem to be the parameter when they make purchasing decisions, instead, “need” is specifically highlighted as a determinant factor, although it takes on different forms. A study on online forums that discuss the availability of unlicensed slimming drugs in the UK shows that “need” is associated with a sense of entitlement (Sugiura, Pope & Webber, 2012). Consumers want to find the slimming medication that was once available online

⁹ The same patterns regarding patients’ identity of being victims or/and perpetrators were also found in the illegal trade with organs, cells and eggs/embryos. Cf. <http://hottproject.com> (Accessed on 29th Oct., 2015)

but then withdrawn from the market due to possible clinical risks. Their virtual ethnography indicates that some consumers clearly understand the situation, but still “need” to get it from wherever available. Whereas for people with financial constraints, especially those in poorer countries, “need” is translated to the affordability and accessibility to essential life-saving medicines, and as a result the legitimacy of medicines does not matter much anymore (Alfadl et al., 2013; Syhakhang, Freudenthal, Tomson, & Wahlström, 2004).

2.5.4 Public awareness and knowledge of falsified medicines (in conventional market)

A tiny fraction of the literature seek to demonstrate public perception of the problem of poor-quality medicines, especially regarding how much medical professionals, consisting of drug dealers, pharmacists and physicians, know about this issue, and how they can develop a preventative role. Surveys, questionnaires and face-to-face interviews are conducted in several countries including both developed and developing nations.

Three significant problems are identified from these studies: no standardized definition on good/poor quality medicines, low awareness of the problem of poor quality medicines, and limited knowledge in how to identify and report falsified medicines. In a study done in Laos with drug sellers and consumers, both groups define the quality of medicines mainly by its efficacy and cost; high price is associated with better quality, and if the illness is cured, then it is considered as a good one (Syhakhang et al., 2004). This article in addition reveals that professional knowledge among drug sellers is limited in terms of proper medicine storage and knowledge in identifying poor-quality drugs. As for the consumers, the results show that they put great trust in doctors and drug sellers and, given financial constraints, affordability turns out to be a far more critical issue (Syhakhang et al., 2004). A relatively recent study conducted in Cambodia among authorised drug wholesalers also indicates that they have various perceptions of falsified medicines and therefore apply different strategies during procurement and redistribution (Khan et al., 2011). In western India, only 1 in 5 informants (including 100 dental practitioners, 100 medical practitioners, and 100 medical wholesale distributors) surveyed know about falsified medicines (Nagaraj et al., 2015). The result from a comparative study done in Poland between healthcare professionals and lay people is alarming as well; it shows that healthcare professionals demonstrate less awareness than lay people on the scale of falsified medicines and the danger of purchasing outside legal sources. The professionals also lack the knowledge on where and how to report falsified medicines (Binkowska-Bury et al., 2013). The situation in the US does not seem any better. A survey conducted among California pharmacists indicates that a majority of them cannot be certain if they have encountered any falsified medicines and over

half of them have never discussed this issue with patients. (Law & Youmans, 2011).

2.5.5 Public awareness and knowledge of falsified medicines (in virtual market)

Empirical studies on consumers' internet literacy on falsified medicines are rare. No qualitative studies are found in this regard. Only two quantitative-based studies, one in Sweden and the other in Romania, are identified presenting the current situation of this issue within each country. Both studies are able to provide some factual data which to some extent illustrates consumers' attitudes and internet health literacy. The recent study in Sweden focuses on the internet sale of prescription-only medicines (Sveriges Läkemedelsverket, 2015). It shows that most people acknowledge the existence of falsified medicines circulating online, yet a considerable amount still consider buying from online pharmacies in the future. Medicines for coughing, erectile dysfunction and sleeping pills are considered by many people as medicines that can be bought online without prescriptions. Main reasons given by respondents include convenience, cheaper price, anonymity and "I know what I need" (Sveriges Läkemedelsverket, 2015). The other study, conducted in Romania, evaluates consumers' attitude towards not only medicines, but also medicinal products (Pál, S. (1) et al., 2015). It indicates that only 1 in 5 respondents are aware that medicines bought online could be of inferior quality, and 1 in 4 could consider buying from international websites if offered cheaper prices. 1 in 3 do not think it necessary to get information of a new medicine from healthcare professionals, and this attitude appears more popular among younger people than older groups (Pál, S. (1) et al., 2015). Although these two reports are by no means comparable, they lead to accordant further research directions: we do not know how people shop medicines online or how self-diagnose culture is practiced. In the Swedish report, an additional question is raised: what is the difference between a pharmacy and a shop? These questions have not been answered by the current literature.

3. CONCLUSION

3.1 Gaps in the literature

Literature shows that the problem of falsified medicines has been widely recognized, but far from being well defined or clearly addressed. Gaps in the literature are identified as the following:

- Many studies were conducted in Southeast Asia and sub-Saharan Africa, and lately the number of studies in the US and the UK is increasing. Regarding the global nature of falsified medicines, studies from other parts of the world are needed. Studies from Middle East and Latin America are especially scarce.

- A global perspective is needed to understand this global issue, especially in terms of border crossing activities, such as tourism and Internet connection.

- Empirical studies on the vulnerability of supply chain are lacking. Various actors constitute the multi-layered supply chain; including manufacturers, wholesalers, retailers, re-packagers, sale representatives, pharmacies, hospitals and doctors. But we do not know much about the interaction among these actors, either do we know in which condition falsified medicines enter the legal distribution network.

- Empirical studies on patients' healthcare seeking behaviours are lacking. Some literature has touched upon this issue, but the data is limited and not representative enough to draw patterns. Moreover, studies from social science, cultural studies and ethics are lacking. In order to understand thoroughly patients' healthcare seeking behaviours, it is important to learn how risk is perceived and balanced in people's daily decisions as well as to understand how people legitimize their medicine shopping behaviours.

- Following the previous point, interdisciplinary research is needed.

- Empirical studies on doctors' and health staff's knowledge about falsified medicines and if/how they follow up patients who seek help for both unknown medical side effects and unusual lack of medical efficacy are needed.

- Knowledge on the possible correlation between medicine falsification and terrorist activities is needed.

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