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Assessment of the informal pharmaceutical market and its contributing factors in Guji and West Guji Zones of Oromia Regional State, Ethiopia

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This is to certify that the thesis prepared by Feyissa Shonora Gata entitled: *Assessment of informal pharmaceutical market and its contributing factors in Guji and west Guji zones, Oromia Regional State, Ethiopia* and submitted in partial fulfillment of the Requirements for the Degree of Master of Science in Pharmacoepidemiology and Social Pharmacy complies with the regulations of the university and meet accepted standard with respect to originality and quality.

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Abstract

A Assessment of informal pharmaceutical market and its contributing factors in Guji and west Guji zones, Oromia Regional State, Ethiopia

Background: Informal pharmaceutical market is common in developing countries due to constrained regulation, low awareness and poor infrastructure. In Ethiopia this practice is given little attention. This study was conducted to assess the informal pharmaceuticals market and identify factors that contributed to the existence and proliferation of the market in remote and gold mining areas of the study.

Methods: The study used descriptive exploratory qualitative research design. Open market places, shops and kiosks were observed. Key Informant Interviews (n=25) and two FGD (n=12) with medicine sellers, health professionals and community were conducted. The data was processed and analyzed manually using thematic analysis

Findings: Wide variety of medicines was found in the market. The medicines were sourced from wholesalers, pharmacies, government institutions, private clinics and contraband. The existence of high demand, lack of adequate supply to the formal channel, lack of infrastructure in the remote areas, lack of proper regulation, low awareness and corruption were identified as main contributing factors to the existence and proliferation of the market.

Conclusion and Recommendations: This study found that informal pharmaceutical practice is widespread in the area and the community patronizes the practice due to the lack of alternative formal health service. It also found that the formal and informal pharmaceutical market is intertwined. The research recommends the provision of needy medicines to those who have no alternative through sustainable supply; access creation and establishment of satellite health posts as it mitigates the practice through fighting corruption, tightening regulation and awareness creation.

Key words: Informal pharmaceutical market, contraband, pharmaceutical regulation, qualitative, *Guji*, Ethiopia.

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Acronyms

AIDS	Acquired Immune-Deficiency Syndrome
CSA	Central Statistics Agency
FMHACA	Food, Medicine and Health care Administration and Control Authority
FMOH	Federal Ministry of Health
FMOM	Federal Ministry of Mining
HIV	Human Immune-Deficiency Virus
IMS	Institute for Health Care Informatics
MDR-TB	Multi-Drug Resistant TB
ORHB	Oromia Region Health Bureau
WHO	World Health Organization

1. Introduction

The spread of informal pharmaceutical markets has been much faster in many countries than the creation of effective regulatory arrangements to influence their performance (Bloom, et.al., 2011). This is especially true in developing countries most importantly in failed and unstable countries where regulation is constrained due to limited resources, inadequate understanding by regulators to their role and lack of incentives to act, especially against those whom they may regard as fellow health workers (Ensor and Weinzierl, 2006).

Many studies conducted on the informal pharmaceutical market in Sub-Saharan countries indicated that the market is widespread due to structural and socioeconomic factors. While the structural factors were related to the strength of the regulatory system the socio-economic factors were related to the convenience, easy access and low price of the medicines in the informal market (Patterson, 2016; All African.com, 2016).

According to studies these pharmaceuticals sold at informal markets are mostly of low quality due to constant exposure to sun, dust and changing weather (Amadi and Amadi, 2014;Shakoor, 1997;Bellereau, et al., 1997). In addition to the deterioration of the quality due to its management the medicines were sold by unqualified personnel that doesn't understand the instructions and information that comes with the leaflets of the pharmaceuticals (WHO, 2002; WHO, 2012). The impacts of these low-quality pharmaceuticals with improper information include treatment failure and serious damage to the patients' health or even death (Abdiet al., 1995).

In Ethiopia though there are no explicit research on the extent of the practice, studies conducted on other topics have indicated the existence of the practice. A study conducted in Butajira town and Jimma town on self-medication revealed that 11% and 19% of the medication for self-medication coming from the informal market (Gedif, 1995; Derressa, Ali, and Enqusellassie, 2003; Worku and G/Mariam, 2003).

Similarly, the most recent study conducted by Food, Medicine, and Health care Administration and Control Authority (FMHACA) of the country, has revealed 9.5% of the pharmaceuticals they obtained to assess the extent of substandard medicines in the country coming from informal market (FMHACA, 2013).

The sale of pharmaceuticals in informal markets is relatively low in urban areas and places where access to health facilities are better and regulatory enforcement is relatively good (Onwuka, 2010). Nevertheless, in place like mining areas where the mining practice is largely illegal and access to health services is limited due to poor infrastructure(FMOM, 2012a;FMOM, 2012b), the sale of pharmaceuticals in open and substandard outlets is expected to be common.

This is true especially in gold mining and remote areas of Guji and West Guji zones of Oromia regional state due to poor regulatory enforcement and the mobile nature of miners which made it difficult to establish stationary health facilities (FMOM, 2012b) luring the informal providers of the pharmaceutical service to fill the gap and compelled consumers to patronize the practice (Bhuiya, 2009).

In spite of these facts and the health hazard an informal market pharmaceutical pose, there was limited research in the country particularly in remote areas like mining villages where vulnerability to informal pharmaceutical market is high.

Therefore, this research tried to assess the type and source of pharmaceuticals as well as factors contributing for informal pharmaceutical market in selected remote and mining Woredas of Guji and West Guji zones, Oromia Regional State.

1.1. Statement of the problem

Ethiopia, regardless of its speedy economic growth for the last couple of years, remains one of the poorest nations in the world, the vast majority of the poor being rural dwellers. Despite past progress, a historic legacy of underinvestment still bears its mark as more than half of the adult population is illiterate and the country's infrastructure deficits remains one of the largest in the world (World Bank, 2016).

As such the country remains prone to the proliferation of informal pharmaceutical market that fills the gap created due to affordability, lack of access and awareness (Davis, 2008). Gujii and West Guji zones in general, the mining areas in particular are one of the most underdeveloped parts in the country in terms of infrastructure and development interventions. For example, according to Oromia Region Health Bureau Report there were 70 health centers in Guji zone and 66 health centers in West Guji zone serving a populatioin of 1,397,633 and 1,166,486 respectively (Oromia Regional Heath Bureau, 2016). Though the health center to population ratio is within the acceptaible range by Ethiopian standard (FMHACA, 2011),the population in the two zones are highly dispersed and the health ceners are largely located in

major towns and far from rural dewellers and artisinal mining areas. The distance,even if they were to afford or want to use it, understandbly discourage the utilization of the service(Bhuiya, 2009).

In the zones, most legal pharmaceutical sale outlets are located in towns quite distant from study area due to the absence of settings that fulfils pharmacy outlets requirements. In addition, the two zones are in close proximity to Somalia and Kenya where illegal cross-border trade is expected to exist.

Against the back drop of such mounting anecdotal evidence of the existence of informal pharmaceutical sale, there seems little policy focus in the country to curb this problem which partly is attributed to lack of research in the area.

2. Literature review

The review of the related literature is organized under the themes that emerged during the review. Following the general description of informal pharmaceutical market situation the literatures are organized along their respective themes with the first section being factors that contributes to the proliferation of the practice followed by the impact of informal pharmaceutical market practice and source and type of informal pharmaceuticals.

General overview of informal pharmaceutical practice

Informal pharmaceutical market is a market where pharmaceuticals are sold outside the existing legal framework(Crespo, 1990).The sale of pharmaceuticals in an informal market is a widespread problem but little attention is given compared to pharmaceuticals distributed through formal sector (Ratanawijitrasin and Wondemagegne, 2002; Cross and MacGregor, 2010).

In most part of the developing countries in Asia and Africa in particular the sale of medicines in an informal market by informal providers is common (Bhuiya, A. , 2009; Bloom, G., et al., 2011; Goodman et.al., 2007; Cross and Macgregor, 2010).

In poor parts of Sub Saharan Africa, it is common to find prescription medicines sold in an open market. In Ghana, for instance, hawkers in all major cities sale all kind of products including pharmaceuticals in streets, bus terminals to whomever comes around without any prescription (Gebtor, et al., 2014). Similarly, in Nigeria, Burkina Faso, Tanzania and other western and eastern African countries, the practice is widespread and the sale of prescription pharmaceuticals, including antibiotics and injectables were freely available from drug

hawkers, illegal stores and street vendors(Gebtor, et al., 2014; Goodman et al., 2004;World Council of Churches , 2006;Oladepo, et al., 2007; WHO, 2006).

In Ethiopia, there is no exclusive research conducted on the sale of pharmaceuticals in an informal sector (open market, stalls, shops and streets). However, a study conducted on cross border illicit goods that are trafficked from Somaliland to Ethiopian border town of Hartisheikh found pharmaceuticals sold on the open market like any other commodities (Michaelson, 1999).This same practice was implicated in many other researches conducted for different purposes such as on self-medication (Derressa, Ali and Enqusellassie, 2003;Gedif, 1995), pharmaceutical sector assessment (FMOH/WHO, 2003) and pharmaceutical counterfeit (FMHACA, 2013). Similarly, study conducted on self - medication in Jimma has reported 19% of the pharmaceuticals for self-medication coming from pharmaceuticals sold in an informal sector (Worku and G/Mariam, 2003).

Contributing factors

Informal market comes into being where there exists demand and supply. On the demand side, the informal markets come into existence either when there is no formal market or the goods informally offered are cheaper than the ones offered formally. On the supply side, informal markets emerge on condition that the expected profitability obscures the risk from law enforcement. Like any other business, informality in pharmaceuticals too emerges in response to demand and shortage of supply (Beckert and Wehinger, 2013;Anadach Consulting Group, 2014).

While demand is widely believed to be a motivating factor for medicine sellers at general stores, kiosks, and market stalls, and for those who operate as itinerant and informal clinic

owners, with considerable variation in retailer type across settings, some blame the profit maximizing behavior of vendors (Goodman, et al., 2004). Contrary to this, vendors believe that their sales practice is determined by the demand of their consumers (Ecks S. , 2008a;Van der Geest, Rynolds, and Hardon, ., 1996).

Regardless of the argument for or against whether demand is a true factor for vendors to engage in the practice, the irrefutable fact thought is the role uncontrolled population growth play in fueling demand creating fertile ground for informal practice to mushroom(Anadach Consulting Group, 2014). According to IMS Institute for Health Care Informatics (2015) report, pharmaceutical demand in 2020 will reach 4.5 trillion doses, up 24% from 2015, with 36 percent of that being in emerging markets. That share was expected to grow, due primarily to a growing population which increasingly afflicted with chronic disease (International Finance Coropration, 2017). A prime example in this case is Bangladesh, a country put under high burden of infectious diseases on the one hand, and the emerging burden of non-communicable diseases on the other due to rapid social, economic, demographic, and epidemiologic transition(Government of the people's republic of Bangladesh, 2008;WHO, 2008a;Bhuiya, 2009).

Such rapid economic, social and demographic change not only put countries under immense disease burden but also stretches resources across competing interests no matter how a country is growing. As such public institutions such as hospitals, health centers and health posts suffer from lack of sufficient supplies. Thus, institutions remain within certain limits to order the medicines which they require and smaller centers receive a standard supply within a

given period and make that last for that given period (Van Der Geest, 1982;Van der Geest, 1983)

The shortage of supply and common stock out coupled with poor management of formal health care facilities which are located further from the villagers and in major towns often gave bad impression to the community in need. This is due to the direct and indirect cost the poor and distant villagers have to incur to access the services (Bhuiya, 2009).

According to a study from India and Nigeria poor management and regular stock out has forced villagers in remote areas, the poor in particular, to patronize traditional healers and pharmacy vendors due to their reliability as opposed to the formal(Datta, 2013;Oshiname and Brieger, 1992). Furthermore, informal dispensaries are popular among the distant villagers and poor due to their cheaper service as they require no prescription and ask no pay for consultation (Dawodu and Anadach, 2017; Torres, et al., 2012).

The economic restrictions, the weak drug-regulatory systems and the insufficient controls on production, distribution and importation also promote a rise of the illegal medicines market (WHO, 2003).This, situation is severe in sub-Saharan African countries where there are limited resources and limited pharmaceutical manufacturing capacity regardless of high disease burden(WHO, 2010).

Similarly, a study conducted in Ethiopia blamed weak regulation for the existence of illegal pharmaceutical market in the country. According to this study reasons such as weak regulatory enforcement (64.5%), lack of informal market control (60.8%), weak port control

(50.0%), and poor cooperation between executive bodies (39.6%); and resource constraint (27.8%), were the main factors for the proliferation of illegal pharmaceutical market in the country(Sultan, et al., 2016).

When it come to the actors of the markets Pinto(2004) stress the need to understand the livelihood strategies of informal providers that encourage the proliferation. He argues that the behavior of informal providers and drug sellers is heavily influenced by the intention they have to sustain their lives. According to Pinto(2004) the informal providers and drug sellers encourage their clients to buy more products by providing free consultation which reduce the cost of treatment compared to formal facilities. He also said these informal providers and drug sellers impress their customers by offering credit, being available through the day and night (unlike their counterparts in government facilities), speaking sympathetically and providing what are believed to be effective drugs (Pinto, 2004).

Suppliers on the other hand, patronize illegal market as they can set their own market structure that protect their profit and peer competition pressure unlike the legal market which has legal regulation that has consequences if were to be breached (Fligstein, 2001).

A research conducted in Ethiopian Somali has revealed how much proximity to Somaliland and its liberal regulatory environment for veterinary pharmaceuticals has fuelled an active market for contraband goods. This unregulated market supplies pharmaceuticals either unavailable or illegal in Ethiopia for a cheaper price (Roger and Emma, 2013). This claim was backed by other research which reported the worsening of pharmaceutical smuggling particularly in less regulated remote area of the country (Sultan, et al., 2016).

Impact of informal pharmaceutical sale

FMHACA regulation No. 299/2013 states that no medicine shall be put to public use if its quality, safety and efficacy is not ascertained. Quality, safety and efficacy of a drug is ensured through proper storage, dispensing and use (WHO, 2003). Guideline for storage reiterate that pharmaceuticals be stored in a dry, adequately ventilated shady and cool store room. It also advises to maintain the specified storage conditions with regard to exposure to humidity, sun light, heat, etc to ensure that pharmaceuticals are safe and effective. This same document referring to the physical surrounding of a dispensing area, recommend the dispensing environment to be free of dust and dirt as much as possible. Although the dispensary must be accessible to patients, it advises, care be taken to locate it in a protected place and not besides, or open to a road or other area where dust, dirt, and pollution are common (FMHACA, 2013). This, according to WHO(2003), is meant to averse the therapeutic failure, exacerbation of diseases, resistance to medicines and deaths which will emanate from drug whose efficacy, quality and safety is compromised as a result of poor management.

Irrespective of the consequence (WHO, 2003), such as unintended side effects from super or sub-therapeutic dosages or from drugs used in combination and increased microbial resistance, the spread of health-related markets has enabled many poor people to gain access to drugs and medical services (Bhuiya, 2009;Oladepo, et al., 2007).

Of the drugs accessed by the poor people antibiotics were the most common and the most complained due to the highly unregulated sale which leads to the development of serious health danger both to local and possible even to the world population (Van Der Geest, 1982).

These medicines though they are without the original primary packaging, of which, in many cases, the producer name and country, the batch number and the expiry date are not available, thus preventing any possible control of the origin and the quality of the drug, though they are ineffective and out of date (Brieger et.al , 2004;Okeke, Uzochukwu, and Okafor, 2006), were maintained in the market as a result of lowered price compared to formal which lowers the over all treatent cost (WHO, 2005).

Furthermore, as a result of poor storage condition in many developing countries, drugs are maintained at high temperature and humidity, not in the original packaging and not protected from the sun. These conditions accelerated the drug degradation process with, in some cases, a lowering of the active substance strength and an increase of degradation products and, possibly, of toxicity (Abu, et al., 1990).

In general, the threat posed by medicines sold on the open are that, one cannot tell how safe they are since they are mostly exposed to many unhygienic conditions as well as the vagaries of the weather (All African.com, 2016).

Source and type of informal pharmaceuticals

With regards to source of supply to this market Finlay(2011)claims both licit and illicit manufacturers feeding up the sector and this claim was backed by study form Nigeria that most manufacturers prefer open market since it bypass taxation and quality regulation and has good monetary return compared to selling to wholesale(Akinyandenu, 2013).

The wholesalers too in their own terms compete for this market. According to Rhman, Agarwal, and Tuddenham (2009) the agents of a number of drug wholesalers compete for this same market through gifts and through becoming the source of information about drugs for village practitioners. Yet very few contemporary public health interventions targeting the problems consider the marketing and strategies of this wholesalers and producers (Cross and MacGregor, 2010)

While the push from manufactures and wholesalers is one driving factor that makes pharmaceuticals easily available to informal sectors, in real sense though village sellers of medicine mainly obtained their products from three sources: contraband (medicines smuggled through borders from neighboring countries), legally established pharmacy outlets and from medical service personnel who thus want to increase their income by selling medicines appropriated to their respective institutions(Van der Geest, 1991).

Bishikwabo(1998) in his study on the informal pharmaceutical market in Democratic Republic of Congo said almost half of the vendors he interviewed got hold of the goods from pharmacists while 13 per cent of them got from doctors, and 96 per cent of them got from the

wholesalers where the prices were lower. He also emphasized that almost three-quarters of the interviewees also acquired products through individuals importing them from abroad.

In Ethiopia, although there is limited study on the existence and practice of informal pharmaceutical market, a recent study on the pharmaceutical regulatory framework has revealed the existence of unauthorized sources for pharmaceutical products in all the major commercial cities of the country; with the majority existing in the eastern part followed by the northern region of the country. This same study reported that illegal pharmaceutical products enter into the distribution channel either through legal or illegal ports the majority being through illegal entry rout (Sultan, et al., 2016).

In complement to this, a study conducted on the pharmaceutical system reiterated Somalia as being the major import channel of pharmaceutical for the horn of Africa (Kenya and Ethiopia) due to its duty-free conditions. The study revealed the existence of linkages between the pharmaceutical market in Ethiopia and Somalia which little is known about the routes or the amount of goods that cross the border. This having potential appeal to criminal networks to smuggle counterfeit, expired or repackaged medicines without any impunity (Kohler, et al., 2012).

As for the type of pharmaceuticals sold on the informal market, literatures claim that all pharmaceuticals that ranged from bulk of western health care to therapeutic capsules and tablets are sold (WHO, 2010;Anadach Consulting Group, 2014;Dawodu and Anadach, 2017;Goodman, et al., 2004).

According to Anandanch Consulting Group (2014) analgesics, anti-malarial and multivitamins were some of the most popular drugs sold by hawkers, itinerants and retailers. Similarly studies conducted in East and West Africa where informal pharmaceutical market is well studied revealed the sale of pharmaceuticals in general groceries, kiosks alongside a range of households' goods such as soaps, batteries, candies, biscuits and cooking oils (Brieger, et.al 2004;Goodman, et al., 2004;Van der Geest, 1985).

3. Objective

3.1. General objective

- To assess the informal pharmaceutical market in selected Woredas of Guji and West Guji zones, OromiaRegionalState, Ethiopia.

3.2. Specific objectives

- To assess source of pharmaceuticalsto the informal drug marketin selected Woredas of Guji and West Guji zones
- To identify the common type of pharmaceuticals availablein the informal pharmaceuticals marketin selected Woredas of Guji and West Guji zones
- To explore factors that contribute to informal pharmaceuticalmarkets in selected Woredas of Guji and West Guji zones

4. Methods

4.1. Positionality of the researcher

In this research the researcher's positionality was reflected in contexts that hinged on the researcher being an intellectual, member of the major ethnic group in the area and a professional. As an intellectual and a pharmacist, someone who understand the danger informal pharmaceutical sale pose to the health of the community, there was a need and urgency to expose the practice, the curiosity out of which this research was developed.

From personal experience, the researcher grew up watching pharmaceuticals sold in the open market and the phenomenon under study was not new to him. This in many ways has helped the researcher to easily identify the geographic locations where the practice was concentrated and the people who were engaged in the practice. While knowledge of the phenomenon was an advantage over outsiders, the researcher's social status in the community, was a challenge that hindered the free flow of relevant information. Once the researcher's identity was declared (belonging to the major ethnic group in the area) , the community assumed the researcher as an educated insider who has detail information about the practice and wanted to solve the problem related to the informal pharmaceutical market practice as a pay back to the community where he belongs.This was corrected through concise briefing that the problem would only be solved if and only if the real problem is exposed. Even after they appeared to have understood the objective of the research the participants would intermittently mention solutions during the interview. That is due to the belief that educated members of the community understand community problems without being told and telling them perceived to be disparaging their

credentials. Such was a challenge observed and needs to be noted by fellow researchers who would like to conduct their researches as an insider in a similar community.

On the other hand, the researcher's understanding of the language, knowledge of the culture and being from the same ethnicity, was a unique opportunity to access the area and probe the illegal practice. Though access to the area was easily guaranteed due to the researcher's identity getting down with the interview was not easy until the researcher list down his sub-clan and genealogy. Once the researcher established rapport with them they started talking and even asked for advice on how they safely use the medicines.

4.2. Study area

The study was conducted between November, 2017 to August, 2018 in selected gold mining woredas of Guji and West Guji zones of Oromia Regional state along the southern green stone belt which comprises 'Laga-Dambii', 'Saakkarroo', 'Maggaaddoo-Sardoo', 'Okkotee', and 'Awaxaa-Daawwaa.' The zones have a combined population of 2,564,119 (CSA, 2017) at the time of the study. The Woredas (Adoola, Bulee-Hora, Saba-Boru and Shaakkisoo) where the mining activity predominates have population of 139,942, 348,433, 143,327, and 273,932 respectively (CSA, 2017). In addition, significant unaccounted migrant miners flock to the area from all part of the country on regular basis significantly inflating mining population.

The climate of the area is characterized with midland and lowland weather conditions with annual average rainfall of about 600mm. Subsistent agriculture; agro-pastoral and pastoral mode of life is the main livelihood system of the community. Gujii and West

Gujii zones in general, the mining areas in particular are one of the most underdeveloped parts in the country in terms of infrastructure and development interventions.

Figure 1: Map of the study area

4.3. Study design

Qualitative, descriptive and exploratorystudy design was employed to describe and explore the situation of informal pharmaceutical trade, type of pharmaceuticals and its source and the reason for its existence in the area.

4.4. Study participants

The study involved informal medicine sellers at gold mining sites; health centers heads, health professionals working in the centers, private clinic owners and professionals who work in those clinics, pharmacy personnel working in drug retail outlets in urban settings, woredas drug regulatory bodies, kebele administration, elders who live in those area, users of the medicines in gold mining areas, itinerant traders and contrabandists who supply medicine to itinerant traders and makeshift shops. While people in established

settings like clinics, urban pharmacy settings, and government institutions were approached in their settings, the rest of the participants were identified through people who knew them.

4.5. Recruitment

To access the gold mining sites kebele leaders were consulted so that they inform respective '*Gares*' (vigilante like group organized to control the movement of people in the area). Then respective remote area leaders and gold mining village chiefs were consulted to get access to remote area and gold mining villages. Once access to the village was secured dealers shops were conveniently selected and the attendants were asked for their consent. Those who were willing were invited to participate in the interview. While conducting the interview when the ideas shared by the participants appeared to be theoretically saturating, the interview was stopped in each village.Itinerant traders, contrabandist and remote village shops were purposively approached through people they trust the most. Pro-medics (people who diagnose and prescribe and sell medicines) were also purposively identified through informants and were invited for interview.

As there were few private clinics in the vicinity of study area all were approached for interview and those who were present during the visit were conveniently invited for interview.

Likewise, the heads of health centers in the towns near the gold mining sites were approached and invited for interview. Woreda drug regulatory head and Woreda health bureau, Woreda drug warehouse head were approached for interview. Pharmacy

professionals who were working in relatively big towns compared to other smaller ones (Shakiso, Bule hora) near study area were approached in their settings and those who were willing were invited for interview.

The focus group discussion participants for community members were selected on the basis of a) respect they have in the area b) willingness to participate c) ability to express themselves d) knowledge of the practice and e) confidence to tell the truth without fear of repercussion.

Itinerant traders were approached; some selling in the open market together with clothes and traditional medicine, some through informants who informs the identity and where about of itinerant traders. Most were not willing to take part in the study citing no reason for refusal. Similarly, dealers (shop owners) too were less interested to participate some denying the existence of the practice even after medicines were offered to researcher whilst the researcher posed as a client. For those kiosk and shop owners the interviews were conducted within their shops. For contrabandist and itinerant traders the interview was conducted at the convenient place of their choice. For health professionals, Kebele leaders, Woreda drug regulatory head and health center head the interviews were conducted in their respective settings. Both focus group discussions were conducted in convenient place the researcher chose.

4.6. Data collection procedures

Focus group discussions (FGDs), key informants interviews and observation were the main data collection methods used. The guides for the FGD and the individual interviews were developed through review of related (informal pharmaceutical market) literatures (Beckert and Wehinger, 2013;Baxerres and Le Hasran, 2011; Goodman, et al., 2007; Van der Geest, 1985) (Annex 1-4). The tools were organized under three major objectives: (1) type of pharmaceuticals sold in an informal market in the area (2) source of pharmaceutical in the informal market; and (3) drivers of this informal pharmaceutical market in the area.

During the interview with dealers, professionals, and regulatory body head audio recording was used where the interviewees were willing and was avoided where not. As such 9 interviews were recorded while the rest (16) of the interviews' notes were taken during the interviews. Probing and follow-up questions to get deep insight into the current informal pharmaceutical market situation in the area were done during the interviews. The interviews lasted between 35 and 60 min with an average of 45 min.

Focus group discussion was held with two groups (n=12); one comprised of woreda cabinet and formally educated people in the area and the others were comprised of elders and respected people in the area. The groups' composition was set up to compare the opinion of officials, educated people and laymen. The selection of officials, respected people and elders was preferred over others as these groups of people are believed to speak their mind without fear of any later retribution from authority, dealers and other stake holders. The two focus group discussion lasted 60 minutes (uneducated

community members) and 90 minutes (formally educated). Both focus group discussions were recorded. All the audio of recorded interviews and FGD were discarded after the interviews were directly transcribed in to English.

In addition to key informant interviews and FGD, observations were made by walking through open market on market days. In the gold mining villages, observation was made by posing as simulated clients to see if kiosks stocked medicines. Kiosk keepers were asked the type of medicines they have as if the client wanted to choose from the stock for his ailment. During the observation notes of the type of medicines were taken where possible and was avoided where was inconvenient due to security (fear of repercussion if dealers feel threatened by the researcher).

Field notes were taken from several informal interviews of informants who were approached to guide the researcher to clandestine dealers of pharmaceuticals, from village chiefs who were consulted to gain access to the gold mining villages, from residents whom the researcher engaged in an informal discussion about the practice during informal gathering at tea and coffee shops and from many other occasional discussions with different kind of people. After initial analysis of the data additional field visit, limited interviews of new participants (using the same recruitment methods used on previous visit) and observation was made.

4.7. Data processing and analysis

All interviews were conducted and analyzed by the researcher. The digitally recorded interviews were transcribed directly into English by the principal researcher who perfectly understands the language in which the interview was conducted. The unrecorded interview notes were organized immediately after the interviews. The field notes and observations too were memorized and their memos were written right after the observation and during the night.

The interview guides targeted type and source of pharmaceuticals in an informal market and factors that contributed to the existence of informal pharmaceutical markets in stated study area. The analysis was approached in such a way as to allow codes to emerge from data without prior coding. The coding were largely descriptive, and reoccurring patterns within the data were identified in an inductive or 'bottom up' manner.

Thematic analysis was selected as the preferred method for analyzing the interview transcripts and memos. This is a widely used method for identifying, analyzing and reporting patterns and themes within text data (Braun and Clarke, 2006). It was chosen because it is a flexible technique that is relatively accessible and can be used to analyze data obtained under number of qualitative theoretical frameworks (Braun and Clarke, 2006; Douglas, et. al., 2009).

During the first phase, the researcher became familiar with the data by reading and re-reading each transcript and memos. While reading initial ideas for coding were highlighted line by line. On the second phase initial codes were generated and quoted in

the comment box of a word document and the word document with the comment box with the codes was printed and individual codes were cut out. Once all data had been initially coded and collated in a similar fashion; codes were sorted into potential themes. Following this, the devised set of initial themes were reviewed and refined by checking if the data were cohered together meaningfully within each theme. Then the specifics of each theme were decided upon, and the overall story of the data emerged, generating clear definitions and names for each theme. Finally, the report was written, and compelling excerpts from study participants were chosen to illustrate each theme (Braun and Clarke, 2006). These themes are further discussed in the finding and discussion sections.

4.8. Data quality management

Recognizing the importance of data credibility and reliability the study participants were identified from all stakeholders i.e. users, sellers, regulators and administrators across the vast geographic expanse of the study area. Interview transcript was read and re-read before coding to ensure the meaning the interviewer meant was literally conveyed. To clarify incomplete ideas and concepts more follow up new interview was made by going back to study area. Furthermore, data was triangulated by using different sources i.e. interview, focus group discussion and observation to ensure its credibility.

4.9. Ethical considerations

Ethical approval was obtained from the Ethics Review Committee of School of Pharmacy, Addis Ababa University with reference No. ERB/SOP/39/10/2017 (Annex 6) and Oromia Regional Health Bureau with reference No. BEFO/HBT FH/1-8/66(Annex 7).

All invited participants were given verbal information about the study.Their consents were secured before they take part in the interview. All recordings, transcripts and field notes were made anonymous and participants/interactions were identified only by identification number during analysis.

5. Finding

5.1. Study participants

A total of 25 key informant interview participants were included in the research, 19 of whom were male and 6 of whom were female.The age of the participants ranged between 20 to 60 years. Regarding formal education for dealers, contrabandist and itinerant traders most attended elementary school; while one was high-school complete and one was not formally educated. Professionals who were included in the interview were 2 nurses, 1 pharmacist, and 2 Health Officers. Four government officials 3 from drug regulatory and 1 from *Kebele* administration) were also included in the study (Table 1).

Two focus group discussion (n=12), one consumer but with no formal education and one formal education and mostly of woreda cabinets, were conducted. The age of FGD participants ranged between 29 and 65 years; with mean age of 41.3. In one of the groups where elderly, village chiefs and business persons participated, only one claimed to have completed grade six, while the rest had no formal education (Table 1).

The focus group discussion participants for formally educated was comprised of woreda cabinet members (agronomist, development agent and accountant), private business employee (agronomist, accountant), and clinic owner who used to be Woreda cabinet (Health officer).

During a market walk through observation more than 50 market places (open, stalls) were observed. 11 formal facilities (2 pharmacies, 4 drug stores, 5 private clinics) were observed. More than 100 interactions with people in the area were made.

Table 1: FGD and Key Interview Informants demographic characteristics

Description	KII Participants	FGD Participants
Sex		
Male	19	10
Female	6	2
Age		
20 - 29	6	1
30 - 39	11	6
40 – 49	5	3
50 - 59	2	1
>60	1	1
Categories of practice		
Shop/stall owner	6	
Itinerant trader	3	
Contrabandist	3	
Health Professional	5	1
Government officials	4	3
Consumer	4	8
Education status		
Formal education	20	7
With no formal education	5	5

5.2.Extent of the practice

All respondents in key informant interview admitted that the practice is rampant mostly in gold mining sites and remote rural areas where health institutions are absent and any formal health service is hardly accessible.

According to respondent from Woreda regulatory body, drugs are sold in houses, shades and in open markets during market days of rural areas and in gold mining sites. He claimed that the woreda office has investigated and reached at that conclusion.

> *"… Selling medicines in open market….the sale of medicine in shops and homes by people with no professional training is widespread. We too have investigated and reached at that conclusion" (*Government Official)

Similarly, people who have participated on the focus group discussion too, unanimously agreed on the existence of informal pharmaceutical sales and it didn't take them much to brush off the question of its existence from onset of their discussion. Typical to this was an elderly's comment, him buying medicine the night before from a nearby kiosk. *"I just bought anti-pain last night from that shop for my headache and this is no secret…"(* 65 years old elderly)

And from the observation too it was learnt that the practice was common in most part of rural market area including gold mining sites where regulatory body seldom show up. Even in areas where drug regulatory body is expected to access due to proximity to their offices, it is not uncommon to find medicines sold in stalls, shops and clandestine informal clinics. The best example in case is the sale of medicine by itinerant traders in a

district town of Shakiso in the open both on market and other days where regulation believed to be tight due to the presence of drug regulatory office in the town.

In general, the question of the existence of such practice in the area is considered odd and the response to such question is not only prompt ‘of course’ but also invitea probing gaze that implies“who is this fool who askssuch silly question?”In a worst case scenario, whoever asks such common thing known to everyone can be taken for a secret agent who is using such silly question as a cover to spy the community.To alter this misconception, lengthydeliberation and persuasionwas needed that the research was merely to figure out the practice. It is only after that; the conversation starts to open up. Even with that relative understanding of the reason for your presence, the dealers remain cautious.

On the contrary, consumers, professionals and Woreda officials who reside in towns who were approached informally without being told the purpose of the research, reluctantly revealed that the practice is common and problematic in their area.

While all respondents of an interview and people who participated on the focus group discussion have their own opinion on the level of the challenge the informal pharmaceutical market is posing given their respective interest, one *Kebele* chairman who was approached to get permission to access the gold mining sites was utterly exceptional. At first, he was suspicious and reluctant to cooperate, but after detailed explanation on the purpose of the research, hisexcitement and sense of hope that this thing had eventually gotten attention was so vivid. That was telling that he was conscious about the risk the practice was posing to the community he was leading. He didn’t only say “*this thing is very rampant in this area*”(Kebele chairman) but also meant it through his body

language, frowning to show the disgust he has to the practice.This was his words conveyed with sheer frustration

> *"I have reported several times to relevant authority and there seems no solution to it. They always say we are doing something.But,it is a big hope that this thing would be revealed through researchfindings and be delivered to the highest authority so that they take it seriously and act promptly." (*Government official)

The expression on his face that alternate between hope, concern and frustration was a very good revelation that the practice was not only rampant but also is against his wish to his community though it is a different take for those who actually see benefit in it.

Contrary to the chairman's enthusiastic approach, others direct you to where you would find it in the open everywhere with the gesture that imply 'you are wasting your time researching what is obvious.'

5.3.Types of pharmaceuticals sold

The study had found all type of pharmaceuticals such as ampicillin, amoxicillin, tetracycline, metronidazole, paracetamol, chloramphenicol, rifampicin …., sold in the area mostly in the shops, stalls, open space and carried by people who travel from place to place and sale along their route.

As much as there is no limit to the type of medicines that can be sold in this market there is a limit to what actually exist in the market. This is not because there is a restriction to what type of drugs to be sold rather the knowledge and financial capacity of the consumer that govern the demand. Most often, since it is self-medication, the consumers

ask a specific type of medicine they understand well and suitable to their financial capacity.Preference to what is best to their knowledge is not confined only to consumers but also works for dealers and suppliers such as itinerant traders and contrabandists. They too stick to medicines they know well and understand its use as they have to explain its use to whoever they sale the medicine. That sense of knowing particular medicine both by the dealer and consumer determines the existence of certain medicine in the market.

The knowledge is acquired through trial and error as stated by a female dealer who has no formal education:

> *"... I myself used it(the medicine) and got better. That is how I started this business. Since there is no doctor, since the kids get sick often, I use it for myself and my family. It is from there I started selling the medicine." (*Female shop owner)

All stakeholders in informal market stick to the drugs they know best regardless of its biomedical status. For a drug to enter such market it has to first be tried and succeed or be promoted by someone who has tried and gottenbetter with it. That means, empirical evidence matters more than scientifically proven efficacy and safety. Hence, while the idea by a professional respondent who said *"...there is nothing they don't sale..."(* Pharmacist*)* is true with reference to the absence of restriction, in actual sense though there are only a handful drugs in the market as summarized by an interview respondent dealer who doesn't read but know the medicines only by looking at them:

> *"...the medicines I sale are malaria medicine, cold and cough medicine, Amoxicillin, miziline (metronidazole), paracetamol, gastritis medicine."(* Male shop owner*)*

By malaria medicine he meant coartem, by cold and cough medicine he meant diclofenac, and by gastritis medicine he meant Omeprazole which were kept in small box laid on the table in front of us. Missing from his list were medicines such as Relief, tetracycline, Bacterium, chloramphenicol, ciprofloxacin, rifampicin, contraceptive pills, impotence drugs and vitamins and minerals…. which were mentioned by other respondents. Through observation it was learnt that most of the drugs sold by dealers were tablets and capsules in strips and blister packs. The preference of these dosage forms by dealers is mainly attributed to the ease of retail selling that conforms to consumers' financial capacity.

Figure 2: Medicines and other goods box

A shop owner in his conversation mentioned the suitability of strips or blisters to them as it is easy for them to cut and sale a single blister and for his customers as they can buy the amount they want with respect to their financial capacity compared to syrups.

> *"…customers buy based on their financial capacity. If he has two birr he bye two Panadol tabs. So, I cut and give him two tabs.*" (Male Shop owner)

Figure 3: Medicines on the market

Equally the itinerant traders who supply dealers at their respective gold mining sites too prefer those dosage forms due to their less bulk and light weight to carry in plastic bags. Other dosage forms such us injections and syrups were also mentioned by drug regulator and itineranttrader. Unlike tablets and capsules in strips and blister packs syrups and injections were only brought to the informal market up on request.

Figure 4: medicine confiscated from the itinerant traders

The problem with identifying the type of pharmaceuticals sold on the informal market was that participants often concealed what they sale once they learn that the researcher is not real customer. Thus, two tactics were employed to identify the type of medicines stocked by the shops and carried by itinerant traders. The prominent was simulatedclient.

Through this tactic medicines were observed some jammed into candy jar, some in biscuit box, some spread under a stall, some stuffed in plastic bags together with cloths. While simulated client can reveal much of the information formal interview reveals very little as was observed by this study. The information given out depends on the perception of the participants. They reveal if and only if they ensure information they give out will have no harm on them. All the assurance by researcher has no effect on the decision of the informant. This was best described by the kiosk owner informant who said

> *"The medicine with me ..... you can check for yourself if you want ... are those I have told you ... like say for headache and some other pains.... ." (*Male *Shop* owner)

winking at his wife to take away the box and candy jar filled with different medicines which he later mentioned in his conversation and revealed to have been selling yet refused its picture being taken.

Another was a lady who blatantly denied the sale of any medicine after the researcher has discovered the existence of medicine such as antibiotics, anti-malarial and gastro intestinal medicines jammed in a candy jar placed near a window and even were able to

talk to the young shop keeper who later disappeared after he learnt the researcher to be a stranger not a gold miner.

She said:

> *"We don't sale any medicine since we know its danger. For instance, I have kids and if they get sick I take them to Dawa (a town hours walk from the village) health center. We don't sale medicines here you can ask others who sales medicines over there…."* (Female kiosk owner)

Probably it is due to such secrecy that people afar from the area have the opinion that there is no medicine sold in the open or in shops and even if there were to be they think it would only be pain killers.

Table 2 List of pharmaceuticals observed in the market

Setting	**Pharmaceuticals**					
	Name of Pharmaceuticals	DF	Expiry date	Batch No.	Stated Source	
Shop	Tetracin	Capsule	01/08/21	23827	contraband	
	Metronidazole	Capsule	06/20/21	23338	contraband	
	Paramol	Tab	01/07/21	238..	contraband	
	Relief	Tab	01/11/19	16113	contraband	
	Paracetamol	Tab	--/-- */2020*	*T-5626*	contraband	
	Relief	Tab	01/11/19	16113	contraband	
	Ciprobid	Tab	--/-- /2020		-	
	Artemetherzom-lumetantrine	Tab	--/-- /2018		-	
	Omprazole	Capsule			-	
	Amox-500mg	Capsule	02/2021		-	
Open market	Relief	Tab	Not visible	1703537	contraband	
	Metronidazole	Capsule	Not visible		Pharmacy	
Formal clinic	Relief	Tab	11/2020	1711577	contraband	

Table 3 List of pharmaceuticals that exist in the market

Pharmaceuticals mentioned by participants	Pharmaceuticals confiscated from itinerant traders
1. Ciprofloxacin (cipro) tabs	1. Haemup
2. Chloramphenicol capsule	2. Metronidazole
3. Diclofenac	3. Diclofenac injection
4. Chloroquine	4. Amoxicillin syrup
5. Rifampicin	5. Gentamycin eye drop
6. Vega/ Viagra	6. Tetracycline capsule
7. Anti acid syrups	7. Metronidazole capsule
8. Paracetamol	8. Omeprazole(OLIT 20) capsule
9. Chloroquine injection	9. Relief Tab
10. Procainepenicillin	
11. Multi-vitamins	
12. Tetracycline capsule	
13. Ceftriaxone	

5.4.Source of pharmaceuticalssold

The study found out that much of the pharmaceuticals on the market to be sourced from pharmacies, drug stores, private clinics, government health institutions,from individuals who misappropriate medicines form health institutions and contraband.

In general the source of medicine is so complex that the recipient becomes the source and vise-versa. In summary a) itinerant traders: - which source their medicines from formal market (pharmacy out lets and government and private health institutions) and contraband in turn supply to shop keepers and sale themselves on markets they come by including to individuals who seeks emergency health service as they travel along. b) Stall or shop keepers: - who source their medicines form itinerant traders and contrabandist who occasionally pass by and sale to individuals who visit their stall/shops. c) Open market sellers: - who source their pharmaceuticals form itinerant traders and contrabandist and sales pharmaceuticals on the open on market days on specific locations. These groups of informal traders are different from others that they are stationery and only sale on only one location during the market days of that specified location. d) Informal clinic owners: - who source their pharmaceuticals form contrabandist, itinerant traders and formal institutions and sale the pharmaceuticals in their clinics. e) Market venders: - who source their pharmaceuticals form contrabandist, health institutions and itinerant traders and sale the pharmaceuticals together with other commodities in the shades they erect in different locations within same specified geographic location. f) Peddlers: - who source their pharmaceuticals from contraband and formal institutions and sales their pharmaceuticals during peak gold mining season to

both formal and informal market. These group of traderspops-up only when there is a high demand or severe shortage of medicine in certain area due to certain phenomenon such as peak season or break out.

5.4.1. Private formal institutions

As for the source of pharmaceuticals to informal market different accounts were given by varied groups of respondents. While groups such as clinic owners, pharmacy owners, and health center heads responded in such a way as to fend off being the source of pharmaceuticals for informal market they were pointed at by other groups such as itinerant traders and regulatory officials. Exceptionalfrom theseare dealers who sale the medicines at their respective shops and stalls which said they receive almost all of their supply form either contrabandist or itinerant traders.

For instance, a shop owner who was interviewed at his shop said "*I buy from Somalis who brings the medicines from Moyale. I buy from itinerant traders.*"(Male shop owner) From the interchangeable use of the word itinerant trader and contrabandist by the shop owner at the mining sites as quoted above it is easy to decipher that when they say itinerant traders they meant contrabandist. And shop owners believe the itinerant traders gets pharmaceuticals they sale from contraband, pharmaceuticals smuggled across the border.

Responding to a question as to whether he know where the itinerant traders get their medication the health professional replied "…*they too buy from contrabandist who sale*

medicines at Udet (small town on the border between Oromia and Somali region and believed to be the hub of contraband goods that comes from Kenya and Somalia to the area)". (Male health professional)

But irrespective of the shop owners claim most of the drugs the shop dealers selling during the visit were drugs manufactured in the country by know manufacturing company such as EPHARM, APF and CADILA.The rest of the pharmaceuticals such as relief, coartem, rifampicin, and power were pharmaceuticals claimed to come from contraband. It raises a question why the dealers and the general public in the area made to believe that most of the pharmaceuticals they are selling and using are sourced from contraband when the truth is otherwise (Table 2).

A druggist respondent who was working at Woreda health bureau gave an account that contradicts with the belief of the respondents in gold mining sites. She said

> *"I worked in many private pharmacies and drug shops in this area and the problem of illegal sale of medicine is very much a problem. Loads of cartoons packed with medicines you saw delivered from whole sales yesterday could be sold out overnight to people who come from remote areas. This is common practice in this area and it involves all drug shops and pharmacies"* (Government official)

This claim was backed by a clinic owner at Shaakkisoo who he himself denied selling medicines to informal traders but pointed finger at other pharmacy outlets in particular at someone who he viewed as notorious accomplice by saying

"[Name] is their main source. If you stand in front of his house you see ISUZUs (mini truck) that comes from Merkato(biggest market in Addis) carrying commodities and unload five to six big cartoons of medicines every morning. Soon the informal traders start flocking to his house. We know his pharmacy is short of customers and there is no other way he could have sold out that amount of every day delivery."(Clinic owner)

Similarly, another owner pharmacist claims the extensive sale of medicine to informal traders citing pharmacies including the one accused to be notorious by the clinic owner. From their tones it can be guessed that the revelation was not out of concern rather envy that he is getting too much informal customers.

5.4.2. Government institutions

Another source identified was government institutions which misappropriate medicines allotted to them.Woreda drug regulatory team leader admitted the incident by saying:

"…On this issue, what we see many times…eee…these funded drugs…eee…for instance drugs supplied to health posts or health extensions say drug called coartem was seized from those traders(itinerant). The only place that man can get that drug is from health posts and health extensions!" (Government official)

5.4.3. Contraband

According to a contrabandist and an informal clinic owner, pharmaceuticals smuggled across the borders are not only a source for informal market but also are the source for

formal institutions. When a contrabandist who was interviewed asked about whom she sales her products, she replied:

> *"My costumers are mostly itinerant traders. They buy from me both medicine and clothes I bring from Moyale (border town b/n Kenya and Ethiopia). I also sale to pharmacies (both pharmacies and drug stores) and clinics too, specially vitamins and impotence drugs. Rural clinics too are our customers."* (Female contrabandist)

This claim was confirmed by a nurse clinic owner who has worked in remote gold mining site for nine years. He said

> *".... here there are drugs smuggled through Moyale…it is in plastic bags… mainly they are the Somali's who brings the drugs….eee….they sale those drugs by going around and they sale it to shops too"; "…….all antibiotics. Yes, they are smuggled. Eee….the likes of diclo, paracetamol all these are smuggled from this side..."*

On whether these smuggled drugs go to formal health institutions he said:

> *"…yes, they smuggle from this side and they restock from that side too (formal)."*

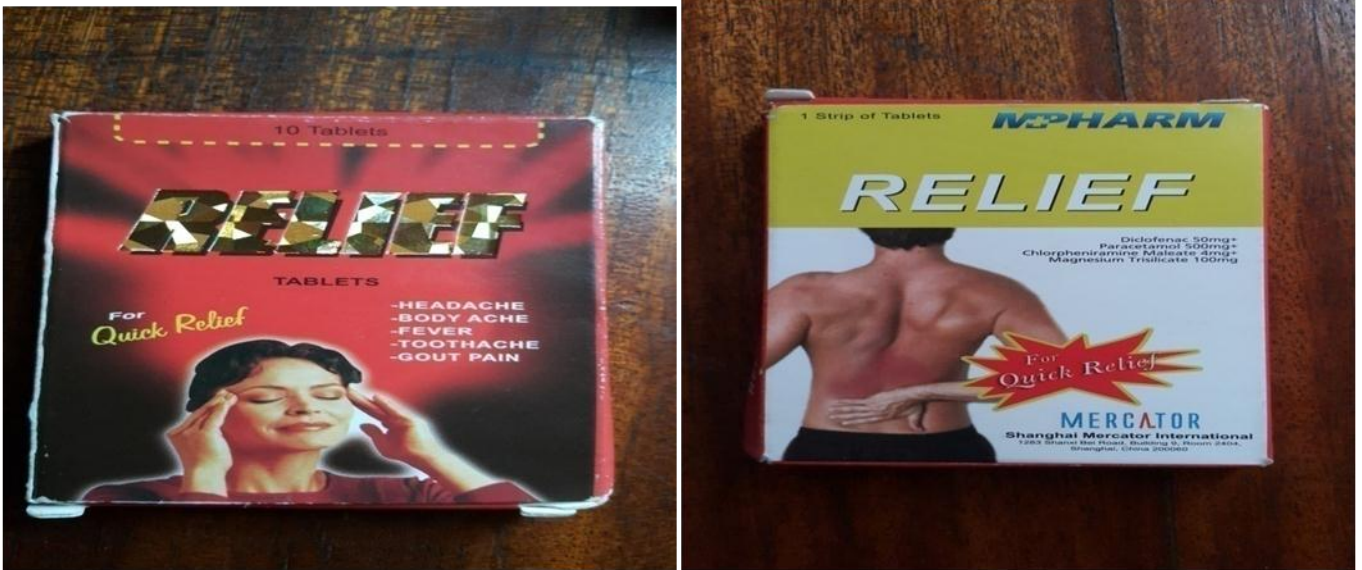

Figure 5: Medicine from contraband

5.4.4. Peddlers

The other source of informal pharmaceuticals is informal peddlers, those who act as a broker. These groups of peddlers are ones who have other job but engage in medicine sale whenever an opportunity pops up.They don’t normally stock pharmaceuticals rather they negotiate the price at one source and sale to other without really investing any money on it i.e. they act on request. They are a good source of pharmaceuticals to pharmacies and private clinics. Their source is contraband, wholesales and government institutions. In this finding we see wholesales being a supplier to pharmacies and informal market and the whole sale itself being the recipient from informal market (contraband). Similarly, the informal market (contraband) being a supplier to wholesales

and pharmacies and in turn they being recipient from wholesale and pharmacies as well as contraband. This was described by a peddler interviewee who said:

> *" I have my own job and I am a 'Bajaj' driver (motor tricycle taxi). I engage in this business when those who want medicine call me. They have my number and whenever there is a shortage they call me and I search for medicine where ever it is." (*Contrabandist*)*

5.5. Consequence of informal pharmaceutical market

From the interview, group discussion and an observation of the market it was noted that pharmaceuticals were subject to mishandling may be leading to deterioration and degradation which could in turn lead to loss of efficacy. The ease of access had exposed consumers to any medicine promoting self-medication which results in drug resistance due to the use of over dose, under dose and inappropriate medicine. The existence of the market had also encouraged the flow of contraband to the area and as such facilitated the intertwining of formal and informal market which harms the health of the community as well as economy of the country.

The respondents have identified different types of consequences as a result of informal pharmaceutical sales. The dealers who sale medicine in their respective shops seems to understand the impact temperature has on the pharmaceuticals they sale. A dealer who claimed to have completed high-school insisted he stores his pharmaceutical in underground:

> *"I store the medicines in a cool place in underground"*

Responding to why he stores underground he said:

> *".... I mean, medicines are spoiled in hot temperature ....*" (Male kiosk owner)

Though they differ on the claim of how they keep their products cool like keeping it under ground, in a cool place in cartoon or in a cool place in a jerry cane, they have that common understanding that the drugs spoil when left in hot temperature. But when it comes to the practical practice of their understanding none were found to have lived up to that. During the visit to their respective shops it was observed that medicines were kept under direct sun light when the sun is direct and in humid place in the open when the sun is away from it merely to be exposed again when the sun shines direct. This is due to either the way the shops are constructed, that is narrow (only an arm length from the supposed window) that the shelves are near the windows or the medicine boxes and jars are kept near windows so that the sellers easily access when needed, apart from the shops entire wall and roof being plastic. Worse to this is what happens to the drugs when it is moved from place to place, according to the clinician interview respondent.

> *"There are drugs that require certain degree centigrade. As you can see in this area the minimum temperature is 32 degree centigrade. You can imagine what happens if it is put in plastic bag and carried around in this scorching sun. What a body temperature does to that drug is obvious"* (Health professional)

The effect of this is degradation and expiry according to the pharmacist respondent *"since it is exposed to all sort of weather it easily expires even if the expiry date is yet*."(Health professional) Due to the degradation and expiry as claimed by the clinician,

treatment failure and drug resistance is getting momentum to the level he has called troubling:

> *"Most people for instance go to better towns for treatment. Amoxa in this area is of no more use. It doesn't cure. The guy is resistant to the medicine since he has taken expired one that has lost its potency due to the scorching sun."* (Health professional)

This claim was complemented by all professional respondents across the board based on their individual experience while practicing their profession in their respective areas.

Aside from professionals who had first hand impression on the effect of drugs exposed to sun or expired, dealers were asked whether they have experienced anything related to drugs they sale be it a complaint from customers that they didn't get better after taking medicines they bought from them or a complaint of any adverse effect due to the medicine customers bought from them. The response to this question was not only unanimous but was also conveyed with some sort of disgust and wishes it won't happen *"Nothing so far. God forbid that. We pray that it won't happen*", said one dealer. This implies that though most of them have no scientific know-how or don't have what it takes to understand the medicines they are selling, they are really conscious about the consequence of drugs they sale in the event the medicines they sale go wrong.

Contrary to dealers claim that there has been no incidents related to the medicine they sale a consumer interview participant who claims to have bought a medicine from open on a market day said:

> *"I bought a medicine for my leg ache from open market and that medicine almost destroyed my legs instead of curing me."* (Consumer)

From an informal conversation made with consumers, it was easy to note that almost all had some doubt on the efficacy of medicines they buy from informal markets or at least had an incident or know someone who had experienced some worst thing due to medicine they bought and used from open market. The problem though is that for most people some unwanted side effects if they are not life threatening are taken for potency and could be recommended to others.

This is true as the community has a culture of sharing medicine he/she has spared from the regimen. It is such recommendation that encourages self-medication hence forth inspiring users to pose as sellers. *"I have no information about medicine but I have started selling after I used and got better"*said a woman dealer. This entails the lack of knowledge as to the dose required for certain ailment and the effect one drug has on other.Reflecting on the conversation they have with patients a health officer who was interviewed said:

> *"When we take their history, they say 'we are from mining sites' and when they are asked whether they have taken any medication they would say 'Yes we have taken tablets, we are fine but not completely cured". This indicates that they are*

on partial treatment. Therefore, we give them full dose for their ailment."(Health professional)

Responding to the impact the practice had on health service a respondent from Woreda drug regulatory has summarized it saying:

> *"At health center first line drugs are given first- and second-line drugs are given only if the first line drug fails. But in villages the second line drug is directly given which is harming the reputation of services given at health center claiming that they are ineffective……. That is why we say it has great impact on the service we are giving. First thing, it has great impact on drug resistance now we are observing MDR in our area."* (Government official)

Similarly, a pharmacist, who was asked the same question i.e. the impact of the practice, has not only stressed the impact it has on the health service but also emphasized on the impact it has on the economy of the country.

> *"Due to the drugs there is also an unwanted side effect and drug resistance. The impact of such practice is heavy on the health service of the country not only that but also due to the supply of contraband the financial loss to the country is immense."* (Health professional)

5.6.Contributing factors

In summary,contributing factors such as monetary rewards that motivated the dealers, lack of access to formal health service to remote areas of the study area, lack of regulation, lack of awareness to the impact of informal medicines, proximity of the area to porous borders with Kenya and Somalia, and corruption were identified.

5.6.1. Monetary benefit

Stating the motivating reason for starting the business most of the interviewed dealers said they have started the business to help the communitywhileone dealer said it was monetary benefit.The contrabandist and itinerant traders interviewed frankly said they have started the business for monetary benefit and all professionals who participated in the interview claimed that the motivating factor for informal market was purely monetary. Similarly, the FGD participants have all stressed that most of the business associated with informal pharmaceutical market is driven by monetary gain than concern for community health.

During an interview, responding to a question of how he has started the business, an itinerant trader who claims to have learnt only up to grade three saidthat the business is so impressive compared to other commodities due to its huge financial return for less effort.

"People used to ask me to bring them medicine from town. They tell me what type of medicines they want. I sell it for some profit which I take it as a compensation for the amount I spent on transportation. People used it and got cured. I also keep veterinary medicines which I carry around. To be honest I also liked the job for it pays of" (Itinerant trader)

Similarly, a contrabandist who were asked about her practice said as quoted below, affirming benefit as a factor that attracts traders to engage in this practice.

> *"I like the business because it earns you huge money with little quantity than the cloths and perfumes I smuggle. I have stopped the business now due to the loss I was hit by. I suffered many confiscations and I lost much of my money there. But, God willing I would have started it but the road is insecure due to the conflict. God willing, I will start it soon."* (Contrabandist)

With the same token all the professionals interviewed stated that almost all stake holders in this practice are for financial gain.

5.6.2. The existence of high demand and lack of proper supply

The existence of high demand due to various reasons in the area is easily observable. Responding whether there is a demand for his pharmaceuticals, an informal dealer respondent said

> *"They always thank us for getting better and even insist me to bring more. There is time when they complain when they miss certain drugs in my shop. They push me to bring more."* (Kiosk owner)

From various interviews it was noted that the demand fluctuates in seasons. In gold mining areas the demand peaks when rivers recede during which the number of artisanal miners flock to mining sites inflating the population. Due to congestion as a result of over population in one specific area, disease such as malaria, diarrhea, TB and other communicable diseases starts to surge. As one respondent said the burden of disease is high during high seasons which a good time for their business.

"As you can see we live here by the river side where there is no network, where there are lots of problems, at this time there is mosquito, there is typhoid, em… malaria. There is nothing you don't find here." (Shop owner)

Regardless of the increase in demand in those seasons which are known to the locals for decades and decades government supply of medicine to the area remains steadfast throughout the year. This problem was reflected during the interview by the dealer and deputy head of a health center respectively.

*"This… from here… when one wants treatment, in order to go to health center….. even there, there are times when they don't find medicine and get stuck. Thus, what we normally do, since we are miners in this area. When our people who work with us get sick they use this medicine" (*Shop owner)

"What should be known about pharmaceuticals is that there is no detailed research on pharmaceuticals. There are three private clinics in this town both for East and West Guji. Due to shortage of drugs in this center, there are times when we send prescriptions outside (to informal market)" (Government official)

A similar opinion was reflected by theWoreda drug regulatory team leader that unmet demand was the cause for the existence and proliferation of the practice.The team leader not only emphasized on the shortage of supply to the area but also pointed out the constraints they face as government force them to receive medicines they already have in stock from government pharmaceutical agency instead of medicines they don't have. The team leader also complains about the shortage of budget to buy needed drugs at any moment and time.

5.6.3. Physical inaccessibility

While demand and supply imbalance to provide necessary health service in the area is one issue the physical inaccessibility of even thosepoorly supplied health service centers is another factor that drives the proliferation of informal pharmaceutical market.

Referring to the geographical inaccessibility of some of the areas where the practice is rampant (open), acontrabandist who claims to have several years of experience on contraband trade ask the alternative to using services provided to them and questions the morality of letting those people who have no access die with their ailment in the absence of any viable alternative.

"To me the reason for proliferation is lack of access to these places. They are really remote and there are no health centers in those areas. To access the nearest health center they have to either walk long distance or pay huge sum for motor bikes. Many don't even afford the cost for motor bikes and they have to walk that long distance. Itinerant traders use this opportunity to sale their drugs. In fact, we can't blame those people for using the

Figure 6: A village 20kms from Daawwaa health centre

drugs. In the absence of any alternative what were they supposed to do? They have to get medicine to their problems." (The contrabandist)

As stated in the quote above in the area motor bike transportation is readily available even to the remotest of the remote.A clinician interviewee who elaborated on the difficulty of access to remote areas and cost of seeking health service from those inaccessible places, states the availability of means of transportation but reiterate the cost it incurs if one were to opt one. The problem though is whether majority of the people who went there to earn their lives on labor can afford or not. That is why the chunk of the poor who don't even afford a strip of amoxicillin let alone pay huge sum for motor bike and further to treatment opt the informal sellers to deal with their dire situation.

5.6.4. Price

Price as a factor is quite arguable as both professionals and consumers have their opinion. For professionals the overall cost is very high though consumers can buy medicine with money they have at hand which makes them to feel the cost at formal institutions to be high given the compulsory full dosage they have to take which is more expensive than informal. A professional respondent argues that the informal pharmaceutical market is highly expensive if unit cost were to be taken in to account. This respondent who works at the health center claims that the price of informal traders is high compared to those formal health institutions negating the assumption that consumers in inaccessible part of the area prefer informal pharmaceutical market over formal due to its cheap price.

> *"We hear even one amoxa capsule is sold for 3 birr. I remember one person telling me that he took three capsules and didn't get better. When I asked him why he took only three he said 'since one capsule is 3 birr and highly expensive I was unable to take more"* (Health professional)

Similarly, another clinician, who claims to be formal but works deep in remote gold mining site complains about people's perception that the formal is taken for expensive when their price is really competitive to that of informal. This respondent too differ price as a factor that pushed consumers to patronize informal over formal.

> *"…Even if it is in its due time the medicine from informal is damaged on its way. It is therefore for that, that you are not getting better; When we say 'don't use it if you can from shops. If you can, come to us,the medicines with us are not expensive. We sale for less price than they do. Why do you do that?' When we advise them this, they don't listen."*

This tells the resistance of users no matter how they are advised that they believe the cost of medicines in formal institutions is not to their capacity. Even when both, formal and informal, are present in the same area users prefer informal due to its convenience to their financial capacity that is less price compared to overall cost of treatment at formal institutions.

Ironically, informal is preferred by formals too of course for a different reason as it gives them an opportunity to sale medicines at higher price compared to selling a strip of 10 capsules for 10 birr which meant one birr per capsule. If one capsule Amoxicillin were to be sold for the amount stated above (3 birr) there is no doubt that the benefit margin that

exists between formal and informal market motivates informal and formal traders to engage in it in their own respect. Yet dealers who were interviewed at their respective sites deny that they are selling it for benefit. For instance, a shop owner who was asked whether he started the business for benefit replied *“we don’t sell for benefit. As you can see we have other commodities, and medicines don’t have that much market.”* Shop owner

5.6.5. Lack of regulation and existence of corruption

Talking about the evil of the practice and lack of containing it, many respondents stressed their frustration including those who were at the woreda health bureau on the inaction of the government irrespective of many reports and complain from the concerned community and formal pharmaceutical dealers that the practice was widespread.

> *“ ...... We often report the practice to Woreda so that measures are taken. Nothing seems to change. Even now, if you go to town, you can find medicine sold in shops. Not only the health posts and health centers, Woreda too has to inspect it on regular basis..... Lots of things are yet to be done even on the side of the government.”* (Formal Clinic owner)

When asked whether any regulatory body has ever visited their shop,dealers who were visited at their respective working areas boldly say regulatory body rarely show up and even then, they seldom talk about medicine. *“No, they come once or twice a year even then they don’t ask about medicine”* s(shop owner). This is more than evidence that those who engage in informal practice take no heed to the law that prohibit the sale of

medicine in an informal outlet encouraging the proliferation of the informal pharmaceutical sale.

Coupled with the lack of regulation, is the chronic corruption that is well entrenched in the sector that gave confidence to informal practitioners to do their business unabated. According to participant in a group discussion the informal practitioners give less attention to the visit of inspectors/regulatory bodies as they know they would send them back easily.

> *" ....here ……. I know three people who sales medicine in their shops. The buyers and the sellers know each other well and the transaction goes without any problem. Even if the inspectors show up there is no as such big fear of the inspectors as they are after money. Once they get their money they disappear without saying a word."* (Formally educated FGD participant)

In addition to corruption the lack of commitment to enforce the law by drug regulatory body in the area was mentioned as a reason for the thriving of the practice.

> *" ... Many professionals who are assigned on controlling the practice are all after money and they don't care about it. Most of them when sent to rural area pass their time hiding in this town and come back as if they were out working on the field."*

5.6.6. Lack of awareness

On the lack of awareness, questions were posed to respondents whether there is a lack of clarity on the law and consequence of the practice. As such it was noted that there was no shortage of clarity both to the law and consequence of the practice from professionals as was clearly stated by drug regulatory team leader:

> *"Of course, our workers know about drug regulation. I think they all know due to the awareness given on regular basis. Since the public needs awareness and we want to abolish this thing they are regularly given awareness as it is the aware who can aware others. All the professionals we have on kebeles have this understanding"*

Yet, professionals believe that the dealers and consumers lack awareness to the law that prohibits the practice and the impact the drugs have.

> *"The problem is that people who buy drugs from illegal source don't know the risk these drugs have and the people needs to be thought about its impact"*said a pharmacist who was asked if there is an awareness on the impact of the practice.

True that, consumers could lack both the law and the impact which make them to believe the medicines they buy from illegal traders are real and people who sells it are knowledgeable. That doesn't mean though there are no people who suspect the medicines and its sellers but use it out of lack of alternatives. When asked if he has ever bought medicine from informal sellers for his personal use, a focus group participant said:

"Yes, I buy from them but not here where I can buy from pharmacy or go to hospital but when I am in gold mining site. They are our only option. Especially in remote places like 'Qolansa' 'Burjuji' and other remote places. Yes, you don't have any option but to buy from there or die walking that long distance to reach 'Dawa' or 'Soda'." (FDG participant)

When it comes to dealers most of them do understand that their practice is illegal yet fall short of knowing whether the medicine they sale would have an impact on the health of the users. The mere fact that they say we use it first and sell it shows their poor knowledge about the impact the drugs have. Yet they are very conscious about the law as was reflected by an itinerant trader who said;

"*The job is like a job of a thief. You run while the government chases you*." (Itinerant trader)

The lack of awareness to the impact of illegal pharmaceuticals could be attributed to poor education level which makes it an insurmountable reason for the proliferation of the practice in the area.

5.6.7. Secrecy of the practice

In addition to all the above factors that contribute to the proliferation of the practice, secrecy of the practice was mentioned as one aspect that makes it difficult to stamp out informal pharmaceuticals sales from the area.

In the area, particularly in artisanal gold mining where the practice is rampant, all the business run give little respect to any law given the remoteness of the place and mobile nature of the activity. Instead they have chiefs mostly the locals who own the land. These chiefs engage in any activity they deem beneficial and medicine sale in the area is one of it. Hence in the event of any inspection they are the ones who fend off any attempt as they too are part of it. This was reflected by a contrabandist respondent who said:

> *"For one thing the place is remote and there is no transportation. If they want they have to walk on foot a long distance. Even if they(inspectors) were to want to will the hardship they have to get permission from the gold mining chief to search and know who is selling the medicine and why. For sure they won't get permission and if they were to force their way through, the community who use the medicine would definitely revolt"* (Contrabandist)

According to this contrabandist we see not only the security challenge an inspector or regulatory body face but also how informal pharmaceutical practice is patronized by the consumers and cooperate to conceal the practice due to the absence of alternative.

> *"The community patronizes the practice as there is no health service in their vicinity. They are right as there is no clinic to serve the community and why would they stop them from buying from these people"*

In one of the gold mining sites, after the researcher secured permission from the chief to access the villages in the site, similar incident of inhabitants concealing the dealers was observed. When asked who sales medicines in the village they would suspiciously say

“they don’t know”especially if they suspect one for a stranger. It doesn’t end there rather in addition to closely following you they alert those who sales medicines to take away medicine they sale.

The best example in case is what happened after the researcher negotiated a chief to access those who sales medicines in his village. The chief was willing that he consented to take the researcher to one of the dealers. As the researcher and the chief started to walk towards the dealer he wanted the researcher to talk to, those who were observing the conversation rushed kids to alert the dealer that the researcher and the chief were heading towards him. Once at the dealer’s kisosk, the already informed dealer was so alarmed but cool due to the presence of the chief, who can decide the fate of the kiosk. In the presence of the chief the dealer was cooperative and was telling that he has all the medicine. But after the chief left the researcher and the dealer to talk in detail, the dealer started to rebut what he has said in the presence of the chief forcing the researcher to end the interview even before it started. He said: *“I don’t have any medicine to sale”, “You can ask others who have”, “I have stopped long ago and no longer in the business.”* (Kiosk owner)

As one respondent said the practice is not only secret but also risks the lives of those who pushes hard to stop it.

> *“You can take these people to court but you don’t know the ramification it could have. For that matter they are not people we know and they are people from other places and you don’t know what they will do to you”*said a clinician who stressed the clandestine nature of the practice.

6. Discussion

This study indicated the existence of wide variety of medicines in the informal market which includes antibiotics, analgesics, antipyretics and antimalarial presented in the form of tablets, capsules, syrups, suspensions and injectables. These medicines were reported to have existed in an informal pharmaceutical market by other studies (Anadach Consulting Group, 2014; Beckert and Wehinger, 2013; Bhuiya, 2009; Bishikwabo, 1998; Datta, 2013; Davis, 2008; Gaudiano, et al., 2007; Goodman, et al., 2004; Roger and Emma, 2013; Snow, et. al., 1992; Van der Geest, 1983).

The study also identified contraband, legal wholesales, private clinics, government health institutions, private pharmacy settings to be the source of pharmaceuticals for informal market in the study area. Other studies reported similar sources depending on the scope of their study (Van Der Geest, 1991; Bishikiwobo, 1998; Goodman, et al., 2007).

Factors such as lack of infrastructure, lack of proper regulation, shortage of supply in the presence of high demand due to high population of the mining area and corruption was identified as contributors to the existence and proliferation of informal market with its grave health and economic impacts. Similarly, most studies conducted on the informal pharmaceutical market stressed mainly demand, lack of regulation and access to health service as the major reasons for the proliferation of the practice (Bhuiya, 2009; Roger and Emma, 2013; Datta, 2013; Sultan, et al., 2016)

Another factor reported by the respondent was proximity of the area to border and contraband route. The same reason was reported by other literatures that less controlled

borders significantly contribute to the proliferation of informal (Roger and Emma, 2013; Kohler, et al. , 2012; WHO, 2003; Sultan, et al., 2016).

This study has shown that informal pharmaceutical sale is widely practiced throughout the study area especially in rural and gold mining sites. Consistent to the finding of this study a study conducted in Nigeria and Ghana reported the practice to be widespread in the rural areas and urban slums of major towns (All African.com, 2016; Anadach Consulting Group, 2014; Brieger, et al., 2004; Oshiname and Brieger, 1992). The difference between this study and others is the absence of overt sale of medicines in urban areas of this study, though the sale of pharmaceuticals together with other goods especially on market days is very much a common practice (Baxerres and Le Hasran, 2011; Davis, 2008).

However, a study by Sultan, et al.,(2016) titled Pharmaceutical Regulatory Framework in Ethiopia: A Critical Evaluation of its Legal Basis and Implementation stated the existence of unauthorized sources for pharmaceutical products in all the major commercial cities of the country; with the majority existing in the eastern part and in the northern region of the country.

On the system of distribution this study has discerned that the source of pharmaceuticals differs based on the type of actor in the distribution channel. For static remote pharmacy dealers the source is itinerant traders who supply pharmaceuticals either on foot or motor bikes right to their places, similar to what is reported in Nigeria and Ghana(Goodman, et al., 2013; Brieger, et al., 2004).

In turn the itinerant traders who supply pharmaceuticals to static pharmaceutical dealers obtains their products from various sources such as pharmacies, government health institutions, whole sales, contraband and other misappropriated sources. Several studies conformed to the finding of this study (Beckert and Wehinger, 2013; Bishikwabo, 1998; Datta, 2013; Van Der Geest, 1991).

Contrary to this though, almost all shop dealers in this study reported that their products was sourced mostly from contraband. This misconception was negated by the finding of this study that most of the products they have stocked were locally manufactured. While the reason for the abundance of the locally manufactured drugs in the area is a matter of further research other literatures stated that local manufactures prefer informal market due to unmet demand, corruption and lack of regulation (Akinyandenu, 2013; Beckert and Wehinger, 2013; Cross and MacGregor,2010; Rhman, Agarwal, and Tuddenham, 2009).

This study has also noticed the flow of medicines from afar major towns and cities to the informal market of the study area and from the informal market of the study area to major cities and towns outside of the study area. This claim was consistent with an old study conducted in the country that reported the sale and purchase of medicines to and from rural merchants (Kloos, 1974). This claim is hard to refute given that the country is developing, populous (102 Million (CSA, 2017)), and in the region where informal

pharmaceutical market thought to be profound (Goodman, et al., 2007; Sultan, et al., 2016).

This study observed the little attention given to the practice irrespective of the existence of necessary conditions to the proliferation of the practice such as high population, disease burden, economic disparity, globalization and corruption (Beckert and Wehinger, 2013; International Finance Coropration,2017; IMS Institute for Health Care Informatics, 2015; Government of the people's republic of Bangladesh, 2008)). Contrary to this though study reported that many countries have long started the fight against the practice admitting the problem this dangerous practice poses to the health of their country (Cross and MacGregor, 2010).

Unlike the lack of policy attention observed by this study, literatures from Nigeria indicated the existence of policy to curb the impact of the practice in that country (Brieger et al., 2004; Dawodu and Anadach, 2017). One such policy example was the implementation of proprietary patent medicine vendors (PPMV): entrepreneurs with licensed retail shops that sell pharmaceuticals together with household goods (Anadach Consulting Group, 2014;Brieger et al., 2004;Dawodu and Anadach, 2017).

This study also noticed that any drug could be sold on the market regardless of its bio-medical efficacy and restrictions, the only limiting factor in the type of medicine to be sold on the market being the knowledge of the consumer and the seller about the

medicine (Baxerres and Le Hasran, 2011; Goodman, et al., 2007; Cross and MacGregor, 2010; Hughes, et al , 2013; Van der Geest, 1983; Van der Geest, 1996).

Most respondent in this study reported that they patronize the informal pharmaceutical market citing various reasons based on their socio-economic status and access to formal health service. Literatures has it that demand for informal pharmaceuticals increase as a result of competitive price in line with the income of consumers compared to overall treatment cost of formal health service, of course, coupled with increase in preferences for product characteristics of their choice, preferences for provider characteristics, ease of access, less waiting times, drug availability and courtesy of the providers compared to formal(Goodman C. A., 2005; Bishikwabo, 1998; Goodman, et al., 2004; Ecks S. , 2008a; Dawodu and Anadach, 2017).

On the other hand, tough the behavior of the medicine sellers to attract their customers vary on the strategy they use based on their settings and means of delivery, this study found that the contrabandist and the itinerant traders were the most concerned with the satisfaction of their customers among the medicine sellers. Pinto (2004) and other literatures (Bhuiya, 2009; Datta, 2013; Oshiname and Brieger, 1992) stressed the need to understand the livelihood strategies of informal providers that encourage the proliferation.

Another issue reported by the participants that is related to the proliferation of the practice in the area was the impact of the practice. Many literatures conducted on informal pharmaceutical market reported impacts such as self-medication due to easy

access, drug resistance due to inappropriate regimen, adverse effects due to inappropriate medicine and economic loss due to the flow of contraband (Derressa, Ali and Enqusellassie, 2003; Van Der Geest, 1982; Oladepo, et al., 2007; WHO, 2005; Brieger, et al., 2004; Okeke, Uzochukwu, and Okafor, 2006). Similarly other studies reported the role informal pharmaceutical market play in providing conducive platform for the transition of falsified and spurious medicines to the formal sectors (Akunyili, 2007; Amadi and Amadi, 2014; Onwuka, 2010).

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Similarly drugs that have failed to penetrate the formal market and whose date has expired pour into the informal market due to the lack of sellers' and consumers' knowledge to understand neither the property nor the information written on the package (Bishikwabo, 1998; Onwuka, 2010).

7. Strength and Limitation of the study

This assessment has collected data from people who have directly participated on the practice and from those who have actual association with the practice. As such it has attempted to triangulate the data from different stakeholders such as pharmacy professionals who are working in the area, drug regulatory bodies of the area, health workers, consumers and informal pharmaceutical traders of the area.

Secretive nature of the practice that limits on the spot note taking during open market and simulated client observation might have hindered comprehensive data collection.

As audio records were useful to retain all the information from the interview it might have negatively impacted the confidence of the participants given the nature of the practice. Equally on the interviews where audio recording were not used full retention of the interview could be limited. And of course, time and money was another limitation of the study.

8. Conclusion and Recommendation

This study has shown that informal pharmaceutical trade exists in the area and found that the formal and informal aspects of medicine distribution are closely interwoven.

Aside from its negative impact this research has also found out that informal medicine market provides an alternative to dire health need of the community where formal means were either absent or deficient.

And it recommends to:

- Conduct further study to know the status of the practice in the country
- Devise focused police that takes every contributing factor into consideration such as the implementation of PPMV (Proprietary Patent Medicine Vendors) which is relatively successful in other countries.
- Ensure sustainable supply where there are existing health facilities,
- Create access through establishing at least satellite health post to the remote gold mining areas,
- Tighten the regulation in such a way that it doesn't deprive the needy medication to those who have no alternative,
- Control corruption in health sector
- Control sever misappropriation in the area,
- Improve border control and
- Create awareness on the danger of informal pharmaceuticals.

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10. Annexes

Annex 1: Focus group discussion and in-depth interview guide(English and Afaan Oromo Version)

1. Where do you buy your medicine when you or your family falls sick? Why?
2. Do you think informal medicine dealers are doing illegal business? Why?
3. How important do you think are the informal pharmaceutical dealers in this area? Why?
4. What do you think would happen if the informal sellers were to be abolished?
5. How do you compare service provide at government centers and others, like illegal outlets?
6. How do you evaluate the efficacy of drugs you buy from informal dealers? Is there any drug related incidents you or someone you know encountered as a result of drugs bought from informal dealers? Why do you think is that? What were the problems?
7. What do you want government to do to improve access to drugs?

Focus group discussion Guide/ Guide for customers in Afaan Oromo

Marii Garee Xiyyeeffannoo

1. Namaafi ykn ifiif qorsa yo bitatuu barbaadane essaa bittattan? Maafi? Qorsamaaniifa'a bittaattan?
2. Worri qorsa gurguru kun maraa seera qabeessa jettanii yaaddanii? Maafi?
3. Worriseeraan ala qorsa naanootanati gurguru kuni hagam barbaachisaa jettanii yaaddani? Maafi?
4. Adoo namoota seeraan ala qorsa gurguru kana dhoogganii maanti maan te'a jettanii yaaddani?
5. Qulqullina qorsa worra seeraan alaati gurguruu kana akkamiti ilaaltani? Ka mana moottumma ho? Garaagarummaan isaan jidduu jiru maani jettanii yaaddani?
6. Marroo qorsa alaa ykn daldaltoota seeraan alaa irraa bittattan irraa aka'ee rakkoon isin ykn nama isin beettanu muudate maanfa'a?
7. Rakkoo daldala qorsa seeraan alaa kana hiikuufi motummaan adoo maangodhee woyya?

Annex 2: In-depth interview guide for dealrs (English and Afaan Oromo Version)

1. How did you start this business? What motivated you?
2. What type of pharmaceutical products do you often deal with?
3. Where do you get your pharmaceutical products?

   Government clinics, from PFSA stores, from wholesale dealers outside the legal framework, from contrabandist, form registered wholesales, from drug stores, from pharmacies, any other source…
4. Have you ever bought drug from illegal source? If so
5. Why do you buy from them?
6. Where do you store your drugs, why?
7. Who are your customers?
8. What do customers feel about your service (feel good or bad)? Why?
9. How confident are you in the quality, safety and efficacy of drug products you sale?
10. How much do you know about drug regulation?(where drugs should be sold, stored, and what type)
11. Do you have professional experience in health service, what?
12. If there were to be an opportunity are you willing to work legally?

Setting	Pharmaceuticals					
	Name of Pharmaceuticals	DF	Expiry date	Batch No.	Stated Source	

Interview guide for dealers in Afaan Oromo

Gaaffii qajeelchaa Daldaltoota qorsa seeraan alaa

1. Daldala kana akkamjalqabde? Maantisikakkaase?
2. Si malee name biraa sii hin gurguraa? (name sigargaaru hinjira)?
3. Qorsoota akkamii fa'a qabatta?
4. Qorsoota gurgurtu kana eessa fa'aa bitta? Irra caalaa eennurraa dhaggata? Maafi?
5. Qorsoota gurgurtu kana akkamiti qabata (bakka kuusaa, gurgurtaa….)
6. Tajaajila keeti kana akkamitti madaalta? Namooti sirraa qorsa bitanu maanfa'a jedhani?(qorsi keeti nu meedhe ykn nahinfayyinye jedhaanee beekanii)
7. Hujii tana jalqabiisaan qara muuxannoo maanii fa'a qabda? Gama qorsaatiin ho?
8. Hujii tana yennaa hujju rakkoon gugurdoon si muudatan maan fa'a?
9. Daldala kana karaa seera qabeesa te'een hujiisaaf carraa akkamii adoo sii mijeesanee feeta?

Bakka	**Qorisa**					
	Maqaa Qorsaa	DF	Guyyaa expiryii	Lakk Batchii	Addee qorsi irraa bitame	

Annex 3: In-depth interview guide for Woreda Officials and Regulatory bodies(English and Afaan Oromo Version)

1. Do you think there is informal pharmaceutical market in your woreda?
2. What do you think motivates people who engage in informal drug market?
3. What type of drugs do you think sold in an illegal drug market?
4. Where do you think is the source of drugs for an illegal market?
5. What are contributing factors for existence of informal drug market in the area?
6. What do you think is the impact of informal drug market on the health of the public and economy of the country?
7. Do you think the communities differentiate between formal drug sale and informal drug sale? How?
8. What regulatory frameworks do you think are there to curb this problem?
9. What do you think is the best way out to curb the problem?

Interview Guide for Worda Officials and regulatory body

Hoggantoota aanaatiif qama seera qorsaa

1. Waa'ee daldala qorsa seeraan alaa kana maan jetta?
2. Namoota daldala kanarrati hirmaatani maanti kakkaase jettee yaada?
3. Qorsoota akkamiifa'atu gabayaa kanarratti argama?
4. Maddi qorsoota kanaa eessa jettee yaadda?
5. Jireena gabayaa kaanaatiif maaltu gummaacha? Sababoota akkamiifatti dalddal kana kunuunsa?
6. Hawaasi naannoo kanaa gabayaa seeraan alaatiif seera qabeessa addaan baasee akkamin beeka?
7. Caasaa seeraa gabayaa kana to'atiisaaf ite'u maal faanti jira? Haga ammaa maafi hujiirra oolee daldala kana hinto'otine? Maant gufuu itti te'e?
8. Rokkoo tana furuuf karaan oli'aanaan ati yaadatu maal fa'a?

Annex 4: In-depth interview guide for professionals(English and Afaan Oromo Version)

1. Do you think informal drug market is major public health problem in your area?
2. What do you think motivate people who engage in informal drug market?
    - Profit? Easy of starting business? Lack of regulation?
3. What types of drugs do you think they sale?
4. Where do they get the drugs?
5. Have any one ever approached you to buy drugs for sale? If yes who are they?
6. Do you think it will have an impact on the safety and quality of drugs? How?
7. Have any one offered you to buy drugs obtained from illegal source?
8. Do you think this practice will proliferate? Why?

Interview guide for professionals in Afaan Oromo

Gaaffii qajeelchaa Ogeesitootaa

1. Daldalli qorsaa seeraan alaa kun naannoo tanatti hagam rakkodha jettee yaadda?
2. Namoota daldala kannatti hirmaatani maanti kakkaassa?(bu'a , laaffinna seeraa,)
3. Qorsoota akkamii gurguran?
4. Qorsoolee kana eessaa argatani jettee yaadda?
5. Namooti qorsoolee gurgurtaa te'anu kana sirraa bitanu nama akkamiiti?(namawaan qorsaa beeku, daldalaaideentu,…
6. Daldali qorsaa seeraa qabeesa hinte'in kun dhiibaa inni tajaajila qulqullinna qabu ka qorsaa irrati geessissu maan jettee yaadda?
7. Aka gabayaan kuni babaldhatu maanfatti/sababoota guumacha godha jettee yaadda?
8. Aka inni hinbabaldhane maalgodhuu qabani?

Annex 5: Oral informed consent (English and Afaan Oromo Version)

Informed consent

My name is Feyissa Shonora and I am a student at Addis Ababa University. I am conducting a research on an informal drug market in the area. The purpose of this study is to determine the source and type of drugs sold in an informal market in the area and gain insight into factors contributing to the persistence of the practice. Once completed, the research will help understand the source and type of drugs and contributing factors to the problem and hence help relevant authorities focus on the issue and curb consequences arising from it.

Participation in this research includes one on one interview and focus group discussion. During our discussion you will be recorded to help me accurately capture your insights in your own words. The records will only be heard by me for the purpose of this study. If you feel uncomfortable with the recorder, you may ask that it be turned off at any time.

You also have the right to withdraw from the study at anytime. In the event you choose to withdraw from the study all information you provide (including tapes) will be destroyed and omitted from the final paper.

Insights reflected by you and other participants will be used in writing the research report which will be read by my advisors. Though direct quotes from you may be used in the paper, your name and other identifying information will be kept anonymous.

By agreeing to this consent I certify that I ______________________________ agree to the terms of this agreement. (Full name)

____

(Date)

Oral consent in Afaan Oromo

Unkaa Eeyyaama beekkumsaan kenname

Maqaan kiyya Fayyissaa Shonnooraa yote’u University Addis Ababa baradha. Naannoo tana keessatti qorannoo waa’ee gurgurtaa qorsa seeraan alaa geggeessuutti jira. Kaayyoon qorannoo tanaa maddaafi gossa qorsoolee seeraan alaatti gurguramu fi sababoota gocha kanaaf gumaachanu hubatuudha. Qorannoon kuni yoo xumurame, maddaafi gossa qorsoolee seeraan alatti gurguramanuufi sababoota gocha kaanfi gumaachanu hubbanoo kennuun angoowaan dhimmi laallatu akka xiyyeeffannoo itti kennanii balaa gocha Kanaan dhaqabuu male akkaitti sanu godha.

Hirmaannaan qorannoo kanaa karaa gaaffii fi deebii tokkoof tokkoottiif marii garee yoote’u yaada hirmaattotaa sirriiti qabatiisaafi woraabbii sagalee teessanii godha.Worabbiin tun kaayyoo qoraannoo tanaatiifi jecha anaqofaan caqafama gara barruutti jijjiirama. Eegasii worrabiin kun hin haqama. Woraabbii geggeefamu kanti addii yodhabde yeroofeetetti narraadhaabi jechuu dandeetta. Kana qofa adoo hintaane yeroo barbaaddetti qorannoo kana keessaa bayuu mirga qabda. Akum ati qorrannoo kana keessaa bayiisaa murteefateeni odeeffannoon ati kennite yoosuu qorannoo kana keessaa haqamti.

Yaadi keetiif kanamoota biraa qorannoo kana keessatti hirmaatan gabaassa qorannoo kanaa barreesiisaaf faydaarra oola. Gabaassi kunileen mari’aachiisaa kiyyaan hindubbifama. Yojecha keeti qajjeeloon gabaassa keessati fayyadamuu fedhe maqaan keetiif odeeffannoo si’ibisuu dande’u marti dhossaa teeti.

Ani___________________________________yaadota woliigaltee kana keessa jeranu maraa dhage’eee eyyama kiyya woliigaltee kanaaf kenneera.

Guyyaa___________________________

Annex 6: School of Pharmacy Addis Ababa University Ethics Review Board Approval Letter

በ ፋርማሲ ት/ቤት
የኢቲካል ሪቪዉ ቦርድ

አዲስ አበባ ዩኒቨርሲቲ
Addis Ababa University

School of Pharmacy
Ethical Review Board

ቀን
Date October 19, 2017

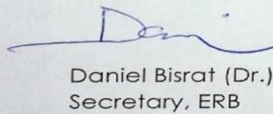
ቁጥር
Ref. No. ERB/SOP/39/10/2017

To: Feyissa Shonora
School of Pharmacy

Re: Ethical Clearance

It is to be recalled that you submitted a study proposal entitled "Assessment of Source and Type of Pharmaceuticals on an Informal Pharmaceutical Market and its Contributing Factors in East and West Guji Zone of Oromia Regional State, Ethiopia" for ethical approval by the School's Ethical Review Board (ERB). The Board thoroughly reviewed the study proposal based on its operational guidelines and found it to fulfill all ethical requirements stipulated in the guidelines. This is, therefore, to inform you that the proposal is ethically approved for implementation.

With best regards,



Daniel Bisrat (Dr.)
Secretary, ERB

00251156 02 12 | 1176 | ቴሌክስ Telex: 21205 | ፋክስ Fax: 00251(11)1558566 | ቴሌግራም Cable: AAUNIV

Annex 7: Oromia Region Health Bureau Ethics Review Board Approval Letter

BIIROO EEGUMSA FAYYAA OROMIYAA

OROMIA HEALTH BUREAU
የኦሮሚያ ጤና ጥበቃ ቢሮ

Lakk/Ref. No. BEFO/HBTFH/1-8/66

Guyyaa /Date 16/2/2010

Waajjira Eegumsa Godina Guji

Nagallee

Waajjira Eegumsa Fayyaa Guji Lixaa

Bolee Hora

Dhimmi: **Xalayaa deeggarsaa ilaala**

Akkuma beekamu Biiroon keenya ogeeyyii, dhaabbilee akkasumas namoota qorannoo gaggeessuuf piroppoozaala dhiyeeffatan piroppoozaala isaanii madaaluun akkanumas iddoo biraatti ilaalchisanii fudhatama argatee (approved) dhiyaateef, piroppoozaala isaanii ilaaludhaan waraqaa deeggarsaa ni-kenna. Haaluma kanaan mata-duree "**Assessment of Source and Type of Informal Pharmaceutical Market and its Contributing Factors in East and West Guji Zone of Oromia Regional State, Ethiopia", 2017"** jedhurratti qorannoo gaggeessuuf barataan digirii lammaffaa ''MSc in Pharmaco-epidemiology & Social Pharmacy" kan ta'e **Fayissa Shonora** piropozaala isaanii Koree "Health Research Ethical Review Committee" Biiroo keenyaatti dhiyeeffataniiru.
Haaluma kanaan Koree "Health Research Ethical Review Committee" Biiroo keenyaa piroppoozaala kana ilaaluun mirkaneessee qorannoon kun akka hojiirra oolu murteessee jira.
Waan kana ta'eef hojii qorannoo kanarratti deeggarsa barbaachisaa ta'e akka gootaniif, akkanumas akka hordoftan jechaa, **barataa Fayissa Shonora** wayitii qorannoon kun qaacceffamee xumurame fiiriisaa kooppii tokko Biiroo Eegumsa Fayyaa Oromiyaatiif akka galii godhan garagalchaa xalayaa kanaatiin isaan beeksifna.
Anis, barataa Fayissa Shonora wayitii qorannoon kun qaacceffamee xumurame fiiriisaa kooppii tokko Biiroo Eegumsa Fayyaa Oromiyaatiif akka galii godhu mallattoo kiyyaan mirkaneessa.

Nagaa wajjin

Mallattoo____________________

Maqaa ____________________

Guyyaa **16/02/2010**

Lakk. Bilbilaa **0911749045**

G/G

Barataa Fayissa Shonoraatiif

Bakka Jiranitti

Teessoo: Tel:+251-011-369-01-49, Fax: +251-011-361-01-27 P.O.Box.24341 E-mail: ohbhead@telecom.net.et
Address: ADDIS ABABA/FINFINNE-ETHIOPIA

Glossary of terms

Pro-pharmacies: retail shops which sale medicines together with other goods.

Itinerant pharmaceutical traders: are traders who do not have a standard place of business from which they operate. They are people who move from place to place in search of customers to sale their pharmaceuticals.