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ASSESSMENT OF MEDICINE REGULATORY PERFORMANCE IN SOUTH - WEST ETHIOPIA: THE CASE OF ILU-ABABORA ZONE, OROMIA REGIONAL STATE

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Assessment of Medicine Regulatory Performance In South - West Ethiopia: The Case of Ilu-Ababora Zone, Oromia Regional State

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This document confirms that Tesfahun Girma has completed a research project called "*Assessment of Medicine Regulatory Performance in South - West Ethiopia: The Case of Ilu-Ababora Zone, Oromia Regional State"* as part of his Master of Sciences in Regulatory Affairs degree(Medicine Regulation Truck). The work follows the rules set by the University and meets the expected standards in terms of originality and quality.

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Abstract

Assessment of Medicine Regulatory Performance in South - West Ethiopia: The Case of Ilu-Ababora Zone, Oromia Regional State, 2023 G.C.

Tesfahun Girma

Addis Ababa University, 2023 G.C.

Introduction: *The implications of ineffective pharmaceuticals regulation is becoming a major problem worldwide. Therefore, in order to address this issue and provide access to high-quality medications, every country should meet the minimum standards of a functional pharmaceuticals regulation.*

Objective: *- To assess medicine regulatory performance in Ilu-Ababora zone, Oromia regional state, south west Ethiopia*

Methods: *A sequential mixed methods (quantitative method followed by qualitative research approaches) was conducted from July to September 2022 G.C. in Ilu-Ababora zone using document review, simulated client visit method and semi-structured interviews. The study participants were regulatory professionals and healthcare providers working in Zonal Health Office, selected Woreda Health Offices and both public and private medicine retail outlets including private clinics. The data was analyzed using descriptive methods for the quantitative part and thematic analysis for the qualitative part.*

Results: *Majority 91.66% of retail outlets from the total 24 issued non prescribed antibiotics at three distinct demand levels. In Ilu-Ababora zone there were 3,944 human health related facilities to be inspected by the zonal health department regulatory teams in collaboration with each woredas regulatory teams. But, at the zonal health department there were only two inspectors. All the woredas except Mettu City Administration, which has two inspectors, has one or none inspectors assigned. They didn't have separate vehicle as well as no budget breakdown for regulatory activities. The regulatory performance is currently very poor. Performance influencing factors like widening of control area, scarcity of resources, capacity building problem, information*

leakage, lack of attention from the stakeholders, communication-related issues, and lack of awareness from the society were identified. Increased circulation of unsafe products, compromising patient's quality of care, and monetary costs were reported as major concerns. As important interventional tactics, sector experts suggested enhancing capacity building techniques, involving sector stakeholders, and strengthening the regulatory structure.

Conclusion: *Despite the availability of comprehensive medicine regulations in Ethiopia, the results of this study show that the enforcement of these regulations is weak and the way regulations are currently being implemented in this area is not very effective and is still in the early stages of development.*

Key words: *Performance, input, output, outcome, inspection, licensing*

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Acronyms

DRA	Drug Regulatory Authority
EFDA	Ethiopian Food and Drug Authority
EPSA	Ethiopian Pharmaceuticals Supply Agency
GMP	Good Manufacturing Practice
KIs	Key Informants
MoH	Ministry of Health
NMRA	National Medicine Regulatory Authority
OTC	Over-the-counter
PFSA	Pharmaceutical Fund and Supply Agency
PMS	post-marketing surveillance
SDS	Specialized Drug Shop
SF	Substandard and Falsified
UTI	Urinary Tract Infection
WHO	World Health Organization
ZHD	Zonal Health Department

1. INTRODUCTION

Having a stronger capacity to regulate medicine has many benefits for the public and private sectors. It means that treatments work better, cost less, and have less antibiotic resistance. It also decreases the amount of falsified and substandard medical products available and makes it faster to approve new medicines (Ball, D., 2016). In countries in sub-Saharan Africa, the situation is even worse. There is a lack of resources and limited ability to manufacture medicines, but there are more people suffering from diseases (Adebisi, YA, et al. 2022). In addition to this, the flourishing of unregulated medicines market is creating collateral damage and is a serious risk for individuals and public health (WHO, 2010). As a result, Countries need strong and practical laws and rules that are able to be followed and enforced properly. A good law establishes a regulatory agency to ensure that the laws are adhered to (MSH, 2013).

The regulation of pharmaceutical sector in Ethiopia covers medicines, premises, pharmacy professionals and practices (EFDA, 2017). These regulation activities are undertaken by Ethiopian Food and Drug Administration (EFDA) at national level and the respective regulatory bodies at regional level (EFDA, 2017). Regulatory activities pertaining to pharmaceutical establishments (local manufacture, import and wholesale) licensing and inspection, import and export control, product evaluation and registration, post-marketing surveillance & pharmacovigilance, and the control of safety and quality of food are all the mandates of federal EFDA while the responsibilities of regional regulatory equivalents include licensing and inspecting drug retail establishments, such as pharmacies, drug stores, and rural drug vendors (HPR, 2019). The issues of promotion and advertising of pharmaceuticals in addition to the issues of alcohol and tobacco products are also covered by the country's regulation (HPR, 2019). For the purpose of implementation of the proclamation, a detailed directives and guidelines have been developed and implemented (ORHB, 2016, EFDA, 2017, EFDA, 2018).

As part of a government institution EFDA has a regular budget from the government to accomplish its routine activities. A total of 610 medicines have been listed on Ethiopian essential medicines list (EEML) (EFDA, 2020). Knowing how the regulatory branches now operate in the Ilu-Ababora Zone can help identify any gaps and untapped potential for enhancing regulatory capacity, advancing public health, and developing pharmaceutical supply. This research makes use of original data from the regulators, management members of Zonal Health Department (ZHD) and Woreda Health Offices, private medicine retailers of Ilu-Ababora Zone as well as ZHD policy statements and documents, to offer a comprehensive overview of regulatory branches performance in South-west Ethiopia by taking Ilu-Ababora Zone regulatory department as an exemplary. The importance of the EFDA Jimma branch and other initiatives to strengthen the regulation of medical products in South-West Ethiopia are also discussed as potential to improve the performance of regulatory authorities.

2. STATEMENT OF THE PROBLEM

The importance of developing a reliable and functioning regulatory system is to safeguard the public from falsified and substandard products which circulate in the market. Thus, it is more crucial than ever before to adhere to international standards and guidelines for pharmaceuticals. Such norms and standards are still being developed by WHO to serve as direction for national regulatory systems (Rägo and Santoso, 2008).

It takes a lot of organizational capacity and resources, continual vigilance, and flexibility to regulate the increasingly complicated pathways of pharmaceutical delivery (EFDA, 2017). Ethiopia's pharmaceutical regulatory law oversees important tasks related to medicines. These tasks include registering medicines, monitoring their safety after they are on the market, and overseeing the licenses and inspections of manufacturers, importers, exporters, wholesalers, and retail outlets. The law also controls the process of clinical trials and the promotion of pharmaceutical products (HPR, 2019). To create a comprehensive system for the regulation of pharmaceuticals, these activities must cooperate (EFDA, 2017).

Even if good medicine regulation is proclaimed in Ethiopia, some studies reveal that there are a lot of breaches of the law, especially as we go far from the capital, Addis Ababa. To mention some, a cross-sectional survey of private DROs in Ambo town found that 36% of the staff members lacked the necessary qualifications for their positions (Gutu, 2020). The other indicator is that retail outlets dispense medicines including antibiotics over the counter; for example, a research conducted in Mizan-Aman town, southwest Ethiopia, indicated that 94.4% of antibiotics were distributed without a prescription (Damisie *et al*, 2019). But multi-drug resistant microorganisms' issue is the current global burden. Additionally, the supervision done by the Ilu-Ababora zonal health office in 2020 also indicates the holding of medicines beyond the allowed list by drug stores and rural drug vendors, including private clinics. According to this unpublished report, private clinics are not allowed to store and dispense other than emergency drugs; but they have a wide range of medicines at hand including antibiotics and hence

participate in drug dispensing (IZHO 2020). Qualitative research confirms that pharmacies are under intense competitive pressure and their employees are trying to maximize profits to survive in the market (Miller and Goodman, 2016).

The Ilu-Ababora zone is not as much developed in terms of infrastructure and services. Most retail outlets are located in large cities, which are far away from the people living in rural areas; i.e., they are more targeting their market share than the public service they are rendering to the society (IZHO, 2020). Even if rural residents could afford or wanted to utilize those services, the distance would logically deter them from using them (Bhuiya, 2009). As a result, illegal traders target those population lacking supply and awareness exposing them to irrational medicine usage. Therefore, the overall regulatory activity becomes challenging since it requires a great deal of effort to cover all that distance. In addition, the zone is near to South Sudan, where there may be illegal cross-border trading. All these problems necessitated this research to be conducted at this specific area.

In summary, there is a need for a better understanding of regulatory system in place and a structured approach in identifying gaps and challenges to ensure a better regulatory system. More specifically, the following research questions need to be addressed:

1. What looks the current regulatory performance at Ilu-Ababora Zone?
2. What are the internal and external gaps and challenges of the regulatory body at Ilu-Ababora Zone to fully practice the regulatory activities?

2.1. Significance of the study

This study has a great role in creating an understanding of the current regulatory performance of Ilu-Ababora zone and also provides a detailed recommendation and way forward for future regulatory activities. The findings can be used as an input for the zonal, regional, and EFDA level administrative bodies and other interested parties to understand the scope of the issue and pinpoint potential intervention areas. It will act as a baseline for more study and investigation because there aren't many regulatory base studies conducted at the zonal health office level in the country. Moreover, it can create professional and public awareness regarding regulatory activities and what is expected of regulatory body.

3. LITERATURE REVIEW

All countries' healthcare systems depend heavily on medical products, thus safe, effective, and high-quality medications must be accessible to the general public. Due to the crucial role they play in society and the difficulties—and occasionally controversies—involved in evaluating their safety, quality, and efficacy, they are heavily regulated (Reggi, 2017). To ensure this, medicine regulation plays an indispensable role in making sure that all critical requirements have been met (WHO, 2010). Access to these medicines and health systems can be improved by good governance. When we talk about good governance in the pharmaceutical sector, we're talking about the creation and application of decent policies and practices that confirms the effective, efficient, and moral management of medicine regulation in a way that is transparent, accountable, and compliant with the law (Anello, 2008, Tobin and Walsh, 2008, Kohler and Baghdadi-Sabeti, 2011).

The development of medicines regulation was majorly due to disastrous events than the evolution of knowledge. For example, the usage of a sulfanilamide elixir in 1937 resulted in the death of over 100 Americans from diethylene glycol poisoning, which led to the introduction of the Federal Food, Drug, and Cosmetic Act in 1938 (Wax, 1995). The act required premarket notification before release of the new drug to the market (Van Boxtel *et al.*, 2008). Currently, only medical items that have been approved by the relevant national medicine regulatory authorities (NMRAs) are allowed to be sold in any given country. Therefore, the lack of properly funded and functioning NMRAs has the impact of limiting access to commodities that are life-saving (Ndomondo-Sigonda *et al.*, 2017). At least 30% of NMRAs worldwide, according to the World Health Organization (WHO), have a restricted ability to carry out the essential regulatory activities (Ndomondo-Sigonda *et al.*, 2017).

National barriers to the provision of medications are being eliminated by market globalization and merging of pharmaceutical company. As a result, reports of substandard and falsified (SF) pharmaceutical items have come from all over the world

(McGinnis and Primo-Carpenter, 2003). The problem is wider in developing countries. This is mainly due to poor control of pharmaceutical product manufacture and trade in both exporting and importing nations (Johnston and Holt, 2014). In Southeast Asian countries, samples of medications were collected from five different classes, and 35% of 1437 failed chemical analyses, 46% of 919 failed packaging analyses, and 36% of 1260 were deemed to be falsified (Nayyar *et al*., 2012). In 21 assessments of medications from six classes conducted in 21 sub-Saharan African nations, 35% of the chemical analyses and 36% of the packaging analyses were failed, and 20% of the drugs were categorized as falsified (Nayyar *et al*., 2012). The health and lives of patients are in great danger because of these poor-quality medicines uses (Ratanawijitrasin *et al.*, 2002)**.** Malaria due to *Plasmodium falciparum* infection causes between 655 000 and 1.2 million deaths a year, but a large portion of this morbidity and mortality could be avoided if patients had access to safe, quality, and efficacious medicines and also used correctly (WHO, 2011; Murray *et al.*, 2012).

The frequency of regulatory visits and severity of sanctions were linked to regulatory compliance, with lower frequency and less severe sanctions being blamed for poor compliance. For example, An intervention in the Lao People's Democratic Republic that involved inspection visits, penalties for egregious sanctions violations, up-to-date regulatory document supply, and reinforcement of the rules resulted in noticeable improvements in the accessibility of essential medications, order in the pharmacy, and information provision, as well as a decrease in the mixing of different medications in the same package (Anttila, 2016). In Bangkok (Thailand), the regulatory aspect of the intervention on dispensing practices led to a decrease in the issuance of a prescription-only steroid compared to the control group (Miller and Goodman, 2016). The same study found that the intervention's regulatory component did not immediately result in a shift in behavior in Hanoi (Vietnam), where less emphasis was placed on sanctions (Miller and Goodman, 2016).

In most African countries including Ethiopia the pharmaceutical markets are mostly generic markets which are presumed to be safe and effective if they are confirmed to be

interchangeable with brands and where the main emphasis is on quality (Yenet, Nibret and Tegegne, 2023). These pharmaceuticals are mostly imported from abroad. So, having a well-functioning regulatory system is a pre-requisite to protect their citizens from SF medicinal products. But, according to the WHO research, only 7% of African nations have a moderately developed regulatory capability, with more than 90% having little to no capacity (Nayyar *et al*., 2015). Any country without functioning NMRAs risks exposing its population to potentially dangerous medical products of varying quality and effectiveness, facilitating the spread of SF medical products, and preventing the prudent use of medical products—all of which are harmful to patient safety and public health (Doua and Geertruyden, 2014).

Most African nations attribute a low rate of post-marketing withdrawal of dangerous pharmaceuticals due to adverse drug reactions to a lack of regulatory competence (Ndomondo-Sigonda *et al*., 2017). The WHO Rapid Alert System reports that the circulation of SF medical items is growing in the African Region, and surveys indicate that quality failure rates might reach up to 28% in some circumstances (WHO, 2016). In 21 assessments of medications from six classes conducted in 21 sub-Saharan African nations, 35% of the chemical analyses and 36% of the packaging analyses were failed, and 20% of the drugs were categorized as falsified (Nayyar *et al*., 2012).

Due to the lack of access to physicians, pharmacists in underdeveloped nations become a key provider of healthcare, and patients frequently seek out their services directly (Barker et al, 2017). This makes it hard to enforce rules about selling antibiotics without a prescription (Damisie et al., 2019). The proportion of antibiotics distributed without a prescription in Eritrea was found to be 87.6%, with ciprofloxacin (47.8%) and co-trimoxazole (37.5%) being the most popular antibiotics (Bahta *et al.*, 2020). 87% of medications were sold without a prescription in pharmacies in the Democratic Republic of the Congo (Bunduki, Mumbere and Mbahweka, 2017).

In Kenya and Ghana, the sale of unregistered medications was relatively frequent. For instance, the regulatory body in Kenya only registered 5 of the 12 brands of amodiaquine syrup. Other instances of regulatory noncompliance included Tanzania's failure to display

practicing permits and Uganda's provision of clinical management without authorization. The problem of unqualified workers serving clients, especially at Specialized Drug Shops (SDSs) that have registration certificates from certified persons, may be of greater concern (Wafula et al., 2012).

Drug policy issues were inadequately conveyed in Tanzania, where 75% of dispensers claimed to have heard about changes to the policy on malaria treatment through the radio and other news sources (Minzi and Haule, 2008). Additionally, shop location was related to a number of practices, with patients receiving better care when they visited pharmacies in larger cities as opposed to those in smaller cities or less affluent regions. This might have happened because people in less affluent locations were less knowledgeable about medications and so more likely to purchase the wrong ones, or it might be a sign that the distribution of qualified staff is biased in favor of metropolitan and wealthy areas (Wafula et al., 2012).

Ethiopia is one of the sub-Saharan African nations where a national medicine policy governs the pharmaceutical sector (HPR, 1993). "The Pharmacists and Druggists Proclamation No. 43/1942" set provisions to regulate both the establishments and the professionals, and it served as the foundation for pharmaceutical regulation. "Pharmacy Regulation No. 288/ 1964" was a more thorough regulation that served as the theoretical basis for the official creation of drug regulation in Ethiopian history. Based on this declaration, the Pharmacy Department's regulatory arm was changed into an independent Ethiopian Drug Administration and Control Authority in September 2001 (HPR, 1999). By "Proclamation No. 661/2009" in 2010, it was reorganized as the Food, Medicine and Health Care Administration and Control Authority of Ethiopia, taking on new duties such as regulating food, healthcare providers and facilities (HPR, 2010). Currently, it is refined into Ethiopian Food and Drug Administration (EFDA) by “Food and Medicine Administration Proclamation No. 1112 /2019” focusing on regulation of food and medicine (HPR 2019). Its’ organization, powers and duties are clearly stated on Council of Ministers Regulation No. 531/2023 (CM 2023).

Even if medicine regulation concept is introduced in Ethiopia as early as 1942, according to several primary data sources, ineffective pharmaceutical regulation processes are to blame for the existence of low-quality pharmaceutical items on the market (Suleman *et al.*, 2016). A review of the Ethiopian quality control laboratory tests performed between 2007 and 2011 for post-marketing surveillance (PMS) reveals that the failure rate of the samples submitted was higher (9.5%–15.5%) than the failure rate of the samples submitted for marketing permission (4.7%–10.7%) (Suleman *et al.*, 2016). Therefore, it is important to critically assess the legal foundation and application of the pharmaceutical regulatory framework in order to study such public health issues.

A research done at Addis Ababa, Ethiopia found that 77.78% of cosmetics shops surveyed had topical corticosteroids (TC) containing preparations at their stock and unregulated sales were among the contributing factors identified for misuse of these groups of drugs (Bantayehu 2015). As we go far from the capital Addis, the issue even gets worse.

Performance evaluation of regulatory agencies is challenging for several reasons. The dangers they pose to achieving regulatory goals and the regulatory "landscape" vary greatly amongst regulators in terms of the features (for instance, size, geography). Greater difficulties in regulating and measuring performance may result from the presence of more providers of widely varying sizes. It is uncommon for regulatory actions to have a one-to-one relationship because: A single action may have more than one intended outcome; and More than one regulatory action may have an impact on any given outcome. There are external effects on outcomes as well as external influences on the behavior of regulated providers. There must be a lag between regulatory acts and the appearance of the corresponding results (Coglianese, 2012).

Whatever the situation, it's critical for policymakers to regularly evaluate regulatory systems to protect the public health from medications whose safety, effectiveness, and quality aren't guaranteed by creating or revising policies and strategies. Additionally, creative strategies for enforcing regulatory compliance must be developed and the legislation to protect the public health should be critically evaluated for

comprehensiveness in addition to assessing its practical implementation through cross-sectional survey on a predetermined schedule.

3.1. Conceptual framework

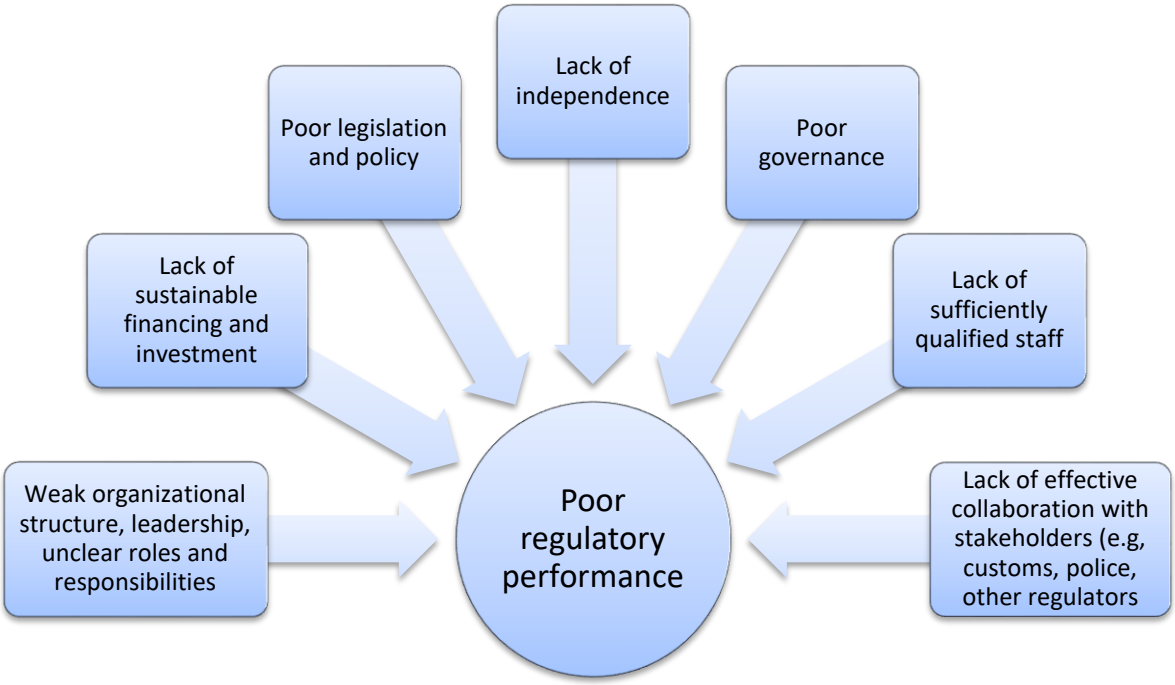

Figure 1: *Causes of Poorly Functioning Regulatory Body (Rägo and Santoso, 2008)*

There are three main parts of the regulatory system that controls and manages rules. The regulatory framework is a group of laws, rules, and regulations. The organizations that make sure these rules are followed. The many assets necessary to sustain the regulatory system in place, like human resource, funds, properties, tools, and information technology. The regulatory outputs depend on the functions and activities concerned (e.g. marketing authorization and inspection). The concepts and principles of good regulatory practice (GRP) apply to the overall regulatory system (WHO, 2021). GRP implementation is made easier by an enabling environment. Some enablers include political and government-wide support; leadership must support effective organization and strong governance. It is also important to have good communication, collaboration, and coordination within and between organizations. Additionally, having enough and sustainable financial resources, competent staff members, making decisions based on science and data, and following good regulatory practices are crucial (WHO, 2021).

4. OBJECTIVES

4.1 General objectives

- To assess medicine regulatory performance in South - West Ethiopia: The Case of Ilu-Ababora Zone, Oromia Regional State, 2022 G.C.

4.2 Specific objectives

- To assess performance of medicine regulatory bodies of the Ilu-Ababora Zone.
- To assess stakeholder opinions on the regulatory performance of the Ilu-Ababora Zone.

5. METHODS

5.1. Researcher's Position and Reflexivity

The positionality of the principal investigator in this study was dependent on the researcher being a professional, an intellectual, and a member of the dominant ethnic group in the area. Being a knowledgeable and skilled pharmacist who is aware of the danger that unethical or unreasonable pharmaceutical distribution poses to the health of the community, the necessity to uncover the practice and seek for solutions sparked the interest that gave rise to this study.

As the principal investigator was born and attended his education there and served at different institutions including Mettu Karl Hospital, EPSS (the then PFSA) Gambella branch, and Mattu University, the event under investigation was not new to him. This has in many ways made it easier for the researcher to pinpoint the places for purposive sampling. Despite having insider knowledge of the fundamental problem, the researcher's social standing in the community posed a barrier to the free flow of crucial information. Once the researcher's identity (belonging to the major ethnic group in the area) was declared, the community assumed the researcher was an educated insider with detailed knowledge of the practice who wanted to solve the problem related to the regulatory body's performance as a way of giving back to the community where he belongs. This was fixed by providing a brief explanation that the issue would only be resolved if the true nature of the issue was made clear. The participants would occasionally bring up solutions throughout the interview even after they seemed to understand the research's goal. These were some of the difficulties found, and other researchers who wish to conduct their studies in a similar group as an insider should be aware of them.

On the other hand, the researcher has a special opportunity to reach the area and investigate the genuine practice because he is familiar with the local language and culture.

5.2. The Study Setting and Study Period

The study was conducted within a three months period of time (from July to September 2022 G.C) in Ilu-Ababora Zone which is found in south-west Ethiopia, and is one of the 22 zones of the Oromia Region. Its main town, Mettu is located approximately 600 kilometers from Addis Ababa and the zone has an estimated total population of 991,257. The Zone has 15 woredas, 27 urban kebeles and 265 rural kebeles, sharing borders with Buno Bedele Zone in the east, Gambela Region in the west, western Welega Zone in the north and Shekka Zone in the south (IZHO, 2020). This Zone is rich in honey production, animal farming, coffee plantation, and cash crop products. It is also densely populated and many nations and nationalities live there.

As to health coverage, there is one general hospital, one primary hospital, one blood bank center, 40 health centers and 273 health posts government owned and one Marie Stopes International Ethiopia Center which works on reproductive health activities mainly and one non-governmental Hamlin Fistula Center in the Zone. There are also about 97 private clinics (18 medium and 79 primary), 43 retail outlets (5 pharmacies, 31 drug stores, and 7 rural drug vendors) in the Zone (IZHO, 2020).

The Food and Medicine Administration Proclamation No. 1112/2019 (HPR, 2019) governs Ethiopia's pharmaceutical industry. Accordingly, enforcement of the regulatory functions is handled by the Ethiopian Food and Drug Authority (EFDA) and its regional regulatory counterparts.

5.3. Study Design

A sequential mixed methods (a cross-sectional quantitative method followed by a descriptive qualitative approach) study design was employed to do the research. Phase 1 used a methodology that simulates a patient visit, which is a more trustworthy way to observe and practice real-world behavior (Boura F 2022). In phase 2, document reviews were conducted to get each detail of activities expected to be done under the regulatory teams and to look into the depth of the current regulatory practice at the area. At the final

stage, phase 3, an extensive interview was conducted in order to comprehend the drivers behind the OTC selling of prescription medications and the reasons why regulatory frameworks aren't being enforced.

5.4. Source and study Population

5.4.1. The Source populations were:

- ✓ All medicine retail outlets found in Ilu-Ababora zone for the simulated client's method.
- ✓ All health offices found in the Ilu-Ababora zone for document review method.
- ✓ All the employees who work in the health offices at zonal and woreda level, as well as the professionals who work in public and private health facilities found in Ilu-Ababora zone.

5.4.2. The Study populations were:

- ✓ All retail outlets in the selected woredas that fulfills the criteria for being included were included for the simulated client's method.
- ✓ The Ilu-Ababora zone health bureau and the selected woredas health offices.
- ✓ Key informants from the zonal health office, professionals from the selected woredas health offices, and private health facilities (medicine retail outlets and clinics) were included for qualitative study.

5.5. Sample size determination

- ✓ Census method was used for simulated clients method since the number of study population was less.
- ✓ The sample size was determined by point of saturation for the qualitative method.

5.6. Sampling procedure

Extreme or deviant case sampling method, which is a technique chosen for important results, such as successes or failures, (Rai and Thapa, 2015) was used to select two study woredas and Zonal Health Bureau for in-depth exploration. The woredas were classified into two strata in terms of infrastructure development; urban and remote woredas. Then

one was selected from the woredas with the largest urban center (main town) which were expected to have a better performance in the pharmaceutical regulation. The other woreda was one from among the most remote ones to explore the situation on the other extreme in terms of pharmaceutical regulation in the zone.

Quantitative study

For the simulated client visit study, all retail outlets that fulfill study criteria and found in the selected woredas were included. With regards to documents review part, all relevant documents including reports that reflect the regulatory performance at different levels starting from the federal level down to selected woreda level was reviewed.

Qualitative study

Individuals working in the regulatory bodies at different levels starting from the EFDA Branch in Jimma and Oromia Regional State to the woreda level, and health professionals from private sector institutions (both medicine retail outlets and clinics) found in the selected woredas were purposively sampled for the study so long as they fulfill the study criteria.

5.7. Inclusion and Exclusion Criteria

Inclusion Criteria:

- All willing professionals who participate directly in medicine regulation and handling were included.
- Retail outlets which were operational for more than one year were included.

Exclusion Criteria:

- Professionals who have less than one year experience

5.8. Data collection

Data collection tool

Standard data abstraction format was adopted from previously conducted research in Eretria (Bahta *et al*., 2020) to capture the information obtained (annex IV).

The document review part was conducted by adapting the WHO data collection tool (annex V) for the review of drug regulatory systems (WHO, 2007).

Questionnaire for private healthcare providers, regulatory teams and management members at Oromia regional health bureau, EFDA Jimma branch, Ilu Ababor zonal health department, and woreda level (Annexes I, II and II) was used for the qualitative study. The interview guide was prepared in English and translated into Amharic and Afan-Oromo. Audio recorder was also used to capture raw data.

Data collection procedure

Quantitative study

The data collection for the simulated client was held using data collectors assigned for the current study. Data was gathered from blinded dispensers using simulated clients in order to capture the usual performance of dispensing. Four simulated clients (two female and two male final-year pharmacy students), who could not be identified by the dispensers, collected the data using the simulated client method, an efficient technique for obtaining reliable data. Under the guidance of the lead investigator, these data collectors received training on data-gathering techniques and were then given the appropriate assignments. They presented with a sore throat and a urinary tract infection (UTI) scenario. To avoid suspicion from dispensers, each medicine retail outlet was visited twice (one for each scenario), with an acceptable amount of time passing between each visit. They used three levels of demand, which is described in detail in the operational definitions part, to get the antibiotic. On the day of data collection, each collected piece of information was examined for accuracy.

The document review was conducted by the principal investigator using a data abstraction format (annex V) as a guide. Assigned individuals (workers) at the selected zonal and woreda health offices documentation section were asked to bring all the

necessary documents regarding medicine regulation activities based on the data abstraction format. At the time the required document was available, the 'yes, no' section on the format was filled accordingly.

Qualitative study

Individual interview was conducted with professionals employed in the regulatory sector, zonal and woreda health office administrators, medicine retailers, and private clinic owners at their work place and coffee shops based on their preference to assess their perception and experiences on the medicine regulatory performance in the zone. The language for the interviews was either in Amharic or Afan-Oromo based on the convenience of the key informants. The interviews were audio recorded, and at each session, notes were collected for the transcription. The principal investigator was in charge of gathering data and transcribing it.

5.9. Data entry and analysis

Quantitative study

The results of the categorical variables were primarily expressed descriptively using frequency and percentages after the data were analyzed using Microsoft Excel (2010). Each form was reviewed for accuracy after data collection, and codes were provided throughout data collection.

Qualitative study

The interview data were transcribed verbatim from audiotapes and notes taken and translated to the English version (Amharic responses to the English version or Afan-Oromo responses to the English version) by the principal investigator and using Google translator at some points. The translated data were analyzed manually through the use of color-coding of verbatim quotes of the participants in MS-Word. Data collection, transcription, and analysis were all done at the same time to provide the interview questions some flexibility and detect point of saturation also. The deductive method was mainly used in the qualitative thematic analysis. Finding areas of the raw data set (text from the interviews) that matched the predetermined codes was the first step in the analyses. The notions from the literature and conceptual framework served as the basis

for the codes employed in this methodology. Issues not covered by the deductive analysis or those that did not fit the themes employed in the deductive technique were coded inductively, where themes were created by examining patterns in the data set. This method involved reading over the data and letting codes develop. The codes were continually revised, and themes were created out of sets of similar codes. As the process progressed, more themes appeared, and smaller themes—referred to as "sub-themes"—were grouped beneath the bigger ones.

5.10. Quality Assurance

Quantitative study

The data was collected through simulated clients visit method and reviewing documents of the regulatory bodies during the data collection procedure. The data abstraction format used for simulated clients' method was adapted from researches conducted previously (Bahta *et al*., 2020). To reduce recall bias and increase the accuracy of the information shared during the meeting, the simulated clients were accompanied by a second coworker. Moreover, prior to data entry, the quality of the data was evaluated for completeness.

Qualitative study

Pilot interviews were done on Buno Bedele zonal health office professionals prior to the interview guide's implementation to assess the questions' applicability in addressing the study's objectives and research issues. As a result, there were some modest changes made to the interview guide, including the addition of more probing questions and the removal of ambiguous and leading questions. To determine whether the meaning of the source and the translated versions is equivalent, the interview result was back-translated. Through discussion with Mattu University staff colleagues, disagreements during transcription, translation, back translation, and coding were resolved. After data collection, the internal validity (quality assurance) was also validated by member verification, where the zonal study participants were given access to the preliminary analysis of the data obtained.

5.11. Ethical consideration

The Addis Ababa University School of Pharmacy Ethics Review Committee gave its approval to carry out the current study with reference number ERB/SOP/370/13/2021. To obtain authorization from the Oromia Regional Health Bureau, a formal letter from the School of Pharmacy, Department of Pharmaceutics, and Social Pharmacy bearing reference number ፋር/ሲዩቲክስ/ 079/14/2021 was also written. Furthermore, approval for research conduct was obtained from Oromia Regional Heath Bureau Health Research Ethical Review Committee (Ref. No. BM/HBRM/1-16/435).

Participants in the qualitative portion of the study received information on the study's objectives and what was expected of them while the research was being conducted. They were advised that participation was entirely voluntary and that they might leave the study at any time. Participants received guarantees of confidentiality and that the responses they provided would be kept private. They were also informed that just the overall statistics would be included in the findings report and that they would not be named specifically. Finally, each participant gave their informed consent.

For the simulated client visit method, no personal identifiers were used when collecting data from the data abstraction form and were kept confidential. The simulated clients were asked to fill out a non-disclosure secrecy agreement prior to the data collection in order to perform the study in strict confidence and prevent disclosing any dispensers' mistakes to third parties. The same procedure was followed for the documents review part too.

5.12. Operational Definitions

Regulatory performance – is defined as governments' effectiveness in achieving inspectees' compliance with public rules and regulations and in assessing social risks (De Boer and Eshuis, 2018).

Inputs for regulators – The resources, personnel, and so on - are similar to those of other organizations (NSAA, 2004).

Outputs - Although it is helpful to make a clear distinction between these, "outputs" in the regulatory context may include the regulator's underlying operations (for example, supervision or inspections, enforcement), or "deliverables" (for example, regulatory decisions, consultations) (NSAA, 2004).

Outcomes - (which in this context can include the provider's outputs) are typically dependent on the sector or activities being controlled and might be expressed in terms of results for consumers, other stakeholders, or the environment. The regulator may incorporate a measure of the regulatory activities or influence via which the desired outcomes will be attained when determining its objectives. (NSAA, 2004).

Routine inspection: is a complete or thorough examination of all features and parts of pharmaceutical businesses, such as manufacturers, importers, distributors, wholesalers, and retail outlets (EFDA, 2018).

Concise inspection: is the assessment of specific areas of compliance inside a facility (EFDA, 2018).

Follow-up inspection: is known as a re-evaluation or re-inspection of the facilities (EFDA, 2018).

Special inspection: is employed to evaluate a new establishment's performance whose range of operations had not previously been known (EFDA, 2018).

Investigative inspection: is implemented in response to particular complaints received about performance of new establishments, complaints, product failures, or recalls, gaps in

professional practice standards, or non-compliance with those requirements (EFDA, 2018).

Sore Throat Scenario: A 22-year-old male partner has been having minor fever, throat soreness, and difficulty swallowing for the past day.

The UTI Scenario: A 21-year-old female partner reported having a burning feeling after urinating for three days in a row.

Antibiotic demand levels

Level 1 indicates the lowest degree of demands because the investigator requested a pain reliever.

Level 2 signifies something more potent than just pain relief.

Level 3 direct request for an antibiotic from the dispenser demonstrates the highest level of demand.

Antibiotics: antibiotics are chemicals that target bacteria and hence meant to treat and prevent bacterial infections (Patel P 2023).

6. RESULTS

This study's findings are reported in two parts: Results of Quantitative study (simulated visits and documents review), and Findings of Qualitative study (the interview results)

6.1. The findings of quantitative study

6.1.1. Information about the study organizations and dispensers

The study was carried out on a total of 24 retail outlets. Majority (20) of them were located in the main town while the rest were found in the rural town. Only two public retail outlets were there and they were even located in the main town. The detailed description of retail outlets is found in Table 1.

Table 1: *Descriptions of the selected drug retail outlets found in Ilu-Ababora Zone, Southwest Ethiopia, July 2022.*

level of retail outlets	**Ownership**		**Location**		**Duration of operation**
	Public	**Private**	**Main town**	**Rural town**	
Pharmacy	1	3	4	0	Mean = 29.5 years Range = 5 to 41
Drug store	1	17	15	3	Mean = 16.6 years Range = 5 to 15
Rural drug vendor	0	2	1	1	Mean = 39 years Range = 36 to 42
Total	2	22	20	4	

Most (20) of the drug retail outlets' dispensers were males. The study participants for simulated clients study was 54.16% pharmacy technicians, 25.00% pharmacists' and 20.84% others (Table 2). The average age of the dispensers was determined to be 42.3 years, and they had an average of 20.5 years of dispensing experience.

Table 2: *Socio-demographic characteristics of dispensers found in selected drug retail outlets in Ilu-Ababora Zone, Southwest Ethiopia, July 2022.*

Variables		**Frequency**	**Percent (%)**
Sex	Male	20	83.33
	Female	4	16.67
Qualification of the dispensers	Pharmacist	6	25.00
	Pharmacy technician	13	54.16
	Health assistant	3	12.50
	Nursing diploma	1	4.17
	Nonprofessional	1	4.17
Age (Mean = 42.3, Range = 26 to 65)			
Work experience (average 20.5, Range = 5 to 42)			

6.1.2. Antibiotics Dispensing Practice.

Clinical scenarios were presented equally throughout the retail outlets involved in this study. Out of the 24 retail outlets where the two clinical scenarios were distributed, 22 (91.66%) dispensed antibiotics without a prescription at three distinct demand levels. The majority, 22 (91.66%), of the 24 retail establishments where a clinical scenario for a urinary tract infection was presented issued antibiotics without a prescription. Among the two clinical scenarios that were taken into account in this study, this one had the highest percentage of sales. For both clinical scenarios, 20 (83.33%) professionals dispensed the antibiotics based on the first level of demand. In general, 85.71% of the bestowed antibiotics were issued at demand level-I.

Table 3: *Pharmacy professionals' OTC dispensing practice of antibiotics with regard to level of demand at selected retail outlets available in Ilu-Ababora Zone, Southwest Ethiopia, July 2022.*

Level of demand	Sore throat n=24	UTI n=24	Antibiotics issued n=42
Level 1	16 (66.67%)	20 (83.33%)	36(85.71%)
Level 2	3 (12.50%)	2(8.33%)	5(11.9%)
Level 3	1 (4.16%)	0 (0%)	1(2.38%)
Refused at all levels of demands	4 (16.67%)	2(8.33%)	0

Out of 24 retail outlets, 2 (8.33%) of the simulated encounters, denied to issue antibiotics over the counter for both clinical scenarios at all levels of request. Concerning each clinical cases, the majority 4 (16.67%) of refusal of antibiotic dispensing arose from sore throat scenarios (Table 3). Accordingly, 2 (8.33%) of them reasoned out the lack of antibiotics during the visit, whereas one of the encounters (4.16%) drive for not dispensing was legal restrictions not to issue antibiotics without prescriptions. Due to concerns about incorrect diagnoses, the remaining one (4.16%) refused to sell antibiotics. In the case of UTI scenario, only one dispenser (4.16%) denied dispensing antibiotics without prescription due to fear of incorrect diagnoses and the other man due to administrative restrictions. In all retail outlets which refused to dispense antibiotics, they made the decision to refer the patient for additional clinical examination. Nevertheless, other than antibiotics, Ibuprofen and Horf (Chlorhexidine HCl 5mg, benzocaine 2mg) lozenges were delivered to the simulated clients.

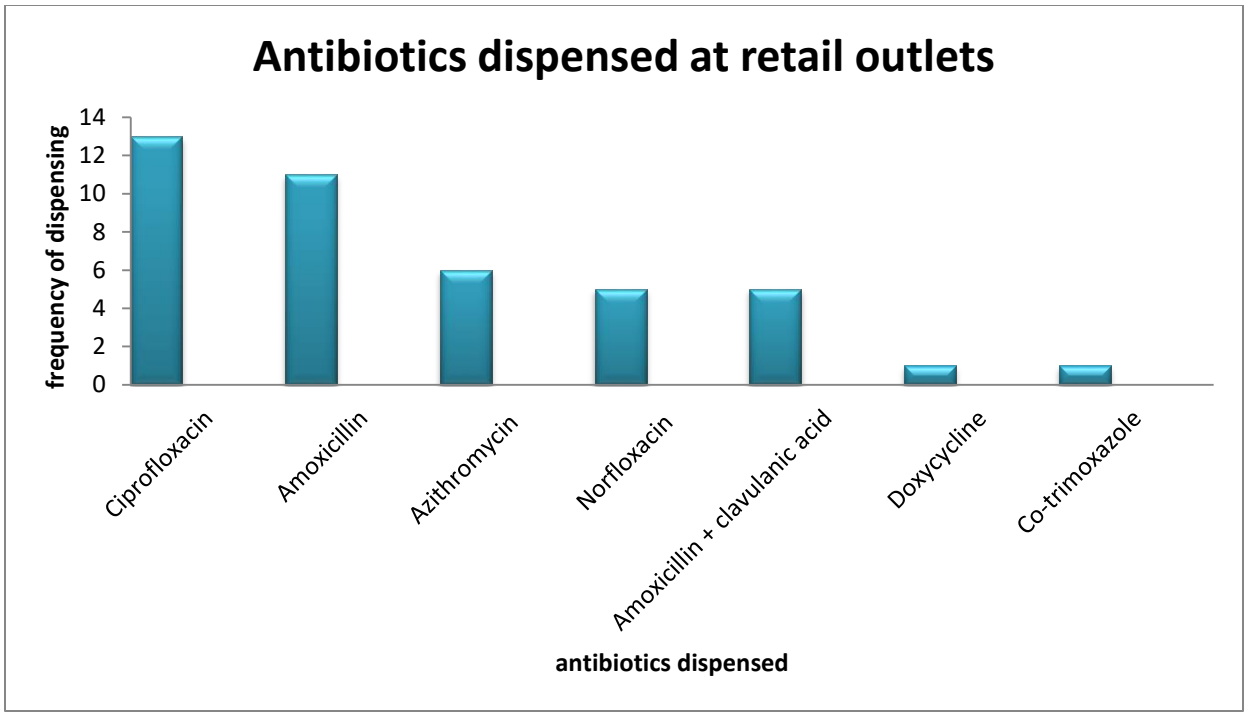

Figure 2: *Antibiotics dispensed in selected retail outlets found in Ilu-Ababora Zone, Southwest Ethiopia, July 2022.*

The commonly dispensed antibiotics were Ciprofloxacin (30.95%) and Amoxicillin (26.19%) (Figure 2). For individual cases, the most often dispensed antibiotic in cases of urinary tract infections was ciprofloxacin, which was given to 13 patients (59.1%) whereas Amoxicillin was frequently, 9 (45.00%), issued for sore throat case (Table 4).

Table 4: *Antibiotics dispensed at retail outlets found in Ilu-Ababora Zone, Southwest Ethiopia, July 2022.*

Clinical scenarios	Antibiotics	Frequency	Percentage
Acute Uncomplicated UTI (n=22)	Ciprofloxacin	13	59.10%
	Norfloxacin	5	22.73%
	Amoxicillin	2	9.10%
	Doxycycline	1	4.55%
	Co-trimoxazole	1	4.55%
Sore throat (N=20)	Amoxicillin	9	45.00%
	Azithromycin	6	30.00%
	Amoxicillin + Clavulanic acid	5	25%

6.1.3. Findings of documents review

Overview of regulatory situation

The findings of the documents review show that in Ilu-Ababora zone there were 43 drug retail outlets, 97 clinics, 774 food & drinking establishments, 47 hotels, 155 butcher houses, 338 small & medium scale industries (e.g., mills), 216 beauty salons, 12 supermarkets, 2205 shops, 13 slaughter houses, and 34 different types of facilities (e.g., prisons, kindergartens, etc.,) to be inspected by the zonal health department regulatory teams in collaboration with each woredas regulatory teams. But, at the zonal health department there were two inspectors assigned out of four allowed in Oromia Region career structure for the regulatory activities; one environmental health and one public health professional. The public health professional was assigned for this department about a month ago without getting any kind of training (either gap filling or induction training). At the woreda level only the main town administration has two inspectors as the Oromia career structure allows. The rest have one or none (none for rural town) inspectors assigned for the regulatory activities. In all these, no pharmacy professional was assigned for the regulatory activity.

The legal and structural aspects of regulatory body

There was no job description for the key personnel at the zonal office, main town or rural woreda. But there were proclamation number 661/2009, 1112/2019 and Oromia Regional Health Bureaus medicine retail outlets licensure guideline at zonal office licensure guideline at main town and nothing at rural woreda. There were no lists of medicines specific for either of the retail outlets level (rural drug vendors, drug shops or pharmacies) at all the three offices. At both the zonal office and main town, there were checklists developed at regional level for practicing.

Separate office was available only for zonal level regulatory team; otherwise the woreda level regulatory teams undergo their activities by sharing room with other departments.

They don't have separate vehicles as well as no budget breakdown for regulatory activities. There was no complete list/database of all the licensed and inspected retail outlets. The good thing is that at zonal level, they have started registering on new software called multi facility register (MFR), a recently introduced database, but not fully automated.

Performance assessment

The zonal office and main town regulatory teams have annual plan breakdown for their main activities. Accordingly, there were 95 concise inspections conducted on medicine retail outlets excluding the inspection of other healthcare institutions and food establishments. Depending on the finding of the concise inspection and specific complaints received about non-compliance with standards of professional practice, they underwent additional six follow-up inspections, three special inspections and twenty investigative inspections within the fiscal year 2021/22 (Table 5). Among four new applicants one failed to meet regulatory requirements but the remaining three new retail outlets granted a license. On the other hand, all retail outlets that had been on duty had renewed their license except a single firm which had its license revoked. Three retail outlets were given warning letters while the other two firms were suspended for a while. There was no retail outlet found that can fulfill the criteria for the selection of model pharmacy.

Table 5: *Ilu-Ababora Zonal regulatory teams plan and achievement regarding medicine retail outlets inspection of the fiscal year 2021/22*

No.	Type of visit	Plan (No. of firms to be visited)	Achievement (No. of firms visited)	% achievement
1	Routine inspection	41	10	24.39
2	Concise inspection	164	95	57.93
3	Follow-up inspection	8	6	75
4	Special inspection	4	3	75
5	Investigative inspection	10	10	100

About complaint handling mechanism there was no standardized and easier way of complaint receiving means from the public on providers' irrational service. i.e., no phone line for a call; they only had suggestion book at their office exit. The public gives misconduct information by directly calling or sending text messages on the inspectors' personal cell phone whenever they got the opportunity.

6.2. The findings of Qualitative study

6.2.1. The socio-demographics of the Key Informants

25 key informants (KIs) with ages ranging from 26 to 62 were all interviewed. Concerning their work area, 6 were from zonal health department, 4 from main town health office, 3 from rural town health office, 7 from retail outlets and 5 were from the private clinics. Table 6 provides the respondents' complete socio-demographic profile.

Table 6: *Socio-demographic characteristics of key informants (n=25)*

Characteristics	Category	Frequency
Gender	Male	21
	Female	4
Age group (years)	25 – 30	2
	31 – 35	4
	36 – 40	13
	>40	6
Academic qualification	Master's degree	8
	First degree	12
	Diploma	5
Profession	Medical Doctors	4
	Pharmacist	5
	Health Officers	6
	BSc. Nurse	3

	Environmental Health	3
	Druggist	3
	Laboratory	1
Work experience (years)	1 – 5	7
	6 - 10	10
	11 - 15	5
	16 -20	1
	>20	3
Work Position	Manager (General, Deputy, or/and Technical)	7
	Inspector	4
	Proxy Inspector	2
	Retail outlet owner	7
	Clinic owner	5
Work area	Zonal health department	6
	Main town health office	4
	Rural town health office	3
	Drug retail outlets	7
	Private clinics	5

6.2.2. Key informants' perspectives on regulatory performance based on their experiences

The data saturation was reached on the thirteenth individual interviewed working in the regulatory bodies and on the twelfth individual for private sector participants. After that, the results of this study were analyzed and interpreted following manual thematic analysis on predetermined thematic areas and organized into 3 major themes including perception of the current regulatory practices, factors influencing the regulatory performance and impacts of regulatory activities on the healthcare system as well as the society. Eleven sub themes were found under the three main themes, and they are listed and explained as follows.

Theme 1: Perceptions of the Ilu-Ababora Zone's existing regulatory practice

As the KIs elucidated there was a perceived regulatory weakness (characterized by performance level below expected, stocking of medicines beyond what is allowed, dispensing by non-professionals, dispensing of antibiotics over-the-counter (OTC), and increased circulation of un-authorized products) and lack of proper implementation of regulatory policies

a. Perceived regulatory weakness

The finding of the interview revealed that the lenience of regulatory activity encouraged the retail outlets to participate in illegal business practice baldly. Some of the KIs elucidated this idea in this manner:

> *"…When we look at the challenges, sometimes inspectors show unnecessary sympathy for non-compliant institutions and leave them unpunished. I think this has propagated the non-compliance of those outlets." [R10, management member]*

> *"…inspection is mostly conducted as a campaign, when the license renewal period arrives or in the second quarter of the fiscal year. Knowing this cavity of the regulatory body, the retail outlets take part in illegal business activities without fear of penalty. So, it's to be expected anyway." [R7, Inspector]*

This study also revealed the performance level below expected of regulatory body, the availability of stocking of medicines beyond what is allowed, dispensing by non-pharmacy professionals, the dispensing of antibiotics without prescription, and increased circulation of un-authorized products.

Performance level below expected of regulatory body at the Zone

KIs were questioned during the interview regarding their opinions of the overall regulatory activities and the current status quo in the zone. As a result, the vast majority of them assessed and described the zonal regulatory performance as being poor, isolated, and reactive in nature. The following accounts from various informants served as evidence to support this:

> *"To be honest, I joined this business five years ago; but never saw any EFDA staff coming for inspection activities. Only health office staff rarely come having a checklist they don't even understand. So, it's hard to say inspection is there." [R15, Retail outlet]*

> *"The regulatory landscape is still developing and reactive overall. Instead of ongoing oversight, it looks to be a one-time campaign. Only when the reporting period arrives and certain non-compliance problems are there, the regulatory team addresses that specific problem. It closely resembles fire brigade work." [R5, Inspector]*

> *"Working here is like being sent for punishment. It's isolated from other teams; it doesn't have its own resources, budgets and so on. To tell the truth I'm not satisfied with this position." [R8, inspector]*

i. Stocking of medicines beyond what is allowed

This study shows both the retail outlets and private clinics hold medicines beyond their allowed list. Majority of the dispensers and the pharmacy owners raised an issue of not getting prescriptions from the available clinics at the expected rate and interference of those clinics in retail business too as the clinics are also dispensing the medicines beyond their allowed standard of service. These ideas were strengthened by:

> *"Your stocking capacity determines your survival in the market; that means you have to hold every drug that is required around this area even if you are not*

allowed. Otherwise you will be out of competition and sooner out of market." [R19, Retail outlet]

"Being a drugstore entrepreneur these days and making a profit is getting harder. Due to failure of regulatory inspection, the clinics have a stock of commonly prescribed medicines and as a result they render the patient a full range of services including dispensing of the drugs. To be honest, I prefer not to miss any opportunity I got to survive in such a business environment." [R17, Retail outlet]

Despite the fact that they consider themselves as one of retail outlets customers, some of the participants from private clinics reaffirmed a blame raised by retail outlets on them. They also raise an issue for their stocking of medicines beyond what is allowed as availability of whole sales prod to buy them restricted pharmaceuticals.

"…if you see our business, we get almost all the drugs we sell to our customers from these medicine retail outlets. That means they don't lose a single penny because of us." [R23, Private Clinic]

"At the time we demand first aid and emergency kit supplies, we enter into an obligatory deal of buying additional drugs they (wholesalers) over-stock. For example, last time I bought losartan 50mg additionally to get intravenous fluids since they refused to give us those fluids unless we buy losartan. So, what can I do with these drugs except sell them to the patient?" [R21, Private Clinic]

ii. Dispensing by non-professionals

According to this study, there was a drug dispensing by not only non-pharmacy professionals but also non health professionals dispense medicines. Some of the clinic owners revealed the recruitment of non-pharmacy professionals in the retail outlets for the dispensing and administration of drugs.

"When I'm busy and leave for a lapse of time, I allow the experienced accountant to cover for me. I know it's unethical; but I can't afford recruiting another pharmacy professional. [R20, Retail outlet]

"Recently, retail outlets have been taking away our jobs. They don't care about the regulatory authority; they diagnose and treat there; they even give injectables by recruiting non pharmacy health professionals. [R23, Private Clinic]

iii. Over-the-counter (OTC) dispensing of antibiotics

The majority of retail outlet workers who were questioned agreed with the finding drawn from the simulated patient visits that the OTC selling of antibiotics is a widespread practice.

"I know, dispensing antibiotics without a legal prescription is unethical; but so many expenses are waiting for me… as you know, I have to cover the house rent, pay salaries of employees, survive in this ever changing market, and so on. Besides, despite my refusal, a neighboring drugstore is prepared to issue. Thus, I commonly sell these products as an OTC running out of option."[R20, Retail outlet]

"Most customers are pretty much confident about what they are asking for. These clients will undoubtedly leave if we persist on not providing them these products (antibiotics), as they will be dissatisfied. Therefore, I prefer to give them what they want with the correct instruction of use". [R16, Retail outlet]

iv. Increased circulation of unsafe products

Some respondents claimed that the lack of a robust regulatory framework may increase the country's supply of SF goods. The availability of such drugs on the market could result from a lack of traceability and create an illicit pharmaceutical market. Legal

suppliers will be discouraged and those involved in the distribution of SF medications will be encouraged as a result of the regulatory body's insufficient audits and inspection.

> *"The absence of regular follow up and a decline in performance of regulatory teams were demotivating legal business practices and fueled the growth of illegal ones and promoted corrupt behavior." [R6, inspector]*

> *"This work is related to property and to human lives too. There are people who work only for money ignoring their professional oath. They dispense medicines irrationally; hold medicines that cannot be tracked by invoices, and keep poor cleanliness of their workplaces. Due to this, there were occasions we revoked their license." [R8, Inspector]*

b. Lack of proper implementation

Participants in all of the interviews acknowledged the need for regular inspections and supervisions in order to make appropriate decisions and execute the law. Nevertheless, the majority of the interviewees, particularly management members, stated that the regulatory activities were regular enough to effectively enforce the regulation.

> *"One of the problems is that there is no regular supervision; control assessment is rarely conducted. That means there are about four routes of inspection; we try to cover one route at a time and even cannot cover all institutions within that route." [R2, Management member]*

> *"For me, the zone's regulatory practices are not well-established. Despite the fact that the regulatory authority created and approved various regulations, guidelines, directives, and working standards, they are not effectively put into practice and remain paper tigers." [R1, Inspector]*

Theme 2: Factors influencing the regulatory performance

The KIs elucidated that a decline in performance of the regulatory body of the zone. Though the individuals assigned to that area strive to work hard personally, the problem still remains unresolved. Several variables appear to be responsible for these failures which are abridged as a wide coverage area for regulatory inspection with scarcity of resources, capacity building problems, information leakage problem, lack of coordination with stakeholders, communication-related issues and lack of access to pharmaceutical services in these areas.

i. Wide coverage area for regulatory inspection

According to the saying of the KIs, the inspection area in the zone is very vast compared to the resources available for regulatory activities. It includes drug retail outlets, clinics, food & drinking establishments, hotels, butcher houses, small & medium scale industries like mills, beauty salons, supermarkets, shops, slaughter houses, and different types of facilities like prisons. This was strengthened by the following account.

> *"Our Zone is so large that the zonal regulatory team cannot reach each and every institution in all the woredas. It means that the woreda teams continue from the area that remained unreached by the zonal team. They then send us a report once a quarter. Finally, the aggregate report of all woredas will be sent to the regional bureau quarterly." [R1, Inspector]*

> *"There are many organizations that are generally related to health and controlled by the Health Office. However, the most talked about is the inspection of supply of medicines and healthcare providing facilities. As of our office, however, all these institutions (facilities related to the health of the society) are inspected and controlled despite the scarce resources that we have." [R3, Management member]*

ii. Scarcity of Resources

a) Lack of assigned professionals in the team

The participants from the health offices mentioned that there were inadequacies in human resources. For an inspection to be successful, a qualified expert with theoretical knowledge, practical training, and experience is required. However, the regulatory team was low on qualified personnel. Inspection and supervision tasks were being carried out by inexperienced individuals, but these tasks necessitate a thorough understanding of regulatory affairs. Professionalism in medical regulatory activities includes both specialization in the field and having at least a basic understanding of pharmaceuticals. Lack of a career structure to accommodate all the required professionals was also an issue raised by the participants.

> *"As a provincial (zonal) health sector, there was a scarcity of human resources. The team would include a variety of professionals. But, in this team you probably couldn't even find a pharmacist; we get them from another group. Currently available specialties are only environmental health and a newly added Public Health professional." [R4, Inspector]*

> *"…there is also another gap in the structure... It means that the career structure didn't expand the space needed for regulatory activities. Although the structure should accommodate food and medicine sub groups, we couldn't even fill the allowed personnel. And hence, this lack of human resource caused a decline in performance from that area." [R2, Management member]*

> *"One of the gaps in performance is the lack of assignment of a full-fledged expert, which means that the expertise is not complete which can perform as a team. Sometimes the professional goes to inspection as a proxy inspector from another group and the reason for the decline of his performance in the regulatory team is that he has other regular jobs he gives priority and is going to be evaluated at." [R6, Management member]*

b) Lack of logistics for regulatory activities

The regulatory activities are mostly field works and hence need a budget for its accomplishment. However, only salaries are budgeted for the assigned personnel. Since all aspects of resource allocation are at a very critical stage of shortage, the regulatory team falls short of making timely inspections. The interviewees from the health offices revealed that:

> *"As is well known, this group does not have its own budget, its own vehicles, and its own resources. Neither the bureau nor the regulatory authority has paid attention to this issue nor has nothing been done so far. We also don't have partners to support us." [R1, Inspector]*

> *"What bothers us is that there is no budget for routine regulatory activities. For example, going to supervision requires fuel, per diem, logistics, etc. but the regional bureau has never allocated any resources for the regulatory work. We try to cover it from other departments' budgets." [R3, Management member]*

The availability of standby vehicles plays a vital role in inspection activities since almost all the regulatory activities are field works and require cars. Though it's difficult to get a car assigned only for regulatory work due to scarcity of budget, some of the interviewees recommended provision of logistics, especially cars for a bit longer duration of days.

> *"Not getting a car continuously for some uninterrupted days is a hindrance to us. You need to get a car for at least two or three consecutive weeks to reach those fourteen districts I told you about. They give you a car for inspection, after you have inspected for three or four days, they call you back since the vehicle is needed for some other work. So, you interrupt the inspection and continue the next time you get a car." [R1, Inspector]*

c) Capacity building problem

Participants said that neither long-term nor short-term professional training was provided to the workforce. Some of the zonal management members explained the issues as follows,

> *"We (the inspectors) don't have a detailed understanding of what drugs are to be held by which institutions. Since no gap-filling or basic training has been given to us so far, this could be one reason for the ineffectiveness of the regulatory work." [R4, Inspector]*

> *"...It is important to stress and put into practice the hiring of inspectors who have received professional training. The majority of the staff ought to have at least basic training in food and medicine regulatory matters. However, these capacity building opportunities are never facilitated by the Office (Regional Bureau)." [R5, Inspector]*

d) Information leakage

Some of the health sector participants affirmed information leakage within the regulatory teams. This handing over of critical information like warning the institution before the arrival of the inspection team is playing a major role in creating a gap for enforcement of regulation. This has contributed to a wide spread of OTC sale of prescription drugs, involvement of unauthorized personnel in the dispensing activity, unauthorized holding of medicine, trading of medicine beyond profit margin etc., within the zone.

> *"... What is occasionally seen in regulatory teams at the district level is that some of the inspection team members try to help the suspects escape from punishment by sending them a warning message about our movement. It means that there are also government bodies that keep these suspects from being tracked at their workplace." [R4, Inspector]*

"Upon receiving rumors on some institutions including clinics about the breach of the laws we leave the office for inspection. But, by the time we arrive there everything looks all right. This is a kind of indicator for the availability of renegade (information leaker) among us." [R11, Inspector]

e) Lack of coordination with stakeholders

As is well known, regulatory activity is the result of cooperation (teamwork) amongst all stakeholders, including the general public in controlling the movement and use of unsafe drugs. Nevertheless, this study reveals that regulatory activity is an abandoned area by all stakeholders. Especially regional health bureau and also there are no partners working with this team at Zonal level.

Coordination with various bodies is required. We need to work in collaboration with the EFDA, the Trade office, the Revenue office, the Security bodies and the like to strengthen this control and inspection activities. [R2, Management member]

"We know the amazing role partners are playing in building the capacity of EPSS throughout the supply chain activities. I believe we deserve similar support from partners. Hence, the concerned governmental body should invite those partners willing to support regulatory activities." [R5, Inspector]

"We must work together with private sector associations too. Why is it that one threats and the other is threatened? To avoid this, the capacity of both the controlling body and the controlled one should be strengthened" [R3, Management member]

f) Communication-related issues

Participants emphasized the value of having an organized information exchange. Effective communication promotes transparency and trust, which also helps to create law-abiding citizens. However, the communication between the private institutions, zonal

regulatory teams, regional health bureau and EFDA was not as it should be. They do not follow formal communication schemes; i.e., no written reports and feedback throughout the chain (starting from retail outlets to regional health bureau). Frequently, their communications were inadvertent. Following is one of the zonal participants' explanations of the problem:

> *"I believe that ineffective departmental, stakeholder, and company collaboration will negatively impact both the overall effectiveness of rules and the success of inspections. There is no established method of communication between the parties, and in an emergency, telegram groups are the only available channel of communication." [R4, Management member]*

Regulators should have well-established procedures for gathering information on the performance of providers because this is essential in enabling them to assess whether providers are delivering the outcomes they intended and whether regulatory intervention is required if providers fall short of their expectations. But this wasn't depicted in the actual scenario.

> *"There is a huge gap of communication between us (regulators and retailers) I can say. They don't request us for a report and also don't give us any updates on drug lists, treatment guidelines, inspection checklists, etc. For example, I heard esomeprazole holding permission grants for drugstores from wholesalers when they started to supply us with invoices. Previously they gave us such pharmaceuticals without invoice." [R19, Retail outlet]*

Additionally, the participants from retail outlets stated lack of staff motivation to prepare reports that would be submitted to the office regularly.

> *"We (retailers) generate a lot of data reports and also keep different types of prescriptions upon our previous governmental experience. But, there is no one looking for those reports; it took them so long to return back and ask for those*

reports; even they forget. As a result, we abandoned that boring process since it only adds a work burden." [R18, Retail outlet]

Besides, some of the respondents from regulatory teams reported distrust of court decisions. When there is a dispute between the firms and the inspectors the case will sometimes go to the court which is responsible for providing the final decision and it will become subjective they said. This ultimately results in delay of enforcement of the regulation and discourages the inspectors.

"Failing to comply with guidelines; there are efforts made by private companies to start the business without obtaining the license from our office. When action is taken against their doings, they try to escape punishment and hence are accused. Nevertheless, there are times when the legal bodies (courts) inclined toward them and even dropped the charges we submitted saying that the way we did the inspection was not correct. This shows the presence of miscommunication between us and misinterpretation of the law" [R6, management member]

g) Lack of access to pharmaceutical services in these areas

Nowadays, pharmacies serve as a primary source of healthcare, thus clients frequently come to them directly. This makes it difficult to strictly enforce laws against nonconforming firms, especially in remote places. This issue is strengthened by the following account:

"Despite illegal individuals trying to operate without permission in some rural hard to reach areas, there are occasions when these illegal institutions were misunderstood and considered right among society. For example, in the rural areas of a couple of villages where we are contacted, action was taken against these illegal institutions and the community argues that the action we take was not right and raised a question that they are going out of options. Therefore, awareness has been created among the society to convince them and combat such illegal acts." [R13, management member]

"In rural communities, where there is no health center and only health posts are available, illegal institutions deceive the society and are accepted as if they are doing right. When we enforce the law on them, the society misinterprets it as if we mistakenly took an action. Understanding the case, then we created awareness that we are ready to license them if they (the institutions) get into the right track." [R9, management member]

Theme 3: Impacts of regulatory activities on the healthcare system as well as the society

Regulatory actions that are ineffective and poorly planned will affect the overall health care system in a variety of ways. Participants pointed out several important repercussions that will follow from a weak and ineffective regulatory procedure. Among the frequently cited effects were compromising the patient's quality of care as well as economic and cost repercussions.

a. Compromise the standard of patient care

The majority of respondents stated that the lack of an adequate regulating practice in the region will expose patients to unfavorable harm and undermine patients' quality of care, ultimately putting the entire health system in danger. The following quotes strengthened this even more:

"This time professionals are ignoring their profession and act only money-centered. They are using medications that they shouldn't prescribe or treat with it. This is because they only wanted to increase the source of their income and it is causing different effects. Especially in malaria predominant areas, we were having various problems because these people tried to treat what they should not have. Someone gives the patient the wrong medication in a small clinic and then the patient's condition even gets worse. [R3, Management member]

b. Cost implication and economic impact

Regarding the economic impact and related expenses, the majority of KIs stated that drugs are not only a crucial part of providing healthcare, but also a benefit to the national economy. It has an effect on both the national economy as a whole and the household budgets of the people. Key informants confirmed that indirect costs such as the unproductive working conditions brought on by prolonged hospital stays may have an influence on the social economy in addition to the unintentional expenses associated with the poor regulatory system.

> *"A solely financial-driven pharmaceutical product supply may result in patient harm rather than benefit, and the community would suffer as a result of those medications used for their medical condition. Prolonged hospitalization, additional expenditure on drugs, and lack of confidence in the treatment are some of the visible effects of a poor regulatory system. [R5, management member]*

7. DISCUSSION

This study tried to evaluate existing regulatory practice, the internal gaps and challenges within the regulatory body, external factors, and its impacts on the healthcare system and the society. As far as the researcher is aware, this is the first thorough sequential mixed-methods study to evaluate and record the regulatory performance of Ethiopia's zonal offices regulatory teams.

The study's quantitative and qualitative findings indicated that the current regulatory practice at Ilu Aba Bora zone shows a weak regulatory system in performance. The regulatory activities were not regular enough to enforce the regulation appropriately. Regulatory work is not a kind of job done once and end, it needs routine follow up (WHO, 2021). This irregularity of inspection gave health institutions courage to follow their own economic desire than provide primary health care services within their allowed professional territory. The interview result as well as the simulated patient visits confirmed the presence of non-prescribed sale of antibiotics. This discovery shows that 91. 66% of antibiotics are sold without a prescription, which is a lot higher than the global average of 62% (Auta et al., 2019). But, it is comparable to studies done at Hazara division Pakistan at which antibiotics were given to 90.5% of patients without a prescription to simulated cases (Ahmad et al., 2022). And is a bit lower than the earlier studies conducted in Mizan-Aman, South-West Ethiopia in which antibiotics were frequently issued (94.4%) without a doctor's order at retail outlets around that area (Damisie et al., 2019). A different study in Eritrea found that 87. 6% of antibiotics were given without a prescription (Bahta *et al*., 2020) which was lower than our study.

The fact that the majority of antibiotics were distributed at first demand level demonstrates the dispensers' negligence with regard to the sales of medications that call for a prescription from a doctor. This can be one indicator of the level of performance of the regulatory bodies in the Zone with regard to prescription-only drug control. A similar occurrence was discovered in a study conducted in Mizan-Aman, Ethiopia, where most antibiotics were given out when the simulators requested any drug to ease their pain,

(Damisie et al., 2019). On the other hand, the Jordanian investigation revealed that 59.2% of antibiotics were obtained through the first level of demands (Almaaytah et al., 2015). This variation could be brought on by variations in sample size and study design. With all three levels of requests, only two drugstores refused to dispense antibiotics without a prescription. These findings show that, although being against the law, the sale of antibiotics without a prescription persists in Ilu.Ababora, Ethiopia.

The document review section also strengthens the above finding in that the rate of routine inspection is only 24.39% while investigative inspection was 100%; an activity resembling fire brigades work. Nevertheless, some studies suggest that lower frequency and less severe sanctions of regulatory visits were blamed for poor compliance (Miller and Goodman, 2016). The first theme in the qualitative study supports the findings from both the simulated client and document review. It shows that there are problems with the way regulations are enforced in the area. Along with the irregularity of the inspection activities, inspectors occasionally exhibit needless compassion for institutions that are not compliant. This was also the case in Ambo town, Ethiopia, where no strict monitoring of compliance requirements observed (Gutu 2020). Having in mind the role of the lenience of the regulatory body to this malpractice (OTC sale of antibiotics); supposed financial benefit, customer retention and competition among pharmacies and clinics also plays a crucial role in promoting it. If it were effectively implemented, the regulatory practice results in positive changes in the behavior of professionals or entities regulated (Coglianese, 2012).

The second theme's first four subthemes discuss the regulatory body's internal gap and difficulties as the cause of its poor performance. A wide coverage area for regulatory inspection and a visible scarcity of resources due to lack of adequate attention from both the regional health bureau and EFDA were playing a major role for this shortcomings. There were inadequacies in human resources; even the available personnel lack experience, skill and training regarding medicine regulation. The inspectors lack knowledge and comprehension on which drugs should be kept by each institution. Though teaching institutions like Addis Ababa University and Jimma University have

started delivering post graduate programs in regulatory affairs, no one from the entire Zone had been sent for education. Availability of renegade within the health office should not be undermined as well since it plays a major role in creating a barrier for tracking down illegal business activities like OTC sale of prescription drugs, involvement of unauthorized personnel in the dispensing activity, unauthorized holding of medicine and the like. Nevertheless, Regulatory activity needs a lot of organizational capacity, resources, and continual vigilance to regulate the increasingly complicated pathways of pharmaceutical delivery (EFDA, 2017)

This was also supported by findings from documents review. At the zonal health department, there were only two inspectors instead of the four who are supposed to be there based on the career structure. Only the main town had two full inspectors, as required by the career structure. The other woredas have either one or no inspectors assigned. The way the Oromia health bureau organizes its career structure has a big issue in how it assigns and manages its staff. Even if the career structure is filled, the professional mix required for regulatory activities would still not be met. Both the licensing guideline and the checklists developed at Oromia regional level focuses on personnel, premises, practice, but not products. With no budget allocated and scarcity of logistics, it is not feasible to be effective in regulatory activities which are mostly field works.

The challenges for proper performance of regulatory activities are not limited to internal gaps; but also external factors creating difficulty for the regulatory team are there. It is vital to have an organized information exchange between stakeholders. The study reveals the presence of an information gap throughout the chain of command. The flow of reports between the private institutions, zonal regulatory teams, regional health bureau and EFDA was not as it should be. The understanding and interpretation of medicine regulations are mostly in favor of non-compliant institutions. This ultimately results in delay of enforcement of the regulation and leads to distrust of court decisions by the inspectors; hence discourage them also. Though the ultimate victim of illegal business is the society, sometimes the society itself challenges the regulatory teams because of

rational drug use awareness lack. Similar result was found at Guji and West Guji Zones , Oromia; where the community relies heavily on informal pharmaceutical practice (Shonora 2020).

The findings of this research expose that antibiotics were easily accessible, which plays a significant role in a widespread antibiotic resistance (Haddadin et al., 2019). Additionally, this may lead to resource wastage to the patient owing to the need for extra prescriptions, hospitalizations for antibiotic failures, and experience of adverse drug reactions (Dalton and Byrne, 2017). In this way regulatory practice failure could bring significant impacts on the society and the healthcare system as well.

The World Health Organization considers broad-spectrum antibiotics like ciprofloxacin, amoxicillin, amoxicillin plus clavulanic acid, and azithromycin—many of which were distributed without a prescription—to be critically important medications (WHO, 2019a). The chance of developing a resistant infections increases with the use of broad-spectrum antibiotics. Even in situations where there are similarly effective narrow spectrum antibiotics that can be utilized as first line therapy, these medicines were frequently praised. For example, in comparison to the first-line narrow spectrum antibiotic trimethoprim, ciprofloxacin is more likely to be selected for and even administered to simulated patients who were of childbearing age without any verification of their pregnancy status. A similar case was detected from Pakistani (Ahmad et al., 2022) and Eritrean (Bahta et al., 2020) studies. In addition to being in the WHO antibiotics watch group (WHO, 2019b) and belonging to the fluoroquinolone class, ciprofloxacin poses a threat due to cross-resistance to other fluoroquinolone medications, especially for those used in the second line of anti-TB treatment (Von Groll et al., 2009).

8. STRENGTHS AND LIMITATIONS OF THE STUDY

One of the study's strengths was that it made an effort to consider and evaluate the system-based regulatory practices and activities of two important stakeholders (regulatory body and retail outlets) who are crucial to managing and maintaining drug safety. The quantitative data is accompanied by qualitative results in order to further explore ideas that the quantitative data is unable to address, such as barriers to the implementation of regulatory activities and prospective changes. In an atmosphere resembling the study setting, the neighboring Buno-Bedele zone, the checklist and interview guide questions were pretested, and any necessary modifications were made. High reliability and validity for objective evaluation are provided by the metrics' adapted from the "WHO Data Collection Tool for the Review of Drug Regulatory Systems," released by the WHO (WHO, 2007). The study's conclusions may also be helpful for enhancing stakeholder communication and acting as a starting point for additional research on the topic.

Additionally, the current study has its own constraints. The biggest obstacle to this study's completion is the lack of comparable studies to compare. The generalizability of the study results may be impacted by the fact that the study did not collect data from a representative sample of the health facilities located in the zone and regulatory authorities at the regional level. Moreover, for the reason that the examined companies' recording and documentation systems were poor, the researcher for this study was unable to obtain crucial process and outcome indicators of the regulatory system, which may have obscured the overall image of regulatory operations in the study setting.

9. CONCLUSION

Despite the availability of comprehensive medicine regulations, the results of this study prove that the enforcement of these regulations is weak and the current regulatory practice in Ilu-Ababora shows a frailty in performance. This idea was strengthened by the current situation observed in business activities of the area; i.e., medicine retail outlets of the zone prioritize business-related activities over providing essential healthcare service to the local population. With all those resource shortages and a lack of autonomy, the Ilu-Aba Bora zone's regulatory performance was, in general, still in its early stages of growth. A strong and multifaceted strategy is necessary to address this issue and ensure that pharmacy practices are in line with national recommendations for rational dispensing practice in addition to strict law and policy enforcement. After this one, a broader study with a wider range of research settings might be carried out to get a greater understanding of what is exactly there across the country.

10. RECOMMENDATIONS

To EFDA

- ✔ Provide regular capacity building training to the zonal and woreda regulatory bodies' professionals as well as private sector health professionals.
- ✔ Provide supportive supervision to the zonal and woreda regulatory bodies'.
- ✔ Harmonize the country's regulatory system.
- ✔ Prepare a platform that facilitates the communication and collaboration of all stakeholders including regional health bureau, zonal regulatory teams, and private institutions. The platform should also accommodate the Commerce office, the Revenue office, the Security bodies and the like to strengthen this control and inspection activities.

To Oromia Regional Health Bureau

- ✔ Give adequate attention to the regulatory sector. It needs reinforcing the team with a subject-matter specialist, a suitable professional mix, updating them through training, and automation.
- ✔ Revise career structure of the regulatory teams discussing with EFDA.
- ✔ Allocate proper budget and at least a single vehicle dedicated for the regulatory activities of the Zone.

To Ilu-Ababora Health Bureau

- ✔ Use a pool system of professionals and resources for a short term problem solving; i.e., it's better to have a strong central regulatory team than having idle teams at each woreda.
- ✔ implement awareness creation training and public communications to address the society's pervasive lack of understanding on the rational use of pharmaceuticals. Then, it will become easier to combat those illegal traders.
- ✔ Conduct regular inspection and monitoring on the regulated institutions.
- ✔ Implement disciplinary regulations to achieve more prudent regulatory performance.

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ANNEXES

Annex I (English version questionnaire)

Addis Ababa University
College of health sciences, School of pharmacy
Department of pharmaceutics and social pharmacy
Consent form for in-depth interview

Introduction

The purpose of this questionnaire is to collect data during an in-depth interview with key informants. The information is required for the thesis entitled '***Assessment of Medicine Regulatory Performance in South - West Ethiopia: The Case of Ilu-Ababora Zone, Oromia Regional State'*** which is being conducted as a partial fulfillment of MSc degree in regulatory affairs (medicine). I'm a postgraduate pharmacy student researching the aforementioned area of study. Finding the primary causes of performance issues and formulating recommendations based on the research's findings are its main goals. Regulatory bodies might use the recommendation to identify modifiable components and take appropriate action to enhance public services. In order to obtain the information I require, I'm offering a semi-structured interview guide. The interview will last 15 to 30 minutes and take place wherever is most convenient for you.

Your participation is entirely voluntary, and we promise to keep any information you share fully private. Your name will never be mentioned in the written or vocal reporting of the publication, and the aggregate responses from many respondents will only be referenced by codes. However, direct quotes from your response may be utilized. Nevertheless, the interview may be recorded using a tape recorder.

Your truthful response to the inquiry is crucial to the study's effective conclusion. There is no right or wrong response, and you can ask for clarification if you're unsure about a question. Are you ready to answer the questions?

Yes/No: _____

Thank you,

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Mettu, Ethiopia.

Questionnaire for Regulatory Teams and management Members at Oromia Regional Health Bureau, EFDA Jimma branch, Ilu Ababor Zonal Health Department, and Woreda level

SECTION A: General information about the Regulatory Team in the bureau.

1. Code given to the bureau: _____
2. Age of the respondent: _____: Sex of the respondent: _____
3. Date of interview: _____ Venue: _____
4. Current position of the respondent: _____
5. Years of working experience in current position: _____.
6. Telephone: _____Fax _____ E-mail_____

SECTION B: Questions based on research topic.

1. How are the regulatory activities like in your area of work?

   _____
   _____

   1.1. What establishments are regulated under your institution?

   _____

2. What are the facilitators and barriers to your regulatory activities?

   _____
   _____

3. The simulated client study result shows the presence of OTC sale of antibiotics and holding medicines above the allowed lists. What do you think the reason for such kind of breach of laws?_____
   _____

4. According to your observations, what problems or worries have retail establishments, the public, and other healthcare professionals spoken about the regulatory body?

   _____
   _____

5. Would you tell me how you communicate with different stakeholders such as EFDA/Health offices, trade bureau, police and local administrative officials, etc.?

   _____
   _____

6. How do you measure the performance of regulatory team?

   _____
   _____

7. What opportunities are there for improving regulatory capacity in Ilu Ababor zone?

   _____
   _____

8. How satisfied are you in your current position?

   _____

9. I now give you the chance to raise any other issue that I have not addressed.

   _____

Thank you for your cooperation!!!

Questionnaire for Private Healthcare Providers and focus groups

SECTION A: General information

1. Code given to the organization: _____
2. Type of organization (Please add (√) as appropriate)
   Pharmacy: ☐ Drug Store: ☐ Rural drug vendor: ☐ Clinic: ☐
3. Number of employees in this firm: _____
4. Respondents designation (Please add (√) as appropriate)
   Owner of organization ☐ Employee ☐ other _____
5. Profession of participant _____
6. Sex of the respondent: _____ Age of the respondent: _____
7. Date of interview: _____ Venue: _____
8. Relevant working experience in year(s) by this profession._____
9. Telephone: _____Fax _____ E-mail_____

SECTION B: Questions based on research topic.

1. Could you tell me your thoughts on the current medicine regulatory activities?
   _____
2. Can you discuss flow of reports with regulatory body?
   _____
   _____

2.1. How do you get information when there is a change in policy, checklists, specification etc...? _____
   _____

3. What kinds of challenges did you think you face in adhering to the specifications of regulatory body?
   _____
   _____

4. What is the motivation behind non-prescribed sale of antibiotics?
   _____
   _____

5. What personal views do you have on inspectors' competency?
   _____
   _____

6. In recognizing certain potential issues that you and regulators may have, what suggestions would you make to enhance regulatory activities?
   _____
   _____

7. How satisfied are you in the regulatory bodies' performance in your area?
   _____
   _____

8. I now give you the chance to raise any other issue that I have not addressed.
   _____

I appreciate your assistance!!!

Annex II (Amharic version questionnaire)

በአዲስ አበባ ዩኒቨርሲቲ

የጤና ሳይንስ ኮሌጅ፣ የፋርማሲ ትምህርት ቤት

የፋርማሲዩቲክስ እና ማህበራዊ ፋርማሲ ትምህርት ክፍል

ቃለ መጠይቅ ማድረጊያ የስምምነት ቅጽ

መግቢያ

ይህ መጠይቅ የተዘጋጀዉ ከወሳኝ መረጃ ሰጭዎች በጥልቅ ቃለ-ምልልስ መረጃን ለማግኘት ሲሆን መረጃዉም በደቡብ -ምዕራብ ኢትዮጵያ፣ ኦሮሚያ ክልል፣ የኢሉባቦር ዞን የመድኃኒት ተቆጣጣሪ አካልን የስራ አፈፃፀም በመመርመር በመድኃኒት ቁጥጥር ጉዳዮች የድህረ-ምረቃ ዲግሪ ማሟያ (የመመረቂያ ፅሁፍ) እንዲሆን የሚጠናዉ ጥናት አካል ነዉ። እኔ በተጠቀሰው የምርምር ርዕስ ላይ ጥናት የማደርግ የድህረ ምረቃ ፋርማሲ ተማሪ ነኝ። የምርምሩ ዋና ዓላማ የአፈጻጸም ችግርን የሚያስከትሉ ዋና ዋና ምክንያቶችን መለየት እና በግኝቶቹ ላይ የተመሰረቱ ምክረ ሃሳቦችን መስጠት ነው። የምክረ ሃሳቦቹ በዋናነት የሚያገለግሉት የቁጥጥር ባለስልጣናትን ሲሆን ሊሻሻሉ የሚችሉ ችግሮችን በመለየት የተሻለ የህዝብ አገልግሎት እንዲሰጡ ሊረዷቸዉ የሚችሉ ናቸዉ። አስፈላጊውን መረጃ ለማግኘት ሲባል በከፊል የተዋቀረ የቃለ መጠይቅ መመሪያን በመከተል ቃለ-መጠይቁ በሚመችዎ ቦታ ላይ የሚደደረግ ሲሆን ከእርስዎ ጊዜ ከ15-30 ደቂቃዎች ብቻ ይወስዳል።

የእርስዎ ተሳትፎ ሙሉ በሙሉ በፍቃደኝነትዎ ላይ ብቻ የተመሰረተ ሲሆን የሚሰጡን መረጃም ሙሉ በሙሉ በሚስጥር ይጠበቃል። በምርምር ሥራዉ የጽሑፍ እና የቃል ሪፖርቶች ውስጥ ጥቅም ላይ እንዲውል ቀጥተኛ ጥቅሶች ከእርስዎ ምላሽ ሊወሰዱ ቢችሉም የእርስዎ ስም በጭራሽ አይጠቀስም፤ እናም ከተለያዩ ተሳታፊዎች የተሰበሰቡ ጥቅል ምላሾች በኮዶች ብቻ ተለይተው ይታወቃሉ። ነገርግን በቃለ መጠይቁ ወቅት የድምፅ መቅጃ መጠቀም ሊያስፈልግ ይችላል።

ለጥናቱ ስኬታማነት በእያንዳንዱ ጥያቄ ላይ የእርስዎ ሐቀኛ መልስ የላቀ ጠቀሜታ አለዉ። ትክክለኛ ወይም የተሳሳተ መልስ የለምና ጥያቄዎቹን በተመለከተ ለማንኛውም ጥርጣሬ ማብራሪያ ማግኘት ይችላሉ። ለጥያቄዎቹ ምላሽ ለመስጠት ፈቃደኛ ነዎት?

አዎ ☐ *አይ* ☐

አመሰግናለሁ!

ተስፋሁን ግርማ
የአዲስ አበባ ዩኒቨርሲቲ፣
የጤና ሳይንስ ኮሌጅ ፣ የፋርማሲ ትምህርት ቤት፣
የፋርማሲውቲክስና የማኅበራዊ ፋርማሲ ትምህርት ክፍል፣
በመድሃኒት የቁጥጥር ጉዳዮች፤ የድህረ ምረቃ ተማሪ
ስልክ +251 917 83 07 86
መቱ ፣ ኢትዮጵያ

ለኦሮሚያ ክልል ጤና ቢሮ፣ በጂማ ከተማ ለሚገኘዉ የመድሀኒት ቁጥጥር ባለስልጣን ቅርንጫፍ ፣ለኢሉባቦር ዞን ጤና ጽ/ቤት እና በወረዳ ደረጃ ላሉ ጤና ጽ/ቤት አመራር አባላት እና የቁጥጥር ቡድኖች የተዘጋጀ መጠይቅ

ክፍል ሀ - በቢሮዎ ውስጥ ስላለ ተቆጣጣሪ ቡድን አጠቃላይ መረጃ።

1. ለጽ/ቤቱ የተሰጠ መለያ ቁጥር፡ _____
2. የቃለ-መጠይቁ ተሳታፊ ዕድሜ _____
3. የቃለ መጠይቁ ቀን:_____ ቦታ: _____
4. የአሁኑ የስራ መደብዎ (ድርሻዎ) _____
5. አሁን ባለው የሥራ መደብዎ ላይ ያለዎት የሥራ ልምድ ዓመታት _____።
6. ስልክ_____ ፋክስ _____ ኢሜል _____

ክፍል ለ - ከምርምር ሥራዉ ጋር ተዛማጅነት ያላቸዉ ጥያቄዎች።

1. በስራ አካባቢዎ የቁጥጥር ተግባራት ምን ይመስላሉ? _____
_____

1.1. በስራ ክፍልዎ (በመምሪያዎ) ስር ምን ዓይነት የንግድ ድርጅቶች ቁጥጥር ይደረግባቸዋል?
_____
_____

2. ለቁጥጥር ተግባሮቻችሁ አጋዥች እና እንቅፋቶች ምንድን ናቸው?
_____
_____

3. ታማሚ መስሎ በመቅረብ የተሰራዉ ጥናት ውጤት አንቲባዮቲክ መድሃኒቶችን ያለ ሃኪም ትዕዛዝ የመሸጥ እና ከተፈቀዱ ዝርዝሮች በላይ መድሃኒቶችን መያዝ እንዳለ ያሳያል። ለእንደነዚህ አይነት የህግ ጥሰት ምክንያቱ ምን ይመስላችኋል?
_____
___ _____

4. የተቆጣጣሪዎች የቁጥጥር ልምድ/ብቃት ከልምድዎ፣ በችርቻሮ ድርጅቶች፣ በህብረተሰቡ እና በሌሎች የጤና ተቋማት በተቆጣጣሪ አካሉ ላይ የተነሱ ጉዳዮች ወይም ስጋቶች ምንድን ናቸው?
_____
_____

5. ከተለያዩ ባለድርሻ አካላት ማለትም እንደ መ/ቁ/ባለስልጣን፣ጤና ቢሮ፣ ንግድ ቢሮ፣ ፖሊስ እና የአካባቢ አስተዳደር ኃላፊዎች ወዘተ ጋር እንዴት እንደሚገናኙ ሊነግሩኝ ይችላሉ?
_____
_____

6. የቁጥጥር ቡድንን አፈጻጸም እንዴት ይለካሉ?
_____
_____

7. በኢሉአባቦራ ዞን የቁጥጥር አቅምን ለማሻሻል ምን እድሎች አሉ?
_____
_____

8. አሁን ባሉበት የስራ መደብ ምን ያህል ረክተዋል? (ለተቆጣጣሪዎች)
_____
_____

9. እኔ አሁን ያላነሳሁትን ሌላ ማንኛውንም ጉዳይ እንድያነሱ እድል እሰጦታለሁ።
_____

ስለትብብርዎ አመሰግናለሁ!!!

ለግል የጤና ተቋማት የተዘጋጀ መጠይቅ

ክፍል ሀ - በቢሮዎ ውስጥ ስላለ ተቆጣጣሪ ቡድን አጠቃላይ መረጃ።

1. ለድርጅቱ የተሰጠ መለያ ቁጥር፡ _____
2. የተቋሙ ዓይነት
   ፋርማሲ ☐ መድሃኒት መደብር ☐ የገጠር መድሐኒት መሸጫ ☐ ክሊኒክ ☐
3. የተቋሙ ቅጥረኞች ብዛት _____
4. የቃለ-መጠይቁ ተሳታፊ ደረጃ
   የተቋሙ ባለቤት☐ የተቋሙ ቅጥረኛ ☐ሌላ ካለ ☐
5. የቃለ-መጠይቁ ተሳታፊ ሞያ ዓይነት _____
6. የቃለ-መጠይቁ ተሳታፊ ጸታ _____ ዕድሜ _____
7. የቃለ መጠይቁ ቀን:_____ ቦታ: _____
8. በዚህ ሞያ ያለዎት የሥራ ልምድ ዓመታት _____።
9. ስልክ_____ ፋክስ _____ ኢሜል _____

ክፍል ለ - ከምርምር ሥራዉ ጋር ተዛማጅነት ያላቸዉ ጥያቄዎች።

1. ወቅታዊዉን የመድሃኒት ቁጥጥር ስራዎች በተመለከተ የሚሰማዎትን ልያካፍሉኝ ይችላሉ?
   _____
   _____
2. ከቁጥጥር ባለስልጣኑ ጋር ስለሚደረግ የሪፖርት ፍሰት መነጋገር እንችላለን?
   _____
   _____

a. የፖሊሲ፣ የቼክሊስት፣ የድንጋጌ... ለዉጦች ሲደረጉ በምን መንገድ ነዉ የሚደርሳችሁ (የምትሰሙት)?_____
   _____

3. የቁጥጥር ባለስልጣኑን የህግ ድንጋጌዎች ከመታዘዝ አንፃር ምን አይነት ችግሮች ያጋጥመናል ብላችሁ ታስባላችሁ?_____
   _____
4. መድሃኒቶችን ያለሀኪም ትዕዛዝ ለመሸጥ የሚያነሳሱ ነገሮች ምንድን ናቸዉ?
   _____
   _____
5. በተቆጣጣሪዎች ብቃት ዙሪያ በግልዎ ምን ምልከታ አለዎት?
   _____
   _____

6. በእናንተም ሆነ በቁጥጥር ባለስልጣኑ በኩል ይኖራሉ ተብለዉ የተነሱ ችግሮች እንዳሉ ሆነዉ; የህግ ተገዢነትን በማሻሻል ረገድ ምን አይነት የመፍትሔ ሃሳብ ያቀርባሉ?
   _____
   _____
7. እዚህ አካባቢ በሚሰራዉ የቁጥጥር ባለስልጣን የስራ አፈፃፀም ምን ያህል ደስተኛ ነዎት?
   _____
   _____
8. ያላነሷኋቸዉ ሀሳቦች ካሉ እንዲያነሷቸዉ ዕድሉን ልስጥዎት።

_____

ስለትብብርዎ አመሰግናለሁ!!!

Annex III (Afan-Oromo version questionnaire)

Yuunivarsiitii Addis Ababaatti

Kolleejjii saayinsii fayyaa, Mana barumsaa faarmaasii,

Kutaa Faarmaasiiyuutiksii fi Faarmaasii Hawaasummaa

<u>Unka hayyamaa af-gaaffii gadi fageenyaa</u>

<u>Seensa</u>

Gaaffiin kun af-gaaffii gadi-fageenyaan odeeffattoota ijoo irraa odeeffannoo argachuuf kan qophaa'edha. Odeeffannoon kun kan barbaachisu barreeffama qorannoo mata duree 'Madaallii Raawwii Hojii To'annoo Qorichaa Zoonii Iluu-Abaabooraa, Naannoo Oromiyaa, Kibba - Lixa Itoophiyaa,' jedhuuf ta'ee kan akka gartokkee xumura digrii lammaffaa dhimmoota to'annoo qorichaa irratti gaggeeffamaa jiruti. Ani barataa faarmaasii digirii lammaffaa mata duree qorannoo armaan olitti ibsame irratti qorannoo gaggeessaa jiru dha. Kaayyoon qorannichaa inni guddaan wantoota ijoo rakkoo raawwii hojiitti nama geessan adda baasuufi argannoowwan irratti hundaa'uun yaada furmaataa kennuudha. Yaadonni kennaman irra caalaatti abbaa aangoo to'annoof rakkinoolee fooyya'uu danda'an adda baasuun tajaajila hawaasaa fooyya'aa ta'ee akka kanaan gargaaruu danda'u. Odeeffannoo barbaachisaa argachuuf jecha qajeelfama af-gaaffii walakkaa caaseffama qabu dhiyeessaan jira. Af-gaaffiin yeroo keessan keessaa daqiiqaa 15-30 kan fudhatu yoo ta'u, bakka isinitti tolutti ni gaggeeffama.

Hirmaannaan keessan fedhii qofaan kan ta'ee fi odeeffannoon isin kennitan guutummaatti iccitii ta'ee kan eegamu ta'a. Gabaasa barreeffamaa fi afaaniif waraqaa qorannichaa sana keessatti akka fayyadamuuf deebii keessan irraa caqasoonni kallattiin fudhatamuu nidanda'u. garuu maqaan keessan gonkumaa kan hinbarreeffamne yommuu ta'u deebiin waliigalaa deebii kennitoota adda addaa irraa kennamu koodii qofaan adda baafama. Haa ta'u malee, yeroo af-gaaffii waraabbii sagalee nifayyadamna.

Gaaffii kanaaf deebii amanamaa isin kennitanu qorannichi milkaa'inaan akka xumuramuuf baay'ee barbaachisaa dha. Deebii sirrii fi dogoggoraa waan hin jirreef gaaffilee ilaalchisee shakkii kamiifuu ibsa qabaachuu dandeessu. Gaaffiiwwan dhiyaataniif deebii kennuudhaaf fedhii qabduu?

Eeyyee ☐ Lakki ☐

Galatoomaa.

Tasfaahun Girmaa
Barataa digrii lammaffaa
dhimmoota to'annoo qorichaatiin,
Yuunivarsiitii Addis Ababa, Kolleejjii Saayinsii Fayyaa,
Mana Barumsaa Faarmaasii, Kutaa Faarmaasiiyuutiksii fi Faarmaasii Hawaasummaa

Af-Gaaffii garee to'annoofi miseensa maanajimantii Biiroo Fayyaa Oromiyaa, EFDA damee Jimmaa, Qajeelcha Fayyaa G/I/A/Booraa fii Aanooleea

KUTAA A: Odeeffannoo waliigalaa

1. Koodii dhaabbatichaaf kenname: _____
2. Saala deebii kennaa: _____ Umurii deebii kennaa: _____ .
3. Guyyaa gaaffii fi deebii: _____ Bakka:_____ .
4. Bakka ramaddii deebii kennaa _____ .
5. Muuxxannoo hojii ogummaa kanaan qabu (waggaan)._____ .
6. Telephone: _____Fax _____ E-mail_____

KUTAA B: Gaaffiiwwan mata duree qorannoo irratti hundaa'an.

1. Hojiin to'annoof hordoffii naannoo hojii keessaniitti maal fakkaata?
   _____
   _____
   1.1. Dhaabbattoota gosa akkamiitu isin jalatti to'atama? _____
   _____
2. Hojii to'annoo keessannii keessaniif deeggartoota waantoota ta'aniifi hudhaa kan ta'an maal fa'a?_____
   _____
3. Bu'aan qorannoo maamilaa fakkeessaa gurgurtaan antiibaayootikii OTC fi qoricha tarreewwan hayyamaman ol qabachuun jiraachuu agarsiisa. Sababni seera kabajuu dhabuu akkanaa maal jettu? _____
   _____
4. Muuxxannoodhuma keerraa kaastee dhaabbattoota ta'ataman, uummataafi oggeeyyii fayyaa irraa rakkoolee qaama to'atu irratti kaafamanu naa ibsuu nidandeessaa? _____
   _____
5. Qaamolee qooda qaban warren akka EFDA, Biiroo Fayyaa, Poolisii, Biiroo Nagadaafi Bulchiinsaa waliin haala kamiin wal dubbisaa akka hojjttanu naa ibsuu nidandeessaa? _____
   _____
6. Dandeettii tuuta to'annoo haala akkamiitiin safartuu? _____
   _____
7. Zoonii Ilu Abbaa-Booraa keessatti dandeettii qaama to'annoo fooyyessuuf carraan jiru maali?_____
   _____
8. Bakka ramaddii amma jirtanu irratti hagam ittiquuftaniittu?
   _____
9. Amma dhimma biraa ani hin ilaalle (hinkaa'in hafe) akka kaaftan carraa isiniif kenna. _____
   _____

Tumsa nuuf gootaniif galatoomaa!!!

Af-Gaaffii Dhaabbata Fayyaa Dhuunfaa fi gareewwan xiyyeeffannoo

KUTAA A: Odeeffannoo waliigalaa

1. Koodii dhaabbatichaaf kenname: _____
2. Gosa dhaabbatichaa (Akka barbaachisummaa isaatti (√) itti dabalaa
   Faarmaasii: ☐ Dukkaana Qorichaa: ☐ Daldalaa qoricha baadiyyaa: ☐
   Kiliniika:. ☐
3. Baay'ina hojjettoota dhaabbata kana keessa jiran: _____
4. Deebii kennitoota moggaasa (akka barbaachisummaa isaatti (√) itti dabalaa)
   Abbaa qabeenyaa dhaabbatichaa ☐ Hojjetaa biro ☐
5. Ogummaa deebii kennaa _____ .
6. Saala deebii kennaa: _____ Umurii deebii kennaa: _____ .
7. Guyyaa gaaffii fi deebii: _____ Bakka:_____ .
8. Muuxxannoo hojii ogummaa kanaan qabu (waggaan)._____ .
9. Telephone: _____Fax _____ E-mai_____

KUTAA B: Gaaffiiwwan mata duree qorannoo irratti hundaa'an.

1. Hojiilee to'annoo qorichaa yeroo ammaa ilaachisee maal akka isinitti dhaga'amu naaf qooduu nidandeessuu? _____
   _____
2. Gahumsa inspeektarootaa (to'attootaa) irratti ilaalcha dhuunfaa akkamii qabdu?
   _____
3. Seera qaama to'atuun baahu hordofuu keessatti rakkoo akkamiitu namudata jettanii sodaattu? _____
   _____
4. Kaka'umsi qoricha farra baakteeriyaa ajaja haakimaan ala gurguruu duuba jiru maali jettu? _____
   _____
5. Dandeettii to'attootaa ilaalchisee ilaalcha dhuunfaa maalii qabdu?
   _____
   _____
6. Rakkinoota isiniif to'attoota gidduutti argamu gidugaleeffachuun, dhimma to'annoo fooyyessuuf yaada furmaataa akkamii laattu?_____
   _____
7. Rawwii hojii qaamolee to'attoota qorichaa naannoo keessanitti hangam quuftaniittu? _____
   _____
8. Amma dhimma biraa ani hinkaasin hafe yoo jiraate akka kaaftan carraa isiniif kenna. _____
   _____

Tumsa nuuf gootaniif galatoomaa!!!

Annex IV (Data abstraction form for OTC sales of antibiotics)

Data abstraction form for sales of antibiotics without prescription (Simulated client visit method)

SECTION A: General information

1. Code of the retail outlet _____
2. Type of the retail outlet (Please add (√) as appropriate)

   Private community pharmacy: ☐ Private Drug Store: ☐

   Non-governmental chain pharmacy: ☐ Rural drug vendor: ☐
3. Location: Metu woreda ☐ Didu woreda ☐
4. Respondents sex (Please add (√) as appropriate)

   Male ☐ Female ☐
5. Estimated age group (in years)
   - ✔ Below 30 years
   - ✔ 30 – 50 years
   - ✔ Above 50 years
6. Has name tag? Yes ☐ No ☐
7. Has worn Protective gown? Yes ☐ No ☐
8. Does the professional license and photo matched with the pharmacy attendant?

   Yes ☐ No ☐

   Not sure ☐ Not found ☐
9. Profession of respondent

   Pharmacist ☐ Nursing Degree ☐ Health assistant ☐

   Pharmacy technician ☐ Nursing Diploma ☐

   Other (please specify) _____
10. Relevant working experience in year(s). _____

SECTION B: **Information related to Antibiotic dispensing**

No.	key indicators of dispensing practices	Coding categories
1	Type of the clinical scenario	1. Acute watery diarrhea 2. Uncomplicated UTI
2	Was antibiotics dispensed?	Yes No (If 'No' skip to no. 8)
3	Level of demand the antibiotic was dispensed	Demand Level ……. 1 Demand Level ……. 2 Demand Level ……. 3
4	Additional Question from Pharmacy Professional Regarding Simulated Clinical Scenario.	Asked the simulator about ✔ possible drug allergies and ✔ concomitant medication usage
5	The name of antibiotics dispensed (if any), **(Multiple answers are possible)**	
6	Instruction told to the simulator how to take the antibiotics	
7	The simulators were warned about the potential side effects of the medicine.	
8	Reasons for not dispensing **(Multiple answers are possible)**	A. Administrative issues B. Referral to health facility C. Illness doesn't require an antibiotic D. Fear of complications E. Unavailability of an antibiotic F. Other (please specify) _____
9	Alternative medications offered in place of an antibiotic (if any)	

Data Collector Code **Date: _____**

Annex V (Data abstraction format for documents review)

SECTION A:

I. Data abstraction format for resources

No.	Factors	Yes	No	If yes check available documents
1	Is there pharmacy professional in the regulatory team?			
2	Is there Environmental health professional in the regulatory team?			
3	Is there public health professional in the regulatory team?			
4	Are there laboratory professionals in the regulatory team?			
5	Is there induction training for newly assigned personnel?			
6	Is there gap-filling training of regulatory experts?			
7	Is there the recent regulation (1112/2019)			
8	Is there the recent policies			
9	Is there the recent regulatory frameworks			
10	Is there the recent standards			
11	a. Is there clear checklist for practicing?			
	b. Is there list of drugs that distinguish between retail outlets?			
12	Is there job description of key personnel?			
13	Is there separate office for regulatory team?			
14	Is there separate vehicle for regulatory activities?			
15	Is there annual plan breakdown?			
16	Is there a list/data base of all the licensed and inspected pharmacies and retail outlets? ✔ MFR sofrtware is recently introduced but not fully automated			
				Remark
17	Currently available number of staff assigned only for regulatory activities			
18	Required number of staff for the regulatory team?			
19	How often do you inspect a single firm within a year?			**Routine**
20	Number of new firms licensed			
21	Number of applicants failed to meet regulatory requirements			
22	Number of firms inspected			
23	Number of firms license renewed			

24	Number of firms license revoked or returned		
25	Number of firms given warning letter due to compliance breach		
26	Number of firms suspended for a while		
27	Number of model pharmacies and retail outlets		
28	Number of complaints come from the public on providers irrational service ✔ No phone line for proposition ✔ They have registration book at their office exit ✔ The public give them misconduct proposition by directly calling the inspectors phone or by texting them		

SECTION B: Data abstraction format for field work of the regulatory team.

Visit Date	Type of visit	Plan (No. of firms to be visited)	Achievement (No. of firms visited)	achievement in percent	Remark
	Routine inspection				
	Concise inspection				
	Follow-up inspection				
	Special inspection				
	Investigative inspection				