Public Integrity

ISSN: 1099-9922 (Print) 1558-0989 (Online) Journal homepage: www.tandfonline.com/journals/mpin20

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To cite this article: Akalework Mengesha, Hilde Bastiaens, Raffaella Ravinetto, Linda Gibson & Robert Dingwall (31 Jul 2025): Can Systemic Corruption be Prevented by Legal Means? The Market for Pharmaceuticals in Southern Ethiopia, Public Integrity, DOI: 10.1080/10999922.2025.2539025

To link to this article: https://doi.org/10.1080/10999922.2025.2539025

Published online: 31 Jul 2025.

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PUBLIC INTEGRITY
https://doi.org/10.1080/10999922.2025.2539025

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Can Systemic Corruption be Prevented by Legal Means? The Market for Pharmaceuticals in Southern Ethiopia

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ABSTRACT

Some international and national regulatory and policy actors assume that strengthening domestic laws and tightening enforcement measures will be sufficient to reduce the extra-legal supply of medicines, whether legal, substandard, or falsified, to patients in low- and middle-income countries. This paper uses a qualitative study of the pharmaceutical market in Southern Ethiopia to argue that this assumption is unjustified, given the common lack of institutional capacity and the complexity of supply chains by which medicines reach local markets. Data are drawn from interviews with pharmacists, wholesalers, pharmacy owners, regulators, law enforcement agents, and health professionals, supplemented by participant observation and review of relevant policy and legal documents. These data were analyzed through the frame of Actor-Network Theory, to trace the journey of medicines from producer to consumer. Officially endorsed regulatory and enforcement mechanisms are entangled in an intricate web of practices involving different actors responding to local demands. The extra-legal supply of medicine, particularly if substandard or falsified, is an important global public health concern, but it will only be reduced by measures that place law and regulation within the context of the social, economic, and cultural factors that shape local markets and undermine the integrity of legal supply chains.

PLAIN LANGUAGE SUMMARY

This research investigates whether the strengthening laws and increasing enforcement can effectively reduce corruption in the pharmaceutical market in Southern Ethiopia. Policy makers often assume that stricter legal measures will solve the problem of substandard and falsified medicines. However, this study shows that legal measures alone are not enough. Through interviews with pharmacists, regulators, pharmacy owners, law enforcement agents and consumers as well as observation and document reviews, this study found that corruption in the pharmaceutical sector is linked to weak regulatory systems, complex supply chains, social and economic pressures. The findings emphasize that, while enforcing stronger laws is important, addressing corruption in this sector requires a combination of legal reforms and practical strategies that consider the realities of local markets and health care needs. Comprehensive approach is important to strengthen governance, improve public trust and ensure access to safe and effective medicines.

KEYWORDS

Law; ANT; corruption; Ethiopia

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Substantial reviews of the literature in economics (Jain, 2001), politics (Kurer, 2005) and development studies (Bardhan, 1997) have emphasized the diversity of actions that might be labelled as corrupt by observers of the behavior of public officials. This has been underlined in subsequent work (Brooks, 2016; Farrales, 2005; Génaux, 2004; Heidenheimer & Johnston, 2002). At the state level, 'grand corruption' (Jain, 2001) involves the control of key public institutions at all levels of government to serve the interests of political and economic elites. Critical organs of the state, and the entire political process, are manipulated to ensure legislation and regulations favor the elites, enabling them to gain political leverage that can be translated into economic benefits.

However, corruption also occurs at a lower level in the form of petty corruption, which falls under 'bureaucratic corruption' in Jain's terms. It involves low- and mid-level officials engaging in small-scale bribery, favoritism, and the misuse of public office for personal gain (Rose-Ackerman & Palifka, 2016). This type of corruption typically affects ordinary citizens in their daily interactions with government institutions. In this case, officials extract informal payments or offer preferential treatment in exchange for personal benefits. It is commonly found in public sectors such as law enforcement, healthcare, and public administration.

The notion of 'corruption' implies some matching notion of 'integrity'. In the classic Weberian formulation (Weber, 1964, pp. 329-41) bureaucracy is an organizational form associated with the rise of modern states. The integrity of office holders derives from their impersonal administration of a body of rules that apply equally to everyone seeking their specific services. While those rules remain subject to interpretation (Lipsky, 1980), the Weberian ideal remains an important constraint on this process. Impartiality is often associated with legality, although it is a broader concept that incorporates ideas of the ethical or moral frameworks that should apply to the interpretation of rules so that they operate fairly and equitably (Ashour & AboRemila, 2019; Broadman & Recanatini, 2001). Bureaucratic corruption occurs where office holders provide or withhold goods, services or other benefits in exchange for something of value to themselves rather than according to the accepted, impersonal, application of the body of rules that are supposed to govern that provision (Brown, 2016). The benefit is not a legitimate component of a person's work duty or compensation but an advantage derived from the status or authority of their office (Corruption Definition, 2025).

Health systems have been found to show significant vulnerability to this type of corruption due to loose administrative oversight combined with poor enforcement practices. As a result, users can experience adverse consequences from obstructed access to critical medicines and services (Bozhenko, 2022). Unless health-related institutions maintain systemic accountability, legal measures alone are inadequate for fighting corruption (Bozhenko, 2022; Haider et al., 2024; Lexchin et al., 2018; Wong et al., 2024). Pharmaceutical market corruption does not result solely from enforcement failure but also reflects structural issues, such as financial incentives, lack of transparency and conflicts of interest (Haider et al., 2024). However, these studies have mainly focused on legal enforcement gaps without understanding how informal networks shape and sustain pharmaceutical markets.

It is important to note that analysts do not regard corruption as necessarily negative. It may be a way to compensate for deficiencies in law, economy and public policy. Bardhan (1997, p. 1322) quotes the political scientist, Samuel P Huntington: "In terms of economic growth, the only thing worse than a society with a rigid, over-centralized, dishonest bureaucracy is one with a rigid, over-centralized, honest bureaucracy". Corrupt payments may increase allocative efficiency by favoring those able to get the greatest returns from a service. They may also be thought of as a form of taxation or co-payment that reduces the costs of government by allowing states to pay lower salaries to public officials (Ang, 2017; Jain, 2001). Generally, however, they are viewed in negative terms. Policy responses include the greater moralization of public officials (Nolan García & Aspinwall, 2019); deregulation so that services are provided through markets rather than bureaucracies (Gillespie & Okruhlik, 1991); and harsher legal and disciplinary measures up to

and including the death penalty (Gillespie & Okruhlik, 1988). All of these focus on the public officials supplying corrupt practices rather than the demand from citizens for favors from officials (Al-Mutairi et al., 2019).

Corruption and the health care system

Building on the broader discussion of petty corruption, health care presents many opportunities for corruption from the highest levels of system-wide procurement to the front-line provision of services. Pharmaceutical supply and services are particularly vulnerable. They deliver high-value products through complex supply chains, from national procurement, regulation and enforcement to decisions about prescription, local procurement and dispensing (Onwujekwe et al., 2020). From the users' side, purchases may often be urgent to address acute condition or essential to sustaining life with a chronic medical condition. The World Health Organization (WHO) (World Health Organization, 2017) indicates that the spread of substandard and falsified (SF) medicines increases when constrained access to safe, affordable, quality products overlaps with poor governance systems, including unethical practice and corruption, In particular, low standards of governance, poor ethical practices in health care facilities and medicine outlets, and corruption in both the public and private sectors, are listed among the (co-)risk factors for the presence of SF medicines – particularly for those which are falsified.

According to WHO, *substandard* medicines are authorized products that fail to meet quality requirements, specifications, or both, while *falsified* medicines deliberately and fraudulently misrepresent their identity, composition, or source. Notably, the WHO definition also includes a third category, i.e. "unregistered or unlicensed" medical products whose quality is unknown because they have evaded regulatory controls. Overall, the availability of SF medicines may result from weak institutional capacity to regulate quality, or to prevent falsification and criminal diversion from the formal supply chain (Olliaro et al., 2020). Both substandard and falsified medicines may enter, leave and return to the official supply chain at various points (Mengesha et al., 2024).

The production and distribution of falsified medical products is generally criminalized. International and domestic health policy actors tend to rely on tools and initiatives that are normative and prescriptive, without fully considering the local social and economic factors that facilitate corrupt behavior. There is insufficient evidence of the efficacy of these regulatory and legal instruments and their impacts remain largely unidentified or ambiguous (Hussmann, 2020). The existence of a legal regime does not, alone, guarantee effective implementation. National laws and regulations may be a form of ceremonial compliance (Meyer & Rowan, 1977) with the requirements of national and international agencies – and extract resources from them – but be compromised by lack of political support or resources for enforcement. Responses to corruption that focus primarily on enhanced surveillance and stricter discipline of public officials have generally yielded poor results (Khan et al., 2016). When considering pharmaceutical services and products, this approach neglects the multiple and intricate supply chains that are shaped by social, economic, and cultural contexts (Mengesha et al., 2024). For instance, patients in certain contexts frequently resort to informal payments to avoid delays in access to urgent medical treatments or medical care (Schaaf & Topp, 2019).

The critical issue lies in how effectively laws and regulations are actually translated into practice. Formal law is an important element in constructing the opposition between 'corruption' and 'integrity' but is not in itself sufficient. Laws are neither self-interpreting nor self-enforcing and must be deciphered and applied by stakeholders and agents in various contexts depending on institutional capacity and the overall complexity of supply chains. Legal tools are a prerequisite for reducing opportunities and incentives for poor practices including corruption but will not in themselves ensure the integrity of pharmaceutical services. As Pound (1910) put it: "The face of the law may be saved by an elaborate ritual, but men and not rules will administer justice."

Pound's examination of the discrepancy between written laws, 'law in the books', and their practical impact as they are given effect by those charged with implementation, 'law in action', represents the foundation for a long line of work in law and society studies (Galanter, 2006; Halperin, 2011).

Ethiopia, for example, has a legal framework and regulatory structure endorsed by a joint assessment conducted in 2017 by the Ministry of Health (MOH) in collaboration with WHO (Ethiopian Food, Medicines, and Health care Administration and Control Authority, 2017). The MOH had previously introduced "Food and Medicine Administration Proclamation No. 1112/2019" governing the regulation of "medications, medical equipment, and cosmetic products." However, it also has a large extra-legal sector through and in parallel to the legally-constituted official supply chains. This paper investigates the influence of law and regulation on local pharmaceutical markets in the light of social, economic and cultural factors that also influence the integrity of supply chains. It does so by adopting Actor Network Theory (ANT) to explore the complexity of connections between the legal framework and its deployment in contexts where legal and illegal are often blurred and uncertain, focusing on local, street level practices and events in the pharmaceutical market.

Actor network theory (ANT)

This paper is a case study in the application of Actor Network Theory (ANT) to trace the pharmaceutical supply chains, both legal and extra-legal, that deliver medicines to Wolaita Zone in Southern Ethiopia. ANT originates in science and technology studies, but has found increasing application in studies of law and society (Cloatre et al., 2024; Cloatre & Cowan, 2018). It challenges conventional sociological approaches by emphasizing the unstable nature of social order (Law, 1994). Stability is produced by the dynamic interactions between *actants* (Latour, 1996). These may be either human or non-human – ANT adopts a *flat epistemology* which does not assume a binary difference between the material world of objects and structures and the human world of action. The human and material worlds interact through processes of *translation*, where actants align their perspectives and interests. Human actions may be translated into material objects and *vice versa*. These organize and make coherent an inherently meaningless stream or array of sense-impressions to a sufficient degree for action to proceed in a particular place at a particular time, and to be associated with other actions 'at a distance' (Callon, 1984).

Law, for example, is a response to the indeterminacy of language, providing a way to fix the meanings of acts, documents or events sufficiently for immediate practical purposes. This happens through the use of formulaic texts with historically shared conventions about their meaning and application and through the rulings of judicial officers about what those texts should be taken to mean in specific or novel situations or applications. Medicine stabilizes the uncertainties of human anatomy and physiology, and their interactions with social and material environments, by producing declarations about health, illness and causation that are taken to be authoritative. Both law and medicine are, however, unstable networks of actants – professionals, support workers, regulatory documents, devices, buildings, and products, such as pharmaceuticals.

Traditional approaches to the management of corruption assume that law operates as a fixed and stable set of rules, a property that can then be used to regulate, for example, pharmaceutical markets in predictable ways with specific results. An ANT approach sees 'corruption' as a description emerging from interactions within a dynamic and heterogeneous network. Law, legal documents and legal institutions are actants working with, and against, other actants to create a market. This operates in ways that succeed for the participants but were not intended by those who wrote the law to meet their own policy objectives. Statutes and regulations expected to reduce or eliminate petty corruption may actually have the consequence of creating new

opportunities for suppliers and users to develop their own, independent, relationships of payment and provision.

The supply of SF medicines is one output from a complex network within which some actants can enroll a range of human and non-human participants to meet the demand from people with needs for pharmaceuticals that are not met through formal, regulated supply chains. The network involves connections and exchanges among various human actors engaged in the trading of medicines, such as manufacturers, suppliers, distributors, healthcare professionals, and informal providers, the staff of regulatory bodies and law enforcement agencies, and consumers. The network also involves non-human elements such as laws and regulations, licensees, governance mechanisms, and, of course, the SF substances themselves (Mengesha et al., 2024). This network interacts with, and draws upon, connections in other networks, of kinship, friendship, political affiliation and economic status. Poor practices including practices labelled as corrupt arise from an intricate system, which generates both deviance and compliance and whose workings need to be traced before they can be reformed.

ANT goes beyond merely categorizing activities as 'corrupt'. It tries to understand how that categorization is created through the connections and interactions within these networks. It recognizes that the description may be attributed to behaviors that are normative or even necessary for network membership (Al-Mutairi et al., 2019). Corruption is not driven solely by individuals seeking personal gain but emerges from an interconnected system of legal, economic and social actants. ANT provides a methodological strategy for identifying the mechanisms through which corruption becomes institutionalized. Rather than simply labeling practices as 'corrupt,' this study examines how particular behaviors are generated within the actor-network. For example, a pharmacy owner bypassing official procurement channels may be engaging in an act that regulators define as corruption but that, within the local network, ensures the continued supply of essential medicines. Such actions are shaped by multiple actants—economic necessity, regulatory gaps, consumer demand, asymmetry of information, and the interplay between formal and informal institutions.

Methods and data

Wolaita Zone is recognized as a hotspot for illegal trade in pharmaceuticals, and other products, because of its road connections to the border town of Moyale. This is one of the crucial entry routes for goods smuggled between Kenya and Ethiopia. The study collected data by means of interviews, participant observation and the analysis of official documents to identify relevant actants and trace the relationships between them.

Purposive, convenience, and snowball sampling were used to identify potential informants. They included pharmacists, distributors – legal and non-legal, pharmacy owners, staff from regulatory agencies, law enforcement officials, and consumers Customers were recruited as they arrived to make purchases at locations where medicines were sold. In total, 43 interviews were completed. All participants had completed tertiary education except for three local vendors and five pharmacy owners who had received only primary education.

The main fieldwork was carried out between October 8, 2020, and December 12, 2020. Six data collectors (a researcher and five research assistants) were involved. Additional data were collected from December 17, 2020, to January 12, 2021, to fill gaps identified in the original material. This included following up participants who had been difficult to meet because of their competing national and regional commitments. MOH and EFDA office holders and professionals were approached with the assistance of an experienced pharmacist identified while signing a data confidentiality agreement at the EFDA. In parallel, potentially relevant, international and domestic, documents of law, regulation and public policy were located and examined as possible actants.

Interviews were conducted with participants in a setting of their choice – usually their offices or quiet outdoor places. These interviews used semi-structured interview guides, first developed in English, and then translated into the local languages of Wolaitigna and Amharic. Fieldworkers both took hand notes and audio-recorded the interaction, where permitted. On average, each interview lasted approximately 70 minutes. Participant observation was used to study the market in action. Five research assistants acted as mystery shoppers, visiting retail outlets to check the implementation of legal instruments. After conducting interviews, additional observations were made to validate the information provided. For example, after speaking with local and national regulatory authorities, attempts were made to visit the facilities they had described.

Field notes and audio files were transcribed in the local languages. These transcripts were then translated into English after being checked for accuracy through repeated reading and revision by the researcher, who is experienced in qualitative research. These data were used to create an analytic description of the actor-network, identifying the socio-legal actants, whether human or non-human, and the connections, or lack of connections, that constituted the pharmaceutical market. This was achieved through a manual coding process, which partly drew on themes foreshadowed in the existing literature and partly on themes identified by their recurrence in the interviews, observations or documents. Selected quotations from informants illustrate the analysis and the coding decisions.

The legal foundations of the actor-network

In principle, it is possible to cut into an actor-network at any point for the purposes of analysis. In a previous paper (Mengesha et al., 2024), analysis was centered on the journeys taken by SF medicines and the ways in which these non-human actants enrolled other human and non-human actants to facilitate their travel from a point of origin, whether in a manufacturing facility or in theft or other diversion from the official supply chain, to an end-user. For present purposes, the focus is on the journey taken by the legal instruments that are intended by their authors to govern the supply chain and to determine what constitutes lawful and unlawful supply. The statutes and regulations that generate the domestic supply networks are themselves vehicles for transferring the product of relationships between actants with different values, interests and engagements from the international to the national level in the expectation of influencing regional and local actants (Cloatre, 2013). A detailed account of the network creating regulations is beyond the scope of the present inquiry and its interest in understanding 'petty corruption'.

Once a legal document, like a statute or regulation, acquires a definitive and authorized form, its effect depends upon enrolling a supporting network of users, interpreters and enforcers. Users are people who refer to legal documents to achieve certainty in their everyday practices. Interpreters and enforcers are the people who decide what the inevitably general statements in any particular instrument mean when it is applied to specific cases. Typically, they are human actors like judges, police officers or regulatory inspectors, although there may also be other documents that seek to guide the interpretation, application and practical impact of the law or regulation. All these actants are embedded in other networks that may supply or deny resources: is the enforcement of pharmaceutical legislation a priority for the allocation of local police time, for example, relative to other criminalized activities?

In the absence of an authoritative, comprehensive founding document, it is difficult for an effective network to come into being. Pharmacists complained about the lack of a current document to guide their work. Until the law-making processes involved in creating a revised framework at the national level were completed, they could not be reviewed and enacted at a regional level. Only then, pharmacists observed, could they create their own protocols to govern everyday practice. Although law is supposed to deliver certainty, for immediate practical purposes, it can actually deliver uncertainty as local actors rely upon it to guide their work and provide

justification for their actions. The legitimacy of their work remains in question until the relevant intermediate steps are completed.

Ultimately, the law reaches a local context, where it enrolls two implementing offices: the Health and Health-Related Services and Products Quality Control Team, and the Ethiopian Food and Drug Control Authority branch office in Hawassa (a regional city). The former operates with structures at regional and district levels, focusing on regulating drug retail outlets. The EFDA office is responsible for regulating wholesalers in the region but has no organizational presence at zonal and district levels. According to Food and Medicine Administration Proclamation No. 1112/2019, the authority's jurisdiction is limited to the regulation of medicine, medical devices, and cosmetics. However, this law does not seem to have changed actual practice significantly, as the regional authority still primarily oversees medicine regulation at drug retail outlets. Informants have noted that, despite the changes introduced by the proclamation, operational practice has remained largely unchanged from the previous mandate under Proclamation No. 661/2009. Some informants report that the differences in structures and disparity in resources, between these two offices has diminished regulatory enforcement, especially by the EFDA.

Because of the country's ethnic-based and decentralized political system, numerous independent entities are responsible for medicines regulation and control. Each must be separately enrolled in the actor-network. In theory, the law gives EFDA the authority to enforce product regulations throughout the whole country. However, a semi-autonomous Addis Ababa Food, Medicine and Healthcare Administration and Control Authority prevents the EFDA from conducting retail outlet inspections independently in the nation's capital city. During the Covid-19 pandemic, for example, pharmacies selling fake sanitizer products were being closed in Wolaita but allowed to remain open in Addis Ababa. Within Wolaita, the Quality Control team had found a retail pharmacy operating without a registered pharmacist and closed it for three months. In the same town, EFDA had found a wholesaler without a registered pharmacist and only closed them for one month. The retail pharmacy's owners naturally saw this as unfair, particularly as the wholesaler was a much larger facility.

The law struggles to enroll appropriate human resources and secure sufficient budget and technological equipment. All the federal, regional, and local implementing offices kept these issues under constant scrutiny. The problem gets more complex and challenging as we move to more local levels. The branch EFDA office is responsible for overseeing a vast region that includes parts of Oromia and Somalia regional states, resulting in a significant disparity in the scope of work and human resources available. The situation in Moyale, the entry port on the border with Kenya, is an example of the challenges faced by a branch office. The EFDA branch office collaborates with the customs authority. However, only one pharmacist is assigned to the port. In their absence, customs authority officials have to take on their specialized responsibilities. An informant at the federal FDA office commented: "There is a shortage of human resources in the FDA office in general. The authority has, with all its branch offices, only 614 employees." The regulatory office occasionally conducts surveillance operations and gathers whistleblower information but has little support for legal actions, especially guidance on compiling a case and demonstrating actual harm. The combination of an uncertain foundation and limited resources makes it difficult for law to enroll other actants and to travel effectively from national to local levels.

The fluid nature of this actor network presents challenges in producing a stable local order within which corruption can be defined in a clear and consistent fashion. Actants contest the primary objective of enrolment. Is it to control and direct behaviors and actions, particularly of human actors, in order to safeguard public health? Is it to support the aspirations to run profitable businesses, creating local income and wealth through participation in the pharmaceutical market? Legal instruments enroll regulatory agencies to enforce public health or consumer protection goals that potentially conflict with the financial interests of market actors. If the law cannot

ensure that all legitimate actors in the market are treated equally, or equitably, there is a risk of undermining that very supply of stability and legitimacy.

Many informants, from private clinics, drug retail outlets, zonal justice departments, zonal police departments, and customs authorities, believe that law cannot achieve local impact because of its failure to connect relevant actors to the network it is trying to generate. Nor has it successfully enrolled the organizations, in which it needs to be embedded, particularly at lower administrative levels. The result is a high degree of uncertainty in the legal status of medicines, and their various supply chains, at the point of delivery. In the absence of an effective actor-network, delivering stable and consistent interpretation and enforcement, it becomes difficult to establish that any particular transaction can be declared to be corrupt.

The uncertain status of SF medicines

If law is an institution for delivering certainty of meaning, it fails in this case. Both legal and organizational documents use the term "counterfeiting", for example. Food and Medicine Administration Proclamation No. 1112/2019" (Ar. 2(19), proposes the following definition:

> "Counterfeiting" means a deliberate or fraudulent mislabeling of a product in respect of its identity and/or source including the packing material, identification or trademark, trade name, any special mark thereon of an authentic product and presenting such falsely labeled product as if it is manufactured by the genuine manufacturer."

This limits its application to medical products with mislabeled sources and identities. It only covers the regulatory and legal aspect of issues that arise when registration, retail and distribution regulations are breached. There is no reference to substandard medicines, which represent a totally different problem, not in terms of harm to health but in terms of supply chains and enforcement interventions. There are also various and seemingly confusing (if not accompanied by a definition) terms. The following statements are from Article 36(7) and Article 62(1) of Food and Medicine Administration Proclamation No. 1112/2019", respectively.

> It shall be prohibited to dispense or sell, in any way, expired, damaged, substandard, diverted, or illegal medicine.

> The doing of any act which causes a regulated product to be adulterated, misbranded, counterfeited, and substandard.

Interviews with community pharmacists, physicians, regulators, and enforcement agencies indicated that there was no clear consensus about the definition of substandard and falsified medicines. The legal text invokes a language ('i.e., 'counterfeit') which WHO member states agreed, in May 2017, to reserve for intellectual property issues and controversies and eliminate from public health discourses, substituting "falsified medical products." Although other terms are introduced, they are not defined, so the user of the text is expected to infer what might be meant by 'expired, damaged, substandard, diverted, illegal, adulterated, or misbranded' medicine. The legal text offers little help to the actor-network in stabilizing the meaning of these terms to make them a basis for action by those in the local supply chain and its regulators. This stabilization could only be achieved by enrolling other actants to construct an authorized translation of the text to be used in action.

In practice, the problem is dealt with by creating *black boxes*. This ANT term refers to the way in which meanings may be stabilized by a set of processes that are concealed from the user of the outputs. In this case, for example, it is the production of an authorized medicines list or reliance on the manufacturer's adherence to good practice. Retail pharmacists and druggists must trust the integrity of the supply chain. At most, they can identify products that passed the expiration date on the packaging, unless the packaging itself is obviously counterfeit (Mengesha et al., 2024).

Coupled with the lack of clarity about the definition of the problem, such assumptions make it difficult for local actors to get a clear picture of its scale and mechanisms. Some of them see the SF issue as a (sometimes, overlapping) situation where people take medicines without medical evidence, based on their own beliefs or preferences. Others define it as an issue of stock management, transport and storage (which can indeed cause medicines to become substandard). If the network does not deliver secure knowledge at the point of sale, it may be difficult for the human actors at that location to be certain that they are acting with integrity and in compliance with the law. Certain practices, however, are widely regarded as reliably indicative of corrupt behavior by human actors.

'Corruption' and the actor-network

This section looks at five activities that are traditionally considered to be corrupt practice: bribery; misappropriation and nepotism; fraud and theft; concealment and obstruction of justice.

Bribery

Officially, bribery – the offer or acceptance of cash, goods or services other than, or in addition to, approved fees to secure priority access to a public resource – is considered to be a criminal act. From a network perspective, the issue is less clear-cut. On the one hand, there is a critical shortage of regulated medicines through legally-approved channels, so that supplementary payments can be seen as a rationing device that balances supply and demand. On the other, many local actors see it as a way to ensure their continued existence as businesses in the unstable environment we have described, where they cannot count on sufficient legal supplies at regulated prices or on the fairness of enforcement.

Bribery becomes a way to strengthen relationships in an otherwise fragile actor-network. It creates a chain of obligations in parallel to the legal instruments that officially mobilize the network. These obligations are sustained by links to other networks constituting the institutions of the legal system. One informant cited a case where their attempts to prosecute a high-profile local businessman for importing and distributing unregistered medicines had been frustrated by his connections to the police. They had caught him with a truck full of medicines but he had been released within two or three months and returned to smuggling. Similarly an attempt to enforce restrictions on the opening of pharmacies in close proximity to government hospitals had been overridden by a letter written within the regional president's office.

At street level, the vital knowledge in everyday practice is not that of law but of the interests of the regulators. They have the power to inflict costs, for example by temporarily closing down a business if their demands, especially financial ones, are not met. There is a complex interplay between formal laws and informal practices, where adherence to the legal framework is influenced by unspoken norms, power dynamics, a 'demand' driven by limited access to medicines, and the practical realities of navigating bureaucratic systems. Sticking to the letter of the law was a source of potential trouble for everyone.

Misappropriation and nepotism

In local contexts, pharmacist's certificates and professional licenses are misappropriated mainly for business purposes deviating from the statement of the law on paper. The role of the pharmacist is limited to dispensing medicines, with minimal involvement in other critical aspects such as purchasing or procurement. This discrepancy may indicate a disconnect between regulatory expectation and the actual duties performed by pharmacists within the facilities. Pharmaceutical facilities are often owned and managed by individuals who lack a professional background in

pharmacy. These owners are businessmen, overseeing the sourcing and management of medicines despite their limited or absent expertise in pharmaceutical practice. This raises concerns about potential regulatory violations, such as the delegation of critical pharmacy responsibilities to non-licensed individuals and the circumvention of professional standards by business-oriented owners. This emphasis on business interest over professional expertise may compromise patient safety and quality of pharmaceutical care provided. However, when other regulatory or information systems are weak, nepotism can act as a temporary remedy to control quality and maintain transaction integrity. This provides facility owners, for example, with a practical solution to safeguard the business from decline, given the scarcity of qualified personnel in the market. Article 39(1) of Food and Medicine Administration Proclamation No. 1112/2019 states:

> Any person involved in the business of medicine and medical device trade shall take every precaution to ensure the legality of its suppliers, use legal receipt, and make an immediate report to the executive organ and other appropriate law enforcement organ when the illegality of the medicine and medical device is known to him.

In community pharmacies and other retail establishments, several informants lacked professional credentials. Some people declined when asked to participate in an interview, stating they lacked knowledge of the issues. In several cases, it appeared that other public health and chemistry professionals were dispensing medicines. Facilities were observed to employ high school students and unqualified close relatives of the owners as dispensers, performing a role legally restricted to pharmacists. Article 36(1) Food and Medicine Administration Proclamation No. 1112/2019 states:

> Medicine shall only be dispensed by a pharmacy professional acting within his/her scope of practice.

Under these circumstances, the professional license plays a key mediating role in the pharmaceutical market. As one enters a pharmacy or retail facility, the license certificate is positioned on a high perch on the wall to be seen by visitors or the clientele. On many occasions, the owner of this professional license was not an employee of that facility. The professional licenses are rented to the owner on the understanding that the pharmacists (owners of the certificate) will be available if the need arises, i.e. when there is an inspection by regulators. In return, the license's owner receives a monthly payment. The display of licenses serves as a symbol of professionalism, regulatory compliance and credibility. Licenses are actants that create the appearance of professionalism and good practice but do not guarantee it.

Consumers commonly visit medicine outlets before seeking a diagnosis and treatment from the proper medical facility. They buy medicines without presenting any prior authorization from a qualified medical professional. For them, it is vital to ease the difficulty of obtaining health services, especially the unendurable costs resulting from expensive diagnostic tests. Some of the informants from the community have a slight awareness of maintaining it as illegal behavior, when many have pointed out that it is no problem at all. Consumer behaviors are affected by complex of associated factors including perception of convenience, affordability, and awareness of legal and health implications.

Fraud and theft

The data suggests that various actors including pharmacists, owners, and other actors have developed interconnected strategies to circumvent regulations and facilitate extra-legal supply of medicines. These alternatives involve collaborative efforts aimed at evading scrutiny and profiting from illicit activities. One practice involves the unauthorized repacking and relabeling of medicine, which may involve altering the packaging or labeling to misrepresent the origin or quality of the product, undermining the integrity of the legal supply network. Article 36(10) of Food and Medicine Administration Proclamation No. 1112/2019 states:

> Every professional shall notify the regional health regulator or executive organ or health regulators at different level when he knows of defects associated with the quality, safety, and efficacy of medicine.

Health professionals' theft from government-run hospitals, clinics, and health centers also commonly disrupts the controlled supply chain. These range from outright burglary to fraudulent reporting to cover up the diversion of these medicines—whether government-purchased or donated by non-governmental organizations—from their intended networks.

The health-based pharmaceutical network must enrol local justice agencies - police, customs departments. The translation of legal documents into practical controls depends upon their integration as checks on local supply outlets. In practice, these cases do not often—if ever—appear. The police lack either a clear understanding of this area of law and their responsibilities or a '*black box*', summarizing, but not detailing, the legal documents to guide their practice.

Concealment and obstruction of justice

Trials are uncommon, and disputes are usually resolved by informal means. Actants from outside the health system, like police officers, may not consider that they have a duty, or relevant expertise, to contribute to the network by enforcing laws and regulations about medicine quality through proactive monitoring and enforcement activities. Regulatory inspections are rare. These sporadic engagements with the network may be driven either by external pressure on the agency or by a need for local personnel to demonstrate their activity, rather than sustained commitment to regulatory duties. When inspections do occur, local officials are told to focus on symbolic enforcement targeted at easily observable signals. The cases in our data primarily related to violations of licensing regulation, such as possessing medicines without legal authority. Little attention was given to broader quality and safety issues The focus has shifted from the overall quality of medicines in licensed community drug retail establishments to a specific aspect, namely the licensing of the retailer. A license, even if mandatory, is not sufficient to guarantee the quality of medicines in a given facility, which is rarely investigated.

Art 24(1) of Food and Medicine Administration Proclamation No. 1112/2019 states:

> Every medicine and medical device institution shall hire a health professional upon ensuring that the professional is duly registered and competent to perform the task.

The use of term "health professionals" has left room for varying interpretations regarding who is authorized to stock and dispense medicines. Individual actants can exploit this ambiguity to supply medicines without appropriate qualification and oversight, undermining regulatory standards and compromising patient safety. Many informants argued that the regulations should state clearly and specifically that only pharmacists can be authorized to stock and dispense medicines.

Terms such as 'storing' and. 'holding' (**መያዝ ና ማከማቸት**) are also contested. The law forbids the storage of medicines without a license, creating an ambiguity when it comes to holding certain pharmaceuticals. The text is subjectively interpreted and operationalized by enforcement agents in ways that tend to minimize sanctions. Another area of uncertainty is the operational definition of 'harm'. Inspectors claim that, when they present cases of storing medicines without legal authority, judges and other law enforcement agents often require additional evidence of harm caused by such acts. The inspectors could not provide this (probably because that would require complex and expensive laboratory and clinical investigations), resulting in the failure of prosecutions. Many argue that laws should be proactive so that storage without a license is punishable in itself, as stated in the proclamation. Art 67(1) of the law states:

> Any person who, by sub-standardizing, misbranding, or counterfeiting a regulated product, manufactures, import, store, wholesale or sell it in retail; or provide or distribute for use by the public shall be punishable by simple imprisonment for not exceeding three years and a fine not exceeding Birr two hundred thousand.

> If the product's defect would cause grave harm to human health or life, he shall be punishable by imprisonment not exceeding seven years and a fine not exceeding Birr five hundred thousand

The focus on licensing violations, which are easy to investigate and sanction, obscures the root problem of assuring the quality and legitimacy of pharmaceuticals reaching the local market. Suppliers are penalized for technical breaches rather than placing medicine users at risk.

Discussion

This case study suggests that a focus on domestic law and increased enforcement efforts are not on their own sufficient to achieve the integrity of a supply chain and combat extra-legal supplies of falsified and unregistered/unlicensed medicines. Street level drivers of demand and supply of medicines must be addressed, and understood in the context of local social, economic and political actors, practices and events linked within a complex network. Tracking the journey of laws and regulations about the supply of pharmaceuticals through the engagements of different actants with different values, interests and engagements demonstrates the difficulty of ensuring that laws and regulations achieve their intended effects at an increasing distance from their origin in formal processes at a national or international level. While Proclamation 1112/2019 plays a major role in structuring pharmaceutical regulation, it does not operate in isolation. The Ethiopian pharmaceutical sector has evolved through various legal and policy frameworks. Early regulations, such as The Pharmacists and Druggists Proclamation No. 43/1942 and The Pharmacy Regulation No. 288/1964, provided the foundation for drug regulation (Suleman et al., 2016). The National Drug Policy (Transitional Government of Ethiopia, 1993) introduced strategies for drug supply, pricing, and quality control, emphasizing the need for effective enforcement. Beyond pharmaceutical regulations, the Ethiopian Criminal Code (Proclamation No. 414/2004), Article 271, criminalizes unethical medical practices and corruption. Besides, Regulation No. 299/2013, under Proclamation No. 661/2009, formalized the Health Professionals' Code of Ethics, while the Federal Health Professional Ethical Committee, established in 2014, reinforced ethical oversight.

The interaction between these regulatory frameworks together with various directives has resulted in overlapping mandates and enforcement challenges. While these legal instruments provide the base for pharmaceutical governance, inconsistencies between new and old regulations and fragmented oversight have created gaps that allow poor practices, including corruption and the supply of SF medicines, to persist. Agencies such as the Ethiopian Food and Drug Authority (EFDA) and the Ministry of Health oversee pharmaceutical regulation, but fragmented oversight, resource constraints, and weak coordination hinder the successful enforcement of laws. In addition, the lack of a fully integrated monitoring mechanism allows informal networks and unlicensed actors to thrive within the pharmaceutical supply chain.

A weak Pharmaceutical Supply Chain Management Information System (PSCIMS) limits transparency in medicine distribution and undermines efforts to track medicine flow from manufacturers to end-users. Similarly, the lack of electronic prescription tracking and digital health record systems enables unauthorized medicine sales, increasing the risk of SF medicines entering the market.

Our actor-network approach challenges the assumption that legal regimes will be sufficient to ensure the integrity of local actors, compelling compliance and delivering effective regulation. It supports the view that the specificities of different environments and actants shape the translation of legal instruments into practice. Due attention must be given to the distinctive, micro-level, political and cultural systems within which the law operates.

We have shown how the influence of law has been resisted, or at least misunderstood, at street level due to its inability to enroll and stabilize the heterogenous network of the local pharmaceutical market. Institutional-level mediators make its deployment and effectiveness problematic.

Legal instruments have been created through a high-level political process but their impact depends upon low-level actors with limited understanding and resources.

Law competes with other claimants to the finite human and material resources that are required to generate the intended order. There is a critical shortage of the professionals (i.e., pharmacists and legal experts) who are vital for implementation. Enforcement also suffers from limited budgets and equipment. Actors' wider ties and enrolment in other networks complicate the enforcement process. In the local setting, an actor-network of law and regulation is reshaped by the interests of other actants, predominantly humans, to create a market that is only partially stabilized.

The law can become the source of confusion and difficulties it seeks to resolve. In this case, for example, it poorly defines and conceptualizes the problem itself by only focusing on the 'counterfeiting' of medicines. This limits its application to intellectual property rights (Cvetanovski et al., 2016; Mihăilă et al., 2018) and leaves public health and consumer protection issues in limbo. Rather than ordering street-level application, it creates uncertainty for actors who wish to be seen to act with integrity, while creating space that can be exploited by those who are more concerned with economic than moral interests.

Within the actor-network, professional licensing should contribute to the delivery of a stable and trustworthy local order. In practice, licensing creates new connections, enrolls other actants, and can become a point of instability. The display of certificates in pharmacies represents the market for medicines as well-regulated and properly functioning. The decoupling of certificates from pharmacists presents an opportunity for corruption.

'Corrupt' practices are not simply a legal or moral concern but are deeply embedded in institutional structures and networks. If reforms cannot alter the institutional characteristics of societies to promote compliance with laws and regulations, then anti-corruption measures based purely on legal regimes are likely to fail. Efforts to alter the behavior of actors are also likely to fail if they do not acknowledge that these actors operate inside interconnected networks and social contexts that may promote alternative understandings of appropriate conduct – for instance, the WHO notes that, even if the circulation of falsified products is often promoted by corruption and other shortcomings of regulation and governance, a high proportion of cases occur where these problems overlap with constrained access (World Health Organization, 2017). Moreover, integrity may look very different in contexts where nepotism is expected as a means of securing scarce resources and allocation by merit is censured.

Law fails to stabilize the local order with unstable enrolments and key actors engaged in competing networks such as those attempting to secure the economic foundations of local businesses in a fragile market. The extra-legal supply of medicines offers security through familial, friendship, and professional networks that compete to enroll potential actants. Consequently, actions that might be considered corruption from a legal or regulatory standpoint may be seen as essential good practice in safeguarding one's business and satisfying membership obligations in other networks.

If a system fails to recognize and effectively address such challenges at the local level, everyday practice will continue to be marked by ceremonial regulatory measures, informal handling of cases involving actions in breach of formal law such as bribery, nepotism, and kickbacks, misappropriation of professional licenses and professionalism, and indifference to the requirements of legal texts. Devising effective anti-corruption measures needs a more holistic approach that considers the entire system and the complex determinants of both integrity and corruption.

Conclusion

This paper has investigated the influence of law and regulation on local pharmaceutical markets and looked into whether corruption can be prevented by legal means alone, through a case study of the market for pharmaceuticals in Southern Ethiopia. Our work has underscored the critical need to go beyond merely establishing legal frameworks for regulation of medicines. It emphasizes the necessity

of understanding how laws are interpreted and applied in local contexts and the nature of different actants within a complex network of policy, practice and implementation.

Global health research has emphasized the existence of unregulated markets and local practices, which differ significantly from official regulatory regimes (Ipek, 2021). The intricate supply network and varied actors present a vulnerability that can be exploited, resulting in a supply of SF medicines. We have highlighted the importance of balancing an understanding of the complexity and shortcomings of the law, regulation and translation of policy into practice with recognition of the street level drivers of access to pharmaceutical medicines and the challenges this could pose for reform endeavors. The legal network needs to work with the market by building an alliance of relevant actors, ensuring that everyone benefits from a stable, secure and trustworthy market.

This study demonstrates that corruption in pharmaceutical supply chains arises from the accumulation of petty corruption, which legal frameworks alone struggle to address without considering localized economic and social factors. The interplay of socio-economic and legal factors produces an environment favorable to confusion and disruption, which hinders people's capacity and right to obtain safe and quality medicines. Understanding the circumstances within which behaviors are deemed 'corrupt' by the regulators and law-makers, but could be considered necessary, needs a customized and comprehensive approach that goes beyond merely disciplinary measures. Building regulatory institutions that are seen as trustworthy may be vital but they alone are insufficiently effective to address the irregular supply of medicines and the public integrity of the system.

Disclosure statement

The authors have no relevant conflicting interests and are fully responsible for the article's content, including any errors or omissions. All translations are by AM.

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Appendix A. Coding process

A. Theoretical framework and analytical orientation

The coding and analysis of data in this paper was grounded in actor network theory- conceptualizing both human and non-human entities (actants) as forming part of dynamic and relational networks. This framework shaped the selection, organization and analysis of data, based on foreshadowed themes.

B. Coding procedures

Data sources and data management

- 43 interviews were conducted in local languages, audio recorded, transcribed and translated into English.
- Other data included:
  - Field notes from observations and 'mystery shoppers';
  - Document analysis of proclamations, directives and annual reports.
- Interview transcripts were manually coded using selective thematic coding with ANT guided analytical memoing
- Observations and mystery shoppers were used for verification to:
  - Confirm the actual presence and circulation of SF medicines as reported by interviews and documents;
  - Corroborate claims of market practices such as unregistered medicines.
  - Observations were not thematically coded but enabled field level validation for claims about parallel supply chains and the symbolic role of regulation in everyday market relations.
- Official document analysis

  - These documents were analyzed to define the legal framework intended to regulate the pharmaceutical market. They provided a normative baseline to compare with practices reported in interviews or captured in field notes. This analysis supplied evidence of translation failures, network instability and non enrolment, as predicted by ANT. These texts were not coded in detail but informed analytical memos and allowed the identification of mismatch between law in the books and law in action.

The coding process involved three sequential and iterative stages:

i. Initial themes and identifying actants
   - ANT guided attention to both human (e.g pharmacist, regulators) and nonhuman (SF medicines, laws, licenses) actants
   - Transcripts were reviewed to identify actant roles, movements and relationships
   - Initial memos captured references to ANT constructs; enrolment, translation, black-boxes, obligatory passage points and network instability

ii. Selective and thematic coding

Selective coding was applied to segments relevant to the research objective as identified by ANT theory. Thematic codes developed from both the data and the guiding theory.

Theme code	Description	ANT concept
Legal ambiguity	Informants described Unclear, contradictory or ineffective laws	Law as unstable actant
Regulatory performance	Inspections are symbolic	Black boxing compliance
Market survival rationales	Bribery or illegal practice are justified by economic survival	Translation to local ethics: alternate rationality
Manipulation of licenses	Licenses are used for display, not for practice	Symbolic enrolment
Parallel supply chain	Informal network treated as more reliable	Alternative actor-network stability

C. Axial coding and network mapping

Themes are grouped under analytical categories to trace how the networks formed or failed. Translation failure or success assessed through;

✓ Actor alignment or resistance
✓ Successful or failed enrolments
✓ Points where law failed to translate in to daily practice

Example: Proclamation No 1112/2019 failed to translate into daily practice because of institutional fragmentation and limited enforcement capacity leading to network instability.

D. Triangulation and iterations

- Codes were triangulated across interview transcripts, field notes, and documentary sources.
- Deviant cases were reviewed for deeper insight into network fragility or competing logics.
- Recurring themes were sharpened through constant comparison.

The coding process enabled theoretically coherent analysis of SF medicines circulation through fragile and fragmented network of actors, institutions and texts.

Appendix B. Characteriscs 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)	2
	Tertiary education (Technical & vocational, College and University)	33
Participant categories	Pharmacists	8
	Physicians	3
	Wholesalers	4
	Owners	6
	Regulatory staff	7
	Law enforcement staff	6
	Consumers	6
	Local vendors	3
	Former smugglers	2

Appendix C. Interview topic guide

This study used a semi-structured topic guide in Wolaitigna or Amharic. The topic guide allowed for open-ended conversation and enabled the interviewer to explore participant perspectives in depth.

- Key Topics (in English version)
  - Legal framework
  - Awareness and interpretation of the proclamation No 1112/2019
  - Perceived gaps or contradictions
- Laws interpreted, adopted and ignored
  - Implementation challenges
  - Corruption vs. legal navigation/Informal practice
  - Bypassing or bend law or manipulate
  - Enforcement or regulatory inspections
  - Organizational issues
  - Bureaucratic inconsistencies
- Licensing and market Access
  - Obtaining and renewing professional licenses
  - Compliance requirements and loopholes
  - Access to formal vs. informal distribution networks
- Circulation of medicines
  - Knowledge of regulatory oversight on imports and distribution
  - Informal supply chains
- Actor roles and network stability
  - Influence of key human and non-human actants (laws, licenses, medicines)
  - Conditions that stabilize or destabilize the pharmaceutical market
  - How actors enroll or resist legal and institutional authority
- Law and translation
  - Instances where laws fail to influence behavior or outcomes
  - Disconnection between written texts and regulatory practice

Appendix D. List of documents

I. Proclamation No. 1112/2019 – Food and Medicine Administration Proclamation
   - Core legal framework

II. Proclamation No. 661/2009 – Establishing the former Food, Medicine and Healthcare Administration and Control Authority (FMHACA)
   - Provides context to the evolution of pharmaceutical regulation

III. Regulation No. 299/2013 – Related to health professionals' licensing and operations
   - Referenced in connection with licensing procedures and enforcement

IV. Administrative Proclamation No. 1183 – Public consultation and stakeholder involvement in policy development
   - Referenced in discussions on legal drafting and consultation practices

V. National Drug Policy (1993) – Policy background on access, quality, and affordability
   - Cited to trace historical regulatory goals

VI. Pharmacy Regulation No. 288/1964 – Historical regulatory text
   - Used to illustrate legal discontinuities and legacy gaps

VII. Proclamation No. 43/1942 (E.C.) – Early pharmacists and druggists legislation
   - Cited in historical legal tracing

VIII. EFDA Sector Transformation Plan II (EFDA, 2021) – Strategic vision document
   - Referenced in analysis of implementation frameworks and system fragmentation

IX. WHO Medical Alerts (2022) – On substandard paediatric medicines in Africa
   - Used as international context for SF medicine threats

X. Criminal Code Proclamation No. 414/2004
   - Cited regarding legal definitions of counterfeit/substandard medicine offenses