

Substandard and falsified medicines in African pharmaceutical markets: a case study from Ethiopia

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Abstract

Background: Substandard and falsified (SF) medicines are a global health problem. Their high prevalence is a threat to public health in low- and middle-income countries (LMICs). However, there are few street-level investigations of how this market works. This case study examines the supply and demand for SF medicines in Southern Ethiopia.

Methods: A cross sectional qualitative design, using semi-structured interviews supplemented by participant observation, was adopted. Study participants were selected using purposive, convenience, and snowball sampling techniques. They included pharmacists, physicians, wholesalers, pharmacy owners, regulatory staff, law enforcement agents and the local community. A total of 43 interviews were conducted. The study used Actor-Network Theory (ANT) as an analytic framework.

Results: The findings show that efforts to address the problem of SF medicines in Ethiopia struggle because of the lack of a clear framing of the issue and consensus on how it should be understood. The pharmaceutical market in Wolaita Zone, Southern Ethiopia supplies a wide variety of SF medicines from diverse sources. The supply chain emerges due to the barriers to accessing essential medicines. The socio-cultural context in which these medicines operate plays an important role in the market. Control of SF medicines will require a matching range of interventions rather than a single method.

Conclusion: The evidence of confusion, ambiguity, and uncertainty in defining the problem of SF medicines suggest that more research and policy work is required to refine understanding of the issue, and of the local market conditions that join demand and supply for different medicines in Ethiopia and comparable contexts in sub-Saharan Africa. The current global policy emphasis on stricter regulation and enforcement does not adequately address the social and economic factors that create user demand that is met by SF medicines.

Highlights

- ✚ The problem with SF medicines is that no clear framing and consensus exists.
- ✚ The market supplies a wide variety of SF medicines from diverse sources.
- ✚ The story of SF Medicines shows the barriers to accessing essential medicines.
- ✚ Stricter regulation and enforcement do not adequately address factors creating user demand for SF medicines.
- ✚ Control of SF medicines will require a matching range of interventions rather than a single method.

1. Introduction

WHO (2017) report that an average of 1 in 10 medical products circulating in low-and middle-income countries (LMICs) are either substandard or falsified (SF). These medicines can result in adverse health outcomes, treatment failures, development of resistance, and reduced confidence in the health system (Kelesidis et al. 2007, WHO 2020; Renschler et al. 2015; Ozawa et al. 2018; IOM 2013; Petersen et al. 2017; WHO 2017; Pyzik, and Abubakar 2022). Non-specialists often understand the problem of SF medicines as exclusively one of outright fakery, using poor-quality or sham ingredients to produce pills, tablets or liquids that resemble legitimate medicines but either have no action, ineffective action or are toxic because of the materials used. But there is also an important problem of substandard medicines, which appear to be legitimate but whose quality, safety and efficacy have not been verified. WHO (2017) define substandard medicines as "approved medical items that fail to meet their quality requirements, specifications, or both". Falsified medical products "deliberately and fraudulently misrepresent their identity, composition, or source". WHO also define a third category of unregistered or unlicensed medicines, whose quality is unknown because they have avoided regulatory controls. In LMICs with weak regulatory authorities, the problem of substandard medicines seems to be particularly relevant, for instance in settings where generics are not routinely tested for bioequivalence as a prerequisite for marketing authorization (Kassie 2016).

Where regulation is weak, people in African countries risk receiving SF medicines every time they visit a pharmacy,(Almuzaini et al. 2013; Ozawa et al. 2018;Gaurvika et al. 2019; WHO 2017; Orubu et al. 2020) , and suffering negative (and even fatal) health outcomes (Hassan et al. 2022; Paul A. 2020; WHO 2017), as recently happened to children given contaminated syrups (WHO 2022a WHO 2022b WHO 2023a; WHO 2023b). Antimicrobials are among the most reported SF products (WHO 2017). For example, in 2013, 122,350 deaths among children under the age of five in 39 Sub-Saharan African countries were attributed to poor quality anti-malarials (Renschler et al. 2015). This study also found significant levels of substandard antibiotics (12.4%) and antimalarials (19.1%), with the highest reported prevalence in Africa (18.7%) and Asia (13.7%) (Ozawa et al. 2018). According to a study conducted in ten sub-Saharan African countries, approximately a quarter of the generic antihypertensive medications on the market are poor quality (Macquart et al. 2018). Ethiopia

has been found to have a significant prevalence of substandard mebendazole, albendazole, and tinidazole: of the tested samples, 45.3% (48/106) were substandard (Suleman et al 2014). Another study also found an increase in the prevalence of poor quality Aldezol® and Metris®, both branded generic metronidazole injections (Sosengo et al. 2021). Addressing public concern about falsified medicines at the Health Regulators summit in Addis Ababa on May 8, 2018, the former Ethiopian Health Minister Dr Amir Aman stated:

Unfortunately, the significant prevalence of falsified medications presents a threat to patients' safety and livelihood... Falsified medications are major contributors to the loss of lives and have a [huge] negative impact on our health sector and economy in general (Addis Standard, 2018, Para.5).

Despite the critical risk to SF medicine users (Gillian and Lawrence 2013; Ozawa et al. 2018; Petersen et al. 2017; WHO 2017; WHO 2022b; WHO 2023a;), there is a lack of street level research on local pharmaceutical markets, in the wider economic sense, and the ways in which their management of demand and supply facilitates, or obstructs, the entry of SF products. Street-level research (Lipsky 1980, p.3) examines the organization of human services starting from their direct engagement with clients or users and considering how this is embedded in formal institutional structures. Research by pharmacists and other (public) health researchers has mainly been concerned with the quality of specific medicines, often focusing on dispensing and storage practices (Sultan et al. 2014; Sewunet et al. 2016; Fitsum et al. 2017; Telku L et al. 2015; Tadele and Genet 2018; Eskinder 2010; Belew S. et al 2019; WHO 2011). Other studies (Gezagegn 2014; Abebe 2016; Mende et al. 2020; Yigzaw et al. 2005; Worku 2013) have examined the criminal trade in illicit drugs (psychotropic substances) and its impact on users. There remains a gap in investigating the trade in SF medicines.

There is no accessible and organized data base on the scale of this problem, the nature and sources of SF medicines and the attempts to control them at the local and national levels (Ethiopia Food and Drug Authority, 2021). Empirical research at a local level is particularly needed, to understand the ways in which economic markets connect demand and supply. Without such knowledge, regulatory interventions are likely to be symbolic rather than effective. This study contributes to filling that gap through qualitative research on the determinants of the market for SF medicines in Wolaita Zone, Southern Ethiopia.

1.1 Theoretical Framework

This research uses an analytic framework derived from Actor-Network Theory (ANT). This approach was developed in the 1980s by Michel Callon and Bruno Latour in France and John Law in Britain to investigate the role of science and technology in structuring power relationships. ANT is influenced by several micro-sociological traditions, such as phenomenology, symbolic interactionism, and ethnomethodology (Law 1992). But it departs from these theories in terms of its conception of society as the co-construction of human, non-human, and hybrid interactions (Callon and Latour 1981).

ANT challenges key assumptions about knowledge, subjectivity, the real, and the social. It focuses on how actants forge connections and alliances that entice the 'social' to establish a structured network that appears to be stable (Law 2008). The term 'actant' is used in preference to 'actor' to emphasize that a network may be organized by non-human as well as human agents. ANT views society as a complex of heterogeneous networks characterized by contingency, instability, and relationality. Like objects themselves, society is fluid and multifaceted. As Law (1992) states; "our task is to study and [characterize] these materials and [strategies] to understand how they realize themselves...". ANT encourages us to trace these heterogeneous networks as they are generated by and enroll actants.

ANT is a helpful approach to the problem of SF medicine because it allows us to escape from the binary classification of legal/illegal to reflect the complexity of the street level market and the networks through which different material objects move from the point of production to the point of consumption.

Even if our own approach to things is conditioned necessarily by the view that things have no meanings apart from those that human transactions, attributions, and motivations endow them with, the anthropological problem is that this formal truth does not illuminate the concrete, historical circulation of things. For that we have to follow the things themselves, for their meanings are inscribed in their forms, their uses, their trajectories. (Appadurai 1986, p.5)

Whyte et al (2002, p.14) apply this thinking to the study of medicines.

In reality of course, things alone do not have a social life. At most they can be seen as agents in the sense argued by actor-network theorists: they form parts of complexes that co-produce effects in particular situations; things and people both can be seen as

actors in that they mutually constitute one another (Prout 1996). But even if one does not accept the radical position that things and people are equally agents, it is essential for anthropologists to describe the lives that medicines have with people and between people.

Things (medicines) and people can be seen as actors in that they mutually constitute one another. Medicines have commodity careers as they move through different settings at the hands of diverse actors towards the destination of their intended consumer.

The case studies in Whyte et al. do not, though, explore the legal dimension of these networks. Medicines mobilize documents (laws and regulations), actors (law enforcers and regulators) and agencies. Legal mobilization classifies both humans and things. Humans may become legal or illegal manufacturers, importers or smugglers, licensed retailers or peddlers, consumers, or patients. The journey's end-point may be clearly lawful (licensed medicines dispensed against a prescription or sold over the counter by an authorized outlet); clearly illegal (recreational psychoactive substances sold in a criminal context); or hybrid (medicines that may be either substandard, or not licensed or withdrawn from the market, and distributed through outlets that may be licensed or may be general retailers that are neither licensed nor involved in the criminal supply of illegal drugs.

Methods

2.1 Study design

When adopting an ANT approach, empirical work is undertaken to trace the network of associations created by a particular actant or group of actants. An ANT analysis can, in principle, cut into that network at any point and trace the connections between the actants from there. We could, for example, start from the consumer and trace how the irregular availability and high cost of licensed medicines relative to local incomes creates the conditions for the enrolment of unlicensed suppliers and products. Alternatively, we could start from the intermediaries and their search for sources of income where these are not available through the officially recognized labor market. It is of the essence of ANT that no single starting point has priority. We have chosen to start from the SF medicine and trace its journey because this best responds to the framing of the policy question. It does not, however, rule out alternative narratives that may be equally relevant to the policymaker. This study uses qualitative methods (interviews, documentary reviews and observation) to explore the

interactions between the various individuals, medicines and groups that make up the social world of a sub-Saharan pharmaceutical market with reference to SF medicines.

2.2 Study setting and participants.

This study was conducted in Wolaita Zone, which is one of twelve zones in the Southern Nations, Nationalities and Peoples' Region (SNNPR). The Zone has an area of 451,170 hectares. Depending on the route taken, the zone is between 300 and 400 km from the capital city, Addis Ababa. Wolaita Zone is known as a hotspot for illegal trade due to its road connections to the border town of Moyale in the south, one of the main entry points for goods smuggled between Kenya and Ethiopia.

Study participants were selected using purposive, convenience and snowball sampling techniques. They included pharmacists, physicians, wholesalers, pharmacy owners, staff of regulatory authorities (national, regional, and local levels), law enforcement agents and consumers. Consumers were recruited in retail outlets as they arrived to make purchases. In total, 43 interviews were conducted between 10/8/2020 and 12/10/2020.

2.3 Data collection and analysis

The field work began with a small-scale preliminary study. Its primary objective was to identify the appropriate actors to interview and to clarify any issues in gaining access to them. This phase mainly involved interviews with officials from regulatory agencies concerned with managing the legal supply network for licensed medicines.

In the main study, data were collected primarily through interviews, using a semi-structured topic guide adapted to the various backgrounds of the informants. This covered their understandings about SF medicines, the perceived scale of the trade, the risks involved, the sources of supply and the potential challenges for preventing and detecting SF medicines. These themes were identified from the descriptions of the policy problem, from previous empirical work, and from ANT theory. Informants were also free to introduce new topics as the interview progressed. The interviews had an average duration of 70 minutes and were conducted by AM.

The market was also observed directly in action. While medicines are commonly sold in general stores and street markets, there are three main types of licensed outlets in the study area. *Community pharmacies* are unrestricted and can sell any medicine that is registered by

the Ethiopian Food and Drug Administration (EFDA), with or without prescription depending on the kind of medicine. They must employ licensed pharmacists, although the businesses are commonly owned by local entrepreneurs. *Drug stores* are medicine shops with a more limited range of medications and are run by a druggist. *Rural drug vendors* have an even more limited range of medications and are run by other healthcare professionals (Belachew et al. 2022). Five research assistants visited licensed retail outlets (4 community pharmacies and 6 drug stores), acting as mystery shoppers, to ascertain the availability of medicines that were commonly reported as SF in organizational reports and interview data. The list of medicine purchases included: antibiotics (ciprofloxacin, metronidazole, amoxicillin, azithromycin); insulin; glucose 40%; “relief tablet”; heparin; dexamethasone; and narcotic and psychotropic products including pethidine, which are subject to particularly strict legal controls and regulatory oversight to prevent potential abuses. Additional observations were made immediately after conducting some interviews to verify what had been said. For example, after interviewing EFDA staff at regional and federal level, efforts were made to observe the facilities they had described.

Documents were reviewed to supplement the data from interviews and observations (policy documents and laws, and official reports from federal, regional, and local governments and agencies). Documents reviewed include Ethiopian Food and Health Products Regulatory Sector Transformation Plan-II (FHRSTP) 2021, Federal Democratic Republic of Ethiopia. ‘Food and medicine administration Proclamation 1112/2019’ (2019) 39 Federal Negarit Gazette 11099 and Wolaitta Zone Regulatory report 2013. These supplemented the interviews with information about the definition of SF medicines, officially recognized actors in the market, measures taken regarding SF medicines and facilities available, and the widely prevalent SF medicines in the area.

The conceptual vocabulary of ANT was adopted as the initial basis for data interpretation. It was used to develop an analytic description of the interactions that made up the social world of the pharmaceutical market. Field notes and audio files were transcribed in the local languages (*Amharic and Wolaitigna*). These transcripts were translated into English after being checked for accuracy through repeated reading and revision by the researcher (AM). Before coding, transcripts were read several times. Two research assistants reviewed each transcript to ensure it matched the audio recording. Themes and subthemes included: i)

Unpacking SF medicines(production and movement of SF medicines), ii) Fluidity and complexity of SF medicines (physical attributes of SF medicine, lack of appropriate technology and functional laboratories), iii) distribution and circulation of SF medicines iv) stability of SF medicine network (social and economic values, weak legal supply chain) and V) Secret of success The data were manually coded to arrange them according to themes and categories containing similar ideas using ANT conceptual tools. The story of SF medicines is told by rearranging themes and, in some cases, framing them as questions. The data analysis presents quotations from the informants as evidence in the development of findings.

2.4 Ethical consideration

This research was approved by the Wolaitta Sodo University, College of Medicine, and Health Sciences Institutional Ethics Review Board (IERB). Permission was also obtained from the local authorities to carry out the research in the study area. Participants gave written informed consent before participation. They were informed that they had the right to refuse participation at any time, to leave the interview at any time, and to skip any questions they did not wish to answer. Participants were assured of confidentiality and informed that their data would be anonymized and used solely for the objectives of the study. Before voice recordings could be made, participants' permission was required. Where this was not obtained, the researcher relied on notetaking.

2. Findings

3.1 Socio-demographic characteristics of the study participants

Interviews were conducted with 8 pharmacists, 3 physicians, 4 wholesalers, and 5 pharmacy owners, 7 regulatory agency staff, 5 law enforcement agents, and 6 consumers. They included 43 people, 19 of whom were women. The participants' ages ranged from 26 to 58 years. All participants had completed tertiary education except for 3 local vendors and 5 pharmacy owners who had received only primary education.

Table 1. Characteristics of study participants

Characteristics		Frequency
Sex	Male	24
	Female	19
Age	26-58	43

Educational level	Primary education (Grade 1 to 8)	6
	Secondary education (Grade 9 to 12)	4
	Tertiary education (Technical & vocational, College and University)	33
Participant categories	Pharmacists	8
	Physicians	3
	Wholesalers	4
	Owners	5
	Regulatory staff	7
	Law enforcement staff	5
	Consumers	6
	Local vendors	3
	Former smugglers	2

3.2 Unpacking SF medicines

In most sub-Saharan African countries, licensed medicines tend to be imported from foreign producers. In Ethiopia, for example, 85% of all pharmaceuticals are imported (FMOH 2015). These medicines are presumed to be manufactured in accordance with good manufacturing practices standards and to have gone through thorough quality control and quality assurance, overseen by the producer country's regulatory authorities (Cloatre 2013), verified by the importing country's regulatory authority. As these actants enter the user country they mobilize a network of organizations that regulate, distribute, and deliver them to prescribers, dispensers, and sales staff, ultimately reaching consumers. This network of supply and demand is further shaped by legal instruments, professional and consumer education, and the economic resources available to both the health system and its users. It is a relatively stable network enacted by a relatively stable object. However, it does not exhaust the set of objects and networks that constitute the market for pharmaceuticals. The legal part of that market co-exists with more fluid objects and networks that seek to operate in the same space, often by adopting forms and enrolling actants that resemble, overlap or, indeed, mark participation in the legal market.

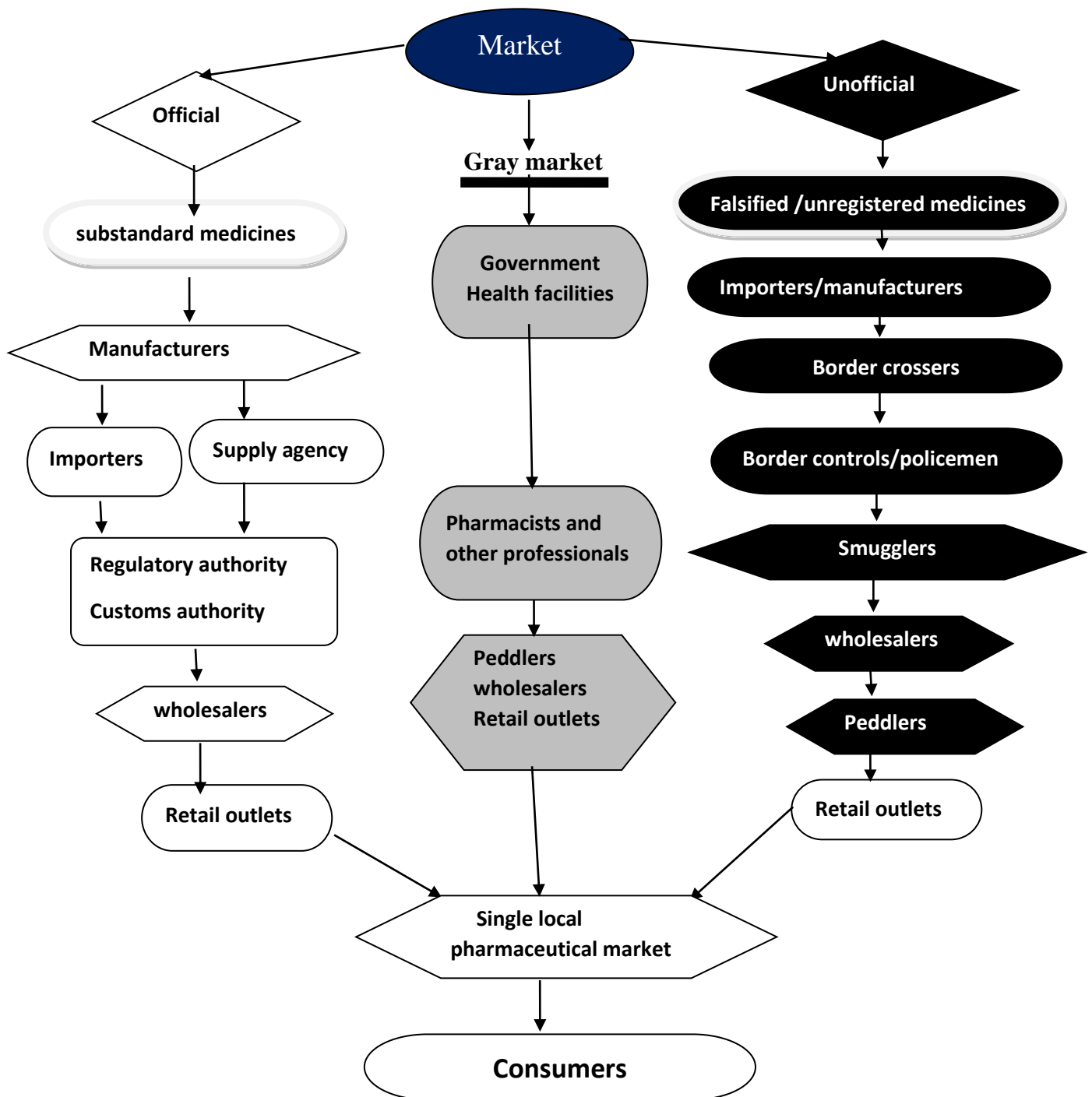
In the following sections, we shall explore these competing objects and networks in more detail, but it may be helpful to summarize the overall framework in advance.

As actants, *falsified* medicines may either disrupt or avoid the licensed supply routes from producer to consumer. Conversely *substandard* medicines, despite the continuous validation that is supposed to characterize the official network, pass through without satisfying the standard quality requirements that should serve as obligatory passage points for network entry and transit, but the official network is unable to enforce. Some medicines may start out as licensed products, but are substandard from the start, or they may become substandard as they move through time and space, from poor storage conditions or the expiry of their shelf-life. They may also leave this network altogether by attracting human actors to steal or fraudulently divert them into a competing network, from which they may still return if they reach a licensed retail outlet and succeed in passing as legitimate. The unofficial network may overlap with, or run in parallel to, another network, enacted by medicines that are authorized but of poor quality (i.e., substandard) or manufactured by unlicensed producers (i.e., falsified), inside or outside the country, or that are manufactured by licensed producers but distributed outside the official supply routes (i.e., diverted), and avoid passage points (quality checks). These networks are fluid because they lack the stabilization provided by licensing and are potentially under threat from enforcement agents. However, they respond to the demands of consumers for supplies that are more accessible and affordable than those delivered through official networks. The material object (SF medicine) stands at one end of a network with the consumer at the other and a set of intermediaries in manufacturing, distribution and sales extracting profit from their positions, reflecting the risks of operating in the shadow of the law (See figure 1)

Our analysis of the local market shows how SF medicines have met with minimal resistance by successfully enrolling key actors to facilitate their entry. These substances, in the case of falsified medicines, are assembled into medicines with the engagement of other non-human actants (packages, labels, colors, and so on) and through co-production/construction by human actants (lay people, pharmacists, technicians, businessmen etc.). This process of assemblage breaks down barriers to entry by making their true material condition hard to determine. The falsified medicines use composition and appearance to mimic licensed medicines. They evolve complex hybrid linkages of social, human, natural, and technical elements in fluid networks, and enroll a wide range of actors, through whom they pass to

consumers and their bodies. These networks interweave with the official supply chain to constitute a single market rather than one that has clearly distinct licensed and unlicensed areas.

Figure 1: The diagrammatic illustration of the journey of SF medicines



The diagram shows the different trajectories mobilized by SF medicines. They may begin either with illegal manufacturers or with legal suppliers, at local or international level. If SF medicines are detected, they may end in the hands of legal authorities, seized, and destroyed. If not detected, they will be consumed by patients, with adverse outcomes that may be detected and reported (acute toxicity) or overlooked (sub-therapeutic efficacy).

SF medicines are a good example of things whose values are constructed subjectively by those involved regardless of their material condition. Substandard medicines are always licensed, but their quality problems went undetected by regulators. Poor quality may result from human error in production, poor manufacturing practice due to ignorance or negligence, poor storage and distribution practices during their travels, or use beyond their expiration date at the end of a commodity career as licensed medicines.

Diversion through theft by health professionals from government health facilities, hospitals, and health centers also compromises their status as licensed products by breaking the regulated supply chain. These may involve overt burglaries or fraudulent accounting to conceal the diversion of these medicines, whether purchased by the government or donated by NGOs, out of their intended networks. Instead, they pass through secretive channels direct to practitioners and wholesalers. Their quality can no longer be documented, even if substantively unchanged. They join the category of unlicensed medicines that add to the complexity of the market. This supply varies with the legitimate availability of medicines in the local market. Where there is a shortage, high prices create an incentive for intermediaries to deflect licensed medicines from official channels in response to the demand from patients facing painful choices, particularly if they have a chronic illness that requires long-term and consistent use of specific products.

Falsified medicines are always illegal, deliberately, and fraudulently misrepresenting their identity, composition, or source for profit. Illegal manufacturers, for example, at the Moyale-Kenya border, see them like any other commodities to be produced and traded economically. This shows that values are not intrinsic to the object. They are created to portray a benefit for the consumer. Producers simulate licensed medicines to infiltrate the market regardless of the risk to consumers.

SF medicines bridge the distance between the financial desires of the producers/suppliers and the health and social needs of consumers—various intermediary actors define them as an object to fulfil their need for income.

3.3 How do SF medicines reach the retail market?

Most SF medicines enter Wolaita Zone from Kenya through the border port of Moyale, although this route is a significant source of supply for the whole of Ethiopia.

“It is very common that all types of medicines including those in short supply, or which are not available in the pharmaceutical market enters through Moyale and distributed to different parts of a country including Addis Ababa”

The Moyale area is also something of a center for manufacturing and for the creation of false identities through apparent formulation, labelling and packaging. Illegal manufacturers design and direct the movement of these objects. They produce them by mimicking licensed medicines: identical external characteristics facilitate movement and avoid troubles in passage through the network. The objects are presented as good quality medicines except for the lack of regulatory approval. Both professionals and laypeople contribute to the production process; pharmacists employ their technical expertise while others contribute working capital. The temporal and spatial dimensions of the commodity career of falsified medicines are complicated and diverse: some begin at a global level and others at national or local level. They may be produced in secret locations (hidden compounds) or imported through international supply chains.

“Let me be very honest with you, it is not straight to say that these medicines are imported through Moyale because commonly they are manufactured there. They are manufactured with same labeling and source information with nationally registered ones. There is place called *Gabo* which is bordering area with Kenya where all medicines which are deemed to be in high demand are produced and distributed. For example, I do know that they prepare syrup for children without any active ingredient”

Moyale is also a legal route for licensed medicines to enter the country. There is border inspection of medicines claiming to be licensed. This passage point identifies a proportion of them as unregistered or falsified.

“There is an inland port under our mandate - Moyale. We find that there are diverse medicines which seem to fulfill all the requirements but when we examine them in laboratory there are no active ingredients. At first sight, they seem to fulfill all the standards requirement but, in most cases, they are falsified medicines. When analyzed in laboratory, they simply become powder or composed of wrong ingredients that could result in severe health problems”

“The source for these medicines is Kenya-Moyale route. These medicines enter the market just like other products. In our case, there is only one port at Moyale but there are many loopholes where these products enter into the country. It is very profitable business. All kinds of medicines come through this channel”

Falsified medicines enroll border controllers and customs personnel to facilitate their passage using a variety of techniques, including bribery and pressure from political office holders (local, regional, and national). At this stage of their travel, border crossers play a significant role in successfully negotiating the passage. These are mostly young people who are unemployed or school dropouts looking for a source of income. They carry the objects across the border and pass them on to smugglers or sell them directly to wholesalers and retailers. While the border crossers might intend this work to be a temporary source of income, it is hard to leave because of their recruiters' fears about compromising the security of the traffic.

Every member of the network is constantly watched. Border crossers who are unsuccessful in their negotiations with border officials run a significant risk of being imprisoned, attacked, or even killed. If they get caught, their recruiters – influential businesspeople - will use every means at their disposal to help them escape: if not, the recruiters will ensure that they do not divulge any information that could endanger the network by threatening them or their families. Border crossers and their recruiters have a business-focused relationship; they do not get to know each other in person. The border crossers' primary duty is to follow and obey orders intelligently. In this type of network, the recruiters must constantly guarantee that all actors follow instructions and carry out their assigned roles. Any diversions and failure will bear severe consequences.

However, unregistered, and falsified medicines also have the option of avoiding government checks altogether by using one of at least twenty unofficial border crossings in the surrounding area, which are uncontrolled and wide-open for illicit commercial traffic of all kinds.

“As a branch office, we have been given a mandate to control and inspect actions at the official border crossing in the Moyale area. However, there are several informal routes and gateways to these medicines. It all appears to be out of control”

Medicines are no different from any other product and are smuggled alongside clothing and electronics. All of these goods can be freely traded in the market.

Diverted and falsified medicines imported through, or manufactured in, Moyale, are distributed by smugglers (including some health professionals) to private clinics, pharmacies, drug stores and wholesalers. There are also individual traveling traders who sell directly to pharmacies, drug stores and, mostly, to rural medicine vendors. Smugglers argue, with the support of others in the networks, that these medicines are high-quality but simply failed to receive regulatory approval. Our informants emphasized that falsified medicines commonly slip into the formal supply channels by successfully mimicking licensed products and avoiding or diverting the attention of enforcement agents. They are not necessarily smuggled through unofficial border crossings and sold through a black market. They are just as likely to have passed through a government customs check and entered the legitimate supply chain.

There are also reports of both licensed and unlicensed medicines changing their identity through the actions of intermediary entrepreneurs within Wolaita Zone who alter packaging in response to the failure of other supply chains to meet demand in the local market. This line involves falsified medicines directed for exchange locally when there is particular demand for specific medicines, whose packaging and source information are easily changed.

“At this moment, TAT (tetanus antitoxin) is not available in the market. They are using Gentamicin by changing the packing and source information

of TAT. They are changing the cover easily by using warm water to get rid of the right information and wrap up it with wrong information”

A licensed product that has passed through an official network for at least part of its journey to the consumer has been transformed into an SF product. It may contain a valid, and validated, active ingredient (gentamicin) but it is now masquerading as TAT (tetanus antitoxin)

Outside official networks, medicines enroll modes of transport and storage that have little regard for the conditions of heat and humidity required to ensure their integrity. Typically, ordinary cars are used, with the medicines hidden in concealed compartments or spare tires just like other commodities traveling through unofficial channels:

“I have been working as a pharmacist for more than a decade. We know that it is all widely open practice and has become a daytime business. These medicines freely enter the market breaching the formal requirements. This infiltration involves all types of medicines that even require refrigerator for storage for transportation such as injections, insulin, and so forth. This makes it more dissolute and unsound”

Diverted and falsified medicines gain access to some intermediaries, like government facilities, less easily than others, like private facilities. Government health providers are not under the same pressure to generate profit and have bureaucratic forms of organization that make it more difficult, although not impossible, to conceal unofficial sources of supply. However, diverted and falsified medicines have ways of acquiring or mimicking market authorizations and appearing entirely legitimate unless analyzed in a laboratory. They may appear to have arrived through official channels and be impossible to challenge from local resources for quality assurance or law enforcement. Equally, those licensed medicines that have left the official network may change their identities as they pass into the private sector.

SF medicines appear to colonize urban rather than rural settings, although all medicines struggle more with travel to rural areas. While they may occasionally enter retail locations directly, the main route in urban areas is through wholesalers, some of whom also run retail outlets. The wholesalers have strong connections to local sources (Moyale port) and beyond (Kenya) through which licensed products reach them. The smugglers who transport the

unregistered, diverted or falsified medicines across the border have a hidden relationship with local peddlers who act as brokers passing the products to wholesalers.

“I can tell you something sensitive. There are people who act as peddlers, connecting us. In most situations, they determine prices after examining the market. They work collaboratively with wholesale facility owners. Otherwise, how do you anticipate we’ll be able to get these medications? It needs a large amount of money as well as an informal connection”

Wholesalers are critical passage points because, in comparison to retail outlets, they have the legal mandate and storage facilities to hold a large stock of medicines. This creates more opportunities for unregistered, diverted, and falsified medicines to conceal themselves among licensed products and circulate on equal terms. The wholesalers perceive them as an alternative to the scarcity and inadequate supply of licensed medicines. They constitute assurance that local retail outlets may rely on the wholesalers as dependable partners and suppliers, keeping network nodes intact. The process is facilitated by the intermediary work of the peddlers and of local police officers who hope to profit financially.

Timing is also important in the successful passage of SF medicines. If retailers are short of stock, successful mimicry of licensed products may not be questioned as closely. For the pharmacy owner, accessing them would be vital in the competitive pharmaceutical market. Many retailers stated that it would be detrimental to the success of the overall business to let a customer go without the medicine they require. One pharmacy owner remarked on his efforts to locate a particular item:

“Glucose 40% is currently unavailable on the market. However, they say that it is somewhere in an individual’s storage. It is sold at a high price and circulates in the market behind closed doors. The source is unknown, and no one has conducted any tests to determine its standard. But, to be honest, I’ve tried to gather information but have yet to receive any”.

3.4 SF medicines as complex fluid objects

SF medicines can only be partially identified by visual inspection. Our informants said that a few medicines could show color changes. Tablets might crumble into powder if gently compressed. The color of liquids was particularly hard to identify.

“Different types of medicines as liquid or solid or semi solid are dispensed here. If the medicine is liquid, we try to check and if we find gouache or powder then we dispose it as waste. For example, if you take paracetamol, it is normally having white color and we if found change in its color we abandon it”

“We receive various complains from our customers. For example, I have received complain about Vitamin C (ascorbic acid) several times. This medicine when it compressed even very gently, it altered to powder. This is one of important conditions to attest that a medicine is counterfeit one. It is still stored in the shelf, and I can show you. In the case of liquid medicines, we identify them if there is packaging problem or if it leaks out. And the color of the medicines changes continuously. I mean, for instance, amoxicillin for children it is packaged with umber color and it impossible to differentiate visually. It is difficult for us to know these issues let alone the community.”

Policy documents represent SF medicines as dangerous products circulating out of legal and medical control. They must be eliminated - seized and destroyed at any point in their journey. However, there are only a few cases in the study area where falsified medicines were identified, recalled from the market, and destroyed. For instance, the zonal regulatory office identified falsified sodium valproate 200mg tablets in the market and disposed of them. The tablets were identified because they were easily breakable and damaged inside the pack.

The passage of SF medicines is facilitated by weaknesses in the legal supply chain's passage points, verifying claims to the privileged identity conferred by licensing. These include lax regulatory oversight and dysfunctional laboratory facilities. For example, our interview and observational data indicated that the quality control laboratory facility at the regional FDA, the only such facility in the region, had closed two years ago. There are two laboratories at the national level: at the EFDA and the national standards agency. These could not handle the

volume of work required to ensure adequate post-marketing surveillance throughout the entire country. Moreover, packaging for medicines is not required to display barcodes, which might help to verifying their integrity before they are sold or dispensed by pharmacists.

Unregistered and falsified medicines easily enroll retail outlets, usually owned by individuals with no professional background who recruit employees who are either unqualified or have a background in other, albeit related, fields, including chemistry, biology, and public health. These actants do not have the authority, the professional expertise, or the opportunity to resist enrolment by checking the quality and sources of the medicines brought into stock by the owners. Their contribution to the network is limited to selling medicines to patients. Medicines are objects that have been wrenched away from professional control.

The free mobility of SF medicines is aided by the way they present their therapeutic effects. Consumers recognized that the pharmaceutical market was delivering some products that were risky and of uncertain quality but found them to be sufficiently effective treatments for some conditions that troubled them. At the very least, the users believed that their suffering was relieved. The meaning they attribute to SF medicines is based on their personal experience, and testimonies from others, rather than on medical diagnosis and prescription. They look for affordable medicines and may find effective ones. They play an integral part in regulating their living condition, taking steps to improve their health, and avoiding complacency. These medicines appear as an entry point to avoid the financial burden of unneeded treatment and diagnosis. They are life savers in the face of distressing financial troubles.

“I think it is routine for me to take medicines without prescription especially when I experience same feelings and symptoms I had experienced before. And the pharmacists also help us to get them. Though there are instances where it didn't work well, I prefer to take medicines before I visit medical center. You know, I don't want to pay for those people as they ask much money for diagnosis and treatment every time you visit. I got close friends, and I listen to their opinion”

“Whenever I feel like I am not well, I tell my family and friends around. I think everyone does that. They would tell you what to do at the end. Mostly, I go nearby pharmacy or medicine store and take medicine. I

never thought that this is a problem at all. I can't be sure about the type of medicines given to me but at least I try to check the expiration date. I found it very effective in most cases. If you go to the medical facilities, they will eventually prescribe you the same medicine or sometimes they negligently order unnecessary diagnosis and treatment outlets" (IDI,)

The pharmacists interviewed maintained that not all the products falling into the category of unregistered or falsified medicines would be ineffective and perilous (tending to ignore the more complex notion of "substandard"). Some of these products could have the appropriate quality but "simply" failed to enter the market through official channels. The issue is less one of quality or effectiveness than of following the correct legal procedures for market entry. They reinforce local beliefs based on customer testimonials and experience rather than established biomedical standards. The 'Relief tablet' medicine is a good case study. It is an unregistered medicine that is not assessed by the regulatory authority but circulates widely and is sold freely in retail outlets. this medicine's efficacy is rooted in the testimony of people in the community. It is taken as self-medication although it is assumed to be a prescription-only medicine. With its name (Relief) and image (red labels with a woman having a headache), it acts as a sign of immediate healing that anyone in the locality can identify regardless of its uncertain nature and quality.

"It is all about patients' perception and belief that matters here. And I do observe these medicines are effective and cure the patients. In most instances, they request medicines based on their experience and outcomes"

"Customers request medicines by name and tell you about the effectiveness of the medicines. For example, they often look for medicine called relief tablet. They tell you that they have tried other medicines and it didn't work. Thus, relief is the best to relieve from any form of pain. When they didn't know the name, they try to explain the image on the pack as I didn't know it before. Genuinely speaking, I heard from my customers for the first time about this medicine" (IDI,)

"There is a problem of medicines resistance, which has become a health concern our time. For example, people take rifampicin to treat diarrhea

related problems. Of course, it treats diarrhea effectively, but the question is what if these patients develop TB? They will be put in the second line treatment¹ and many patients in fact are being treated this way in the area”

Some enrolled vendors are selling unregistered, possibly falsified, medicines based purely on a belief that they are effective, although this outcome might not be guaranteed. Many informants emphasized the risk of severe health problems, both ephemeral and persistent, from taking medicines from unregulated supply channels, while others thought that the main risk was the unknown sourcing of products that were otherwise effective. The assumption that medicines coming from unregulated supply channels, and/or without a marketing authorization, were effective, as well as more affordable, ensured continuing consumer demand and tolerance of possible risks. For example, Viagra (sildenafil) is widely used in the locality. It is a prescription-only medicine intended to treat erectile dysfunction in men. However, many young men use it freely, aiming to ease their concerns over changing expectations for sexual performance. The local social context demands the use of this medicine, regardless of regulatory constraints.

Our data show that, although unregistered and falsified medicines may have substantial adverse impacts at a population level, they are able to entice participants into their networks with the prospect of significant private financial gain. Many participants are attracted by their easy accessibility and high market value, where everyone involved benefits financially in the short term. They are welcomed because they provide quick routes to achieving economic success and meeting social expectations for a better life.

“Let me give you a brief case in point. I am a pharmacist and close to this business for so long. There are three individuals who become wealthy within short period of time. We all know that dispensing medicines at pharmacy or medicines store cannot bring abrupt economic benefits as profit limit is set by the government for each of the medicines. They are highly engaged in this informal business with the intention to make money and maximize their profit. They do this in veiled and enigmatic conduct”

3.5 Understanding the supply chain: Where are SF medicines sold?

Substandard medicines are licensed, so they may follow the official supply chain. Unregistered and falsified medicines easily gain access to the study site because of the large and dispersed network of intermediaries that they enroll on their journey: local health facilities, both public and private; local shops; supermarkets; and street markets. This network does not institutionalize a separation between licensed and unlicensed supply. For example, tetracycline and rifampicin were easily found in local shops, although, legally, they should only be available through pharmacies. Both licensed and unlicensed versions of these medicines (which may or may not be substandard or falsified) are sold freely in street markets. Even medicines that have been withdrawn continue to be available. The Ministry of Health has, for example, directed that rifampicin should only be used in combination therapy for tuberculosis patients, because of concerns about the development of resistance. However, it is openly sold in many places, from unknown sources, as a very effective treatment for diarrhea.

This movement goes both ways. If licensed medicines can be found in unlicensed outlets, SF medicines can also infiltrate licensed outlets – particularly those medicines that are registered but substandard. Some informants even suggested that in some pharmacies all the medicines might be substandard or falsified:

“To be straight out, as a pharmacist I do always observe that the medicines in the pharmacy are brought without invoice. That means many medicines are coming from unknown sources. Frankly, I didn’t want to talk about this and was waiting for you to bring it up. Everyone is afraid to talk about this problem. It puts in you trial. It is a far and wide fact, but one talks about it. It is not taken seriously”

“I can assure you that if you accidentally look over all the pharmacies and medicines store around public transportation site here in the town, you could find that all medicines on the shelf and store are counterfeit. I know it for sure. I have worked in many private and governmental facilities in the town. They bring it cheaply and sell it in ‘normal’ price or high price depending on the market situation. The source for these drugs is Kenya-Moyale route. All kinds of medicines come through this channel”

Informants assume that falsified medicines can be easily manufactured. They are packaged to resemble nationally licensed medicines, using ingredients which may be ineffective or unsafe. When they compete with licensed medicines that are in short supply, they may be sold at very high prices, which patients may struggle to afford. Some informants commented on the manipulation of both official and informal markets by key actors to create artificial shortages and raise prices. The most vulnerable patients in these circumstances were those with chronic illnesses, where a prolonged lack of effective medication could have serious or fatal consequences:

“Diabetic patients are at difficult time due to lack of insulin in the pharmacies. It is very expensive by now and people couldn’t afford the price. They could not cope with the financial burden and are forced not to take the treatment as a result. Many patients are dying due to this. You can see the seasonal death of diabetic patients and it may increase mortality rate in this regard”

While the network starts from a relatively small number of points of entry, represented by legal import channels or unlicensed manufacturing facilities, it ends with a large number of points of exit as the medicines, licensed or falsified, reach consumers. On the one hand this facilitates consumer access and builds resilience into the supply chain. On the other, it creates major challenges for the enforcement of licensing regulations because of the numerous opportunities for SF medicines to infiltrate legal networks or for licensed medicines to slide into unofficial networks.

3.6 Stability of SF medicine network

Unregistered and falsified medicines do not generate a network that is clearly distinct from the legal supply networks for licensed medicines. Their open recruitment of anyone who is interested in being involved, usually for financial benefit in a country where alternative income sources are limited, is an unexpected source of stability. In the absence of a formal, institutional underpinning, their supply chain is assembled underground and weaves itself through and around the licensed supply chains. Unregistered and falsified medicines travel through connections that are flimsy and unstable, involve actors who are not known or predicted, and end up in unforeseen destinations (marketplaces, streets, individual households). However, it is precisely the instability of the connections that opens recruitment.

If actants are easily replaced, the network is difficult to disrupt, compared with a legal supply chain that depends upon formal institutions. If a warehouse containing legal stock burns down, the network is broken for a time. If an SF consignment is confiscated, there will be another along shortly by a different route.

The network in the local market is built around the polymorphic idea known as "*Berha*" (desert route), which describes the specific movement of these medicines from border areas to the locality. It reflects both the temporal and spatial dimensions of the network. *Berha* captures the circulation of medicines within the network to deliver wealth and power for key members. It also signifies the route of these medicines and their unstable networking elements, which are prone to distrust and diversions. It is the medium of communication and shared identity in the face of potential threat from the legal network. The stability of the unregistered and falsified medicines network derives mainly from two important features of the context: the economic opportunities that it offers to participants and the chronic mismatch between consumer demand and legal supplies.

According to World Economic estimates, which include allowance for the size of the informal economy, Ethiopia ranks 127th for GDP per capita out of 144 countries with data available (<https://www.worldeconomics.com/Wealth/Ethiopia.aspx>). Relatively poor countries depend heavily on informal markets and the enterprise of citizens to generate household incomes, where the official economy is unable to supply sufficient formal employment in adequately remunerated salaried or waged occupations. Unregistered and falsified medicines take advantage of this context to offer sources of income to those who are recruited to manufacture, distribute, or retail the products. This is what makes the network viable and ensures its continuity.

These recruits are necessarily closely attuned to the market demand for their products. When asked what led them to be involved in the unregistered and falsified network, one informant from a wholesaler remarked, "Our business and growing our profits are very important to us. We place a strong emphasis on market demand and ways to benefit. We track the shortage and profit from it." This was reported to be the prime motivation for nearly all professional and non-professional actants. They claim that participation in this network is the only way they can compete and thrive in the pharmaceutical market. Economic insecurity and the fear of failure open them to mobilization as network members. They allow themselves to be

enrolled because this is the nature of their business. The owner of a wholesale outlet stated firmly: "Forget about others. If I don't want to accept and work with it, I should have to leave the business, otherwise, it is unthinkable." They are identified as the primary means by which participants can guarantee their continued existence as business entities in a medicines market, which, according to many, is fragile and out of scale.

“You believe it is something I do to raise my profit. If you think that, you are wrong. I also know that many people feel this way. It's really a matter of survival for me. I believe I have already identified myself as a businessman in this sector, thus I do not want to incur losses and close the facility. It has nothing to do with me or my partners; it is very normal, and I am even bemused when people say illegal”

Indeed, some go so far as to imply that it is the legal network of licensed products that is marginal to the larger and more resilient unregistered and falsified network. The official, public, and private, health system has long struggled with medicine supplies that are too limited to meet demand. Although the problems have always existed, they have become more critical because of the worsening economic climate and disruptions to the global supply chain. In recent years, there have been particular shortages of painkillers and medicines for chronic illnesses. Many actors, including the Ethiopian Pharmaceuticals Supply Agency, have recognized this concern, attributing the problem to a lack of foreign currency as well as capacity constraints. The unregistered/falsified network steps in to meet the need.

“We wait five to six months to receive authorization for foreign currency. Even after National Bank of Ethiopia approves, Commercial Bank of Ethiopia takes some time to release it. Then, the ordering and shipping require more time. Overall, the lack of foreign currency has caused a four-to-five-month interruption in the supply of medicine. At the end of the day, when it is already too late, we receive the hard money we requested”

The supply problems of the legal part of the network meet relatively inflexible consumer demands. People who have chronic conditions or acute needs cannot wait ‘four to five months’ for legal supplies:

“My father, who is 64, was diagnosed with type-1 diabetes and the physician prescribed him insulin. Then I had to look for several days all over the facilities. You don’t believe I found it informally from people in the informal market and bought it three times higher than the normal price.”

An unregistered or diverted medicine that was not falsified or substandard saved a life in this situation and enabled the son to fulfil his socially valued obligation to care for his father. The force of social obligations makes it very difficult for consumers to appreciate the risks of the informal market.

Unregistered and falsified medicines enroll consumers by providing supply, even if the tradeoffs between price, quality, and risk are different from those considered appropriate by regulatory agencies.

3.7 Unregistered and falsified Medicines: The Secrets of Success

One of the features of an ANT analysis is that we can acknowledge the extraordinary success of unregistered and falsified medicines in colonizing local pharmaceutical markets rather than seeing this as a mark of regulatory failure. If regulatory efforts have failed, it is not (only) because of the ability of these medicines to evade or avoid enrolment by regulators in officially recognized networks. They have, rather, co-opted those networks on their own terms. They are shapeshifters, fluid objects that are skilled at adapting themselves to the challenges of moving from one network node to the next. They smuggle themselves through or simply by-pass passage points created by regulators to block free movement:

“I think there is serious confusion and negligence in understanding these and what they stand for. It is not rightly defined and communicated to all professionals and other stakeholders including the community”

“The definition is indistinct and confusing because it seems redundant and not applicable in practice. The definitions of these terms transect each other. For example, when you define the idea of fake drug it tends to mean falsified drug. It is problematic in terms of showing real margin among

these terms. That is why I say it creates confusion in understanding the issue”

The fluid identity of SF medicines is displayed in the confusion of terms that describe them. While labels like falsified, diverted, counterfeit, fake, spurious illegitimate, unregistered, substandard, or unregulated may or may not have precise meanings in legal documents, scientific literature, policy statements or the pronouncements of international agencies, they have been rendered uncertain by the time they reach street level, even among regulatory agents.

“In my view three terms have almost similar meanings or sense. They generally imply medicine that do not fit or fulfill the standard. But I think there is a kind of slight difference among them. I think, when we say substandard medicine, we are referring to a failed medicine product as per the existing standard requirement of safety, quality, and efficacy. When we use term counterfeit, it refers to fake medicines that do not fit the requirement. For example, if the medicine has a wrong active ingredient or less active ingredient. Sometimes, in addition to ingredient necessity, it also includes medicines that do not pass-through appropriate procedures though it has the right active ingredient. Lastly, falsified drugs are those with false or wrong name or brand that is misrepresented. In other words, it is the medicine with false information that does not fulfill the requirement. In all three cases, we focus on the product”

“The common denominator for all the three concepts is ‘erroneous’ or ‘ትክክለኛ ያልሆነ’ in Amharic. It could be substandard, fake, or falsified. You could give any kinds of naming to it. What we do is that we operationalize the terms to our context as to different stakeholders. We develop our own working definition. We try to make it simpler without losing its original notion”

Within the health system, SF terms were found to be widely attached to alternatives such as expired medicines; irrationally used medicines or medicines requested without prescription, medicines sold outside formal channels or entering through informal channels, fake

medicines, erroneous medicines, medicines without a market authorization and poorly stored medicines. Some of these are “only” using different wording, but others represent different challenges to regulatory control. Outside the health system, the picture is even more confused. Participants from these networks tended to use the term ‘spoiled’ drug (*የተበላሸ መድኃኒት* in Amharic). This is from an officer of the police and customs authority involved with enforcement:

“When people from the health department inform us that they are going to supervise the facilities, we go along with them. In such instances, I hear that they found spoiled medicines, and in that case, we are urged to take measures. That is why I am continually using the term ‘spoiled’ medicines. In fact, I don’t think that I must know about these things. Our job is to take appropriate measures proposed by the officials from the health department... Frankly, I am not familiar with the terms. We are supposed to work with professionals from the regulatory offices. On our side, we are not pharmacy professionals to know about these things”

While the regulators acknowledge the difficulties of defining SF medicines, they still assume that this can easily be done by local professionals and consumers despite the uncertainty that they themselves confess. Lower-level actors in the system are thought to have a duty to make distinctions that specialists struggle with and come to the same conclusions about risk and risk management.

4. Discussion

It is well-recognized that there is a lack of research about the street level trade in SF medicines. This study has examined the phenomena of substandard and falsified medicines through a qualitative study of the network that links the demand for medicines in the local market in Southern Ethiopia with the sources of supply, as licensed, substandard, and falsified medicines mobilize various intermediary actants and travel to reach the outlets through which they are sold to sick people or those caring for them. Most of our findings are relevant to falsified and unregistered medicines, which enter the market illegally, outside regulatory supervision; however, licensed substandard medicines can also be present at the

same time, making it difficult if not impossible to make clear distinctions across the different categories, for both researchers and informants.

The use of ANT as the methodological and analytical framework for this study has enabled a more nuanced understanding of how SF medicines are defined in the Ethiopian context. It has been observed that the narratives of global health about issues such as SF medicines reflect the dominant knowledge paradigms of the Global North which are then transferred into Global South contexts (Hodges and Garnett 2020). However, SF medicines represent a major threat to public health particularly in the Global South, and “there remains much to do and learn about the social and ethical conditions that produce and exacerbate SF medicines” (Kingori et al 2023). SF medicines should not be represented as a simple case of regulatory failure where the appropriate policy response is more aggressive law enforcement.

There is a good deal of confusion among street level actors about substandard, falsified, and unregistered medicines. This partly arises from the fact that some unregistered medicines may indeed be effective for their consumers, and some substandard or falsified medicines may be ‘partially effective’, but just not as effective and safe as they should be, or able to prevent the emergence of resistance at population level. It also reflects the complexity and interconnection of definitions, and the interpenetration of supply chains and sources. Pharmacies, drug stores and drug vendors commonly received medicines outside legal routes, from manufacturers through wholesalers to retailers. However, these routes did not necessarily deliver diverted medicines, where the source was theft from a government or NGO facility. Conversely, unregistered, and falsified medicines could be inserted into legal supply chains. Alongside their fluidity and multiplicities, SF medicines -and, in particular, unregistered, and falsified medicines- are a good example of valuable objects with diverse meanings as they travel through various actants. For many, they are valuable commodities, giving access to money and power; for others, they are an opportunity to make a living or survive as a business by guaranteeing supply where legal routes are uncertain and fragile. Consumers were able to manage their lives, meet societal expectations and carry out support obligations to the sick.

The SF network is a heterogeneous alliance of actors with distinct value perceptions operating in the shadow of law. It is a concealed network, mobilizing paper documents, actors, and agencies to co-construct a single pharmaceutical market, eroding the policy

assumption of dichotomy. The SF network has enrolled enough actors to overcome potential resistance to its participation in the local market. The actants, human and non-human, collaborating and enrolled, reflect the co-optation of the market by the SF network. The hidden, diverse, and erratic nature of this network builds resilience and complicates any reform efforts to disrupt it through regulation or enforcement.

While, in 2017, the World Health Assembly (WHA) managed to impose some order on the chaos of definitions at a high level of policy, this remains remote from the street level, where the main concern is to provide consumers with the products they request at prices they can afford, preferably without visibly harming them; and where consumers have to deal with the reality that fully quality-assured medicines are often out-of-stock, or unaffordable to them.

Apart from the risks of inappropriate or ineffective treatment, SF medicines have economic consequences. They distort pricing, create incentives for theft and fraud, and are likely to throw additional burdens on the official health system from dealing with the consequences in morbidity and mortality. Potentially, these uncertain supplies also undermine confidence in the market itself and the integrity of the professionals working within it, whether or not they are personally engaged in corrupt practices. These findings are consistent with a range of other studies examining the impacts of SF medicines (Cartwright and Baric 2018; Przysta E. 2013; WHO 2017; Blackstone E. et al 2014; Gillian and Lawrence 2013; Glass 2014)

Nevertheless, the study also found strong views at street and community level that these medicines could be both sufficiently effective and reasonably affordable for consumer purposes. The results might be sub-optimal from a medical and public health perspective but were perceived as adequate against the standards applied by users. Tighter controls on SF medicines and their supply (and even public information campaigns intended to make consumers more aware of the risks) will be insufficient to fix the problem if the health system is not able to prevent shortages and to ensure access to affordable medicines for all. They might even be detrimental to the interests of consumers by further raising prices, reducing the security of supplies, and excluding patients with limited resources or access to retail outlets.

An appropriate policy response from governments would have three dimensions. First, there is a need to reinforce regulation and oversight, by strengthening pharmacovigilance and post-marketing surveillance systems, so that quality problems can be rapidly detected, and products withdrawn from the market. Second, but not less important, quality-assured

medicines should be available and affordable to all through legal supply, by combining policies for price control, social security, and universal health coverage. Finally, regulators, and other legal stakeholders, should develop ways to inform the population about access to quality-assured and affordable medicines, through respectful, non-judgmental, and culturally sensitive language taking account of local concerns, expectations, and beliefs.

5. Study limitation

This is a case study using qualitative methods to examine a particular local market in one country. It aimed only to describe that market in an analytic fashion that could contribute to the assembly of other case studies and the development of more general propositions about the nature of such markets. The data were limited to recorded interviews and hand notes of observations. The collection of photographic evidence was considered but was not acceptable to informants because of the legally problematic nature of the issues being investigated. While SF medicines cover three groups -substandard, falsified, and unregistered- our findings mainly concern falsified and unregistered medicines. Despite these limitations, the data is unique in using an ANT framework to understand SF medicines and how they got into the local pharmaceutical market in Ethiopia – and potentially in comparable sub-Saharan African contexts.

6. Conclusion

Debates about issues like SF medicines are highly specialized, defining them as objects of concern in isolation from an understanding of the social, economic, and political contexts within which they emerge. More critical readings of global health challenge these narratives. Global health is a field of epistemic tension reflecting the often-hidden assumptions of Eurocentric and colonial thought that have been transferred from the minority world (Global North) into the majority world (Global South) and shaped its practice (Biehl and Petryna, 2013; Hodges and Garnett 2020; Richardson 2020; Kingori 2023).

This study has showed the complexity of the demand and supply for medicines at street level in Ethiopia, and the obstacles this may present for reform. There is a lack of agreement among local actors about the nature of the problem, or, indeed, that there is a problem at all. Even if agreement can be reached among international or national policy makers, there will be considerable challenges in outcompeting the unofficial supply chains described here. The only viable alternative - making quality-assured medicines acceptable, available, and

affordable for all - will not be easy to develop, even if it offers considerable population health and economic benefits.

Access to effective and affordable medicines in low-income countries like Ethiopia remains elusive and a site of contestation between global intellectual property, trade and regulatory regimes and public health interests (Global Health Watch 2022). SF medicine supply chains emerge in the vacuum created by the lack of access to licensed medicines. The SF medicines' journeys are prompted and shaped by systemic inequalities; a form of structural violence exerted on the poor (Farmer, 2013). In approaching the complex problem of SF medicines, it is necessary to give due attention to the issues in the sociocultural context in which these medicines operate, which are reflected in the values different social actors attach to them. The response requires wider systemic change, including policy reform that better balances public health concerns, quality assurance, access to essential medicines and people's perceptions and expectations.

References

- Abebe T. 2016. *The Scaffolding of Illegal Drugs Controlling and Prevention: Prevention: A Case of the Drug Controlling Unit of the Federal Police Crime Prevention, at Bole International Airport*. MA thesis, Addis Ababa University.
- Almuzaini et al. 2013. Substandard and counterfeit medicines: a systematic review of the literature. *BMJ Open*
- Appadurai, A., ed. 1986. *The Social Life of Things: Commodities in Cultural Perspective*. Cambridge, UK: Cambridge University Press.
- Baratta F. et al. 2012. Diffusion of counterfeit drugs in developing countries and stability of galenics stored for months under different conditions of temperature and relative humidity. *Pharmacology*
- Belachew S, Hall L, Selvey L. 2022. Community drug retail outlet staff's knowledge, attitudes, and practices towards non-prescription antibiotics use and antibiotic resistance in the Amhara region, Ethiopia with a focus on non-urban towns. *Antimicrob Resist Infect Control*. 11:64.
- Belew S. 2019. Quality of fixed dose artemether/lumefantrine products in Jimma Zone, Ethiopia *Malaria Journal* vol 18, 236
- Biehl, J. and Petryna, A. 2013. *When People Come First : Critical Studies in Global Health*. Princeton, NJ: *Princeton University Press*.
- Blackstone E. et al. 2014. The health and economic effects of counterfeit drugs. *Am. Health Drug Benefits*. 7(4):216–224.
- Callon M. 1981. some elements of a sociology of translation: domestication of the scallops and the fishermen of St Brieuc Bay. Available at <http://unesco.sciences-po.fr/com/moodledata/3/Callon_SociologyTranslation.pdf {Accessed: 25/6/2017}
- Cartwright R. and Baric A. 2018. The rise of counterfeit pharmaceuticals in Africa. Policy brief. EFDA.
- Ethiopia Essential medicine List (EEML). 2020. 6th Ed.
- Cloatre, Emilie. 2013. Pills for the poorest: an exploration of TRIPS and access to medication in Sub-Saharan Africa. *Springer*.
- Federal Democratic Republic of Ethiopia. 'Food and medicine administration Proclamation 1112/2019' (2019) 39 Federal Negarit Gazette 11099

- EFDA. 2021. Food and Health Products Regulatory Sector Transformation Plan-II(FHRSTP)
- FMOH. 2015. National strategy and plan of action for pharmaceutical manufacturing development in Ethiopia (2015–2025). Government of Ethiopia.
- Eskinder E. 2010. *Quality of pharmaceutical care in government hospitals of Addis Ababa, Ethiopia*. MA thesis, Addis Ababa University.
- Farmer P. 2013. *Reimagining global health an introduction*. Berkeley: University of California Press
- Fitsum S. et al. 2017. A household survey of medicines storage practices in Gondar town. *BMC public health*
- Gaurvika. 2019. Review Article Falsified and Substandard Drugs: Stopping the Pandemic. *Am. J. Trop. Med. Hyg*, 00(0), pp. 1–8
- Gezahegn T. 2014. Substance use and associated factors among university students in Ethiopia: across sectional study. *Journal of addiction*.
- Gillian J. and Lawrence O. 2013. Editors committee on Understanding the Global Public Health Implications of Substandard, Falsified, and Counterfeit Medical Products; Board on Global Health; Institute of Medicine, National Academy of Sciences
- Glass D. 2014. Counterfeit drugs and medical devices in developing countries, *Research and Reports in Tropical Medicine*, pp. 11–22.
- Hassan Y. et al. Falsified and substandard medicines trafficking: A wakeup call for the African continent. *Public Health in Practice*
- Hodges S and Garnett E. 2020. The ghost in the data: Evidence gaps and the problem of fake drugs in global health research. *Glob Public Health*. 2020 Aug;15(8):1103-1118.
- Hojjam M. et al . 2015. Monitoring the quality of medicines: results from Africa, Asia and South Africa. *Journal of Tropical medicine hygiene*. 92(6) 68-74
- IOM. 2013. Countering the problem of falsified and substandard drugs. *The National Academies Press*. Available at http://www.nap.edu/catalog.php?record_id=18272
- Kassi M. 2016. Pharmacy in Africa. The Ohio state University, College pharmacy.

- Kelesidis T. et al. 2007. Counterfeit or substandard anti-microbial drugs: review of scientific evidence. *Journal of antimicrobial chemotherapy*
- Kingori et al. 2023. Uncertainties about the quality of medical products globally: lessons from multidisciplinary research. *BMJ Glob Health*
- Lipsky M. 1980. Street-level Bureaucracy: Dilemmas of the Individual in Public Services. New York, NY: Russell Sage Foundation.
- Macquart D. et al. 2018. Substandard drugs among five common antihypertensive generic medications: an analysis from 10 African countries. *J. Hypertens.*, 36 (2) (2018), pp. 395-401
- Mende M. et al. 2020. Why is Illicit Drug use increasing in Ethiopia? From economics perspective of drug use control policy. *CPQ Neurology and psychology*, 3(2) 01-17
- Orubu et al. 2020. Tackling the blind spot of poor-quality medicines in Universal Health Coverage. *Journal of Pharmaceutical Policy and Practice* 13(40)
- Ozawa S, et al. 2018. Prevalence and Estimated Economic Burden of Substandard and Falsified Medicines in Low- and Middle-Income Countries: A Systematic Review and Meta-analysis. *JAMA network open*. 1(4)
- Paul Adepoju. African nations to criminalize falsified medicine trafficking. *Lancet* **2020**; 395: 10221
- Petersen et al. 2017. Surveillance for falsified and substandard medicines in Africa and Asia by local organizations using the low-cost GPHF Minilab. *PLoS ONE* 12(9)
- Prout, Alan. 1996. Actor-Network Theory, Technology and Medical Sociology: An Illustrative Analysis of the Metered Dose Inhaler. *Sociology of Health and Illness* 18(2):198-219.
- Pyzik, and Abubakar.2022. Fighting the fakes: tackling substandard and falsified medicines. *Nat Rev Dis Primers* 8(55).
- Przyśwa .E. 2013. Counterfeit medicines and criminal organizations. *IRACM*.
- Richardson E. 2020. *Epidemic Illusions*. MIT Press Cambridge, MA.

- Renschler, J. et al. 2015. Estimated under-five deaths associated with poor-quality antimalarials in sub-Saharan Africa. *Am. J. Trop. Med. Hyg.* 92 (Suppl. 6), 119–126
- Sewunet A. et al . 2017. Pharmacy professionals’ dispensing, knowledge and attitude towards emergency contraceptives in Gondar: across sectional study. *International journal of reproductive medicines.*
- Sosengo T. Quality of Different Brands of Metronidazole Available in Jimma Town, Southwest Ethiopia: A Cross-Sectional Pharmaceutical Quality Study
General Medicine: Open Access
- Suleman S. et al. 2014. Quality of medicines commonly used in the treatment of soil transmitted Helminth and Giardia in Ethiopia: A national wide survey. 8(12) *PLOS Neglected Tropical Disease*
- Teklu L et al. 2015. Quality Evaluation of Paracetamol Tablets obtained From the Common Shops (Kiosks) In Addis Ababa, Ethiopia. *International Journal of Pharmaceutical Sciences and Research.*
- Tadele M. and Genet Z. 2018. Assessment of Good Dispensing Practice Among Drug Stores in Mizan Aman Town, Southwest Ethiopia. *Scholars research library.* 10(12) 9-20
- WHO. 2011. Survey of the quality of selected antimicrobial medicines circulating in six countries. Geneva, Switzerland
- World Health Organization. A study on the public health and socio-economic impact of substandard and falsified medical products, 2017. <http://www.who.int/entity/medicines/reg-ulation/ssffc/publications/Layout-SEstudy-WEB.pdf>. Accessed 14 June 2020.
- WHO. 2018. Definition of Substandard and falsified medicine {online}. Available at <https://www.who.int/news-rooms/factsheets/detail/substandard-and-falsified-medical-products> Accessed {15 August 2020}
- WHO. 2017. Seventieth World Health Assembly Update. 29 May. Geneva, Switzerland
- WHO. 2017. Global Surveillance and Monitoring System for substandard and falsified medical products. Geneva: World Health Organization.

- WHO. 2006. The African regional health report. https://www.afro.who.int/sites/default/files/201706/african_regional_health_report2006_0.pdf
- WHO Global surveillance and monitoring system for substandard and falsified medical products. 2017. <https://apps.who.int/iris/bitstream/handle/10665/326708/9789241513425eng.pdf?ua=1>
- WHO. 2020. A study on the public health and socioeconomic impact of substandard and falsified medical products. Available from: <http://www.who.int/medicines/regulation/ssffc/publications/se-study-sf/en/>.
- WHO. 2022a. Information Exchange System Alert N6/2022. Ref. RPQ/REG/ISF/Alert N°6.2022. Substandard (contaminated) pediatric medicines identified in WHO region of Africa.
- WHO. 2022b. Information Exchange System Alert N7/2022. Ref. RPQ/REG/ISF/Alert N°7.2022. Substandard (contaminated) pediatric medicines identified in WHO region of Southeast Asia.
- WHO. 2023a. Information Exchange System Alert N1/2023. Ref. RPQ/REG/ISF/Alert N°1.2023. Substandard (contaminated) liquid dosage medicines identified in WHO European Region.
- WHO.2023b. Information Exchange System Alert N4/2023. Ref. RPQ/REG/ISF/Alert N°4.2023. Substandard (contaminated) syrup medicines identified in WHO Region of the Western Pacific.
- Whyte, et al. 2002. *Social Lives of Medicines*. Cambridge, UK: Cambridge University Press.
- Worku A. 2013. Prevalence and consequences of substance use among high school and college students in Ethiopia: review of literature. *African journal of Drug and Alcohol studies*.

World Economics. *Ethiopia's GDP PPP per capita {online}*. Available at <https://www.worldeconomics.com/Wealth/Ethiopia.aspx> {Accessed: 22 February 2023}

Yigzaw k. et al. 2005. Substance abuse. University of Gondar

Healthcare regulators from all over the world meet in Addis Ababa to discuss ways of fighting the spread of fake drugs {online}. *Addisstandard*, May 2, 2018