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Regulatory Compliance of Community Drug Retail Outlets in Ambo Town, West Showa, Oromia Region, Ethiopia

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This is to certify that the thesis prepared by Admassu Gutu, entitled: Regulatory Compliance of Community Drug Retail Outlets of Ambo Town, West Showa Zone, Oromia Region, Ethiopia and submitted in partial fulfillment of the requirements for the Degree of Master of Science in Regulatory Affairs (Medicine Stream) complies with the regulations of the University and meets the accepted standards with respect to originality and quality.

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Abstract

Introduction: If standards for pharmaceutical premises exist in a country, it should define the minimum requirements to operate a drug retail outlet as the regulation. Food, Medicine and Healthcare Administration and Control Authority of Ethiopia (FMHACA) prepared private drug retail outlets model directive based on proclamation 661/2009. The directive states about the requirements for qualifications of the technical personnel and the adequacy of the premises, processes and equipment in order to grant a license for providing the drug retail outlet services. This study aimed in assessing the regulatory compliance of the community drug retail outlets in Ambo Town based on the minimum standard set by EFMHACA.

Method: A descriptive cross-sectional survey on all community drug retail outlets in Ambo Town was conducted from April to May 2019. Checklist based observation and measuring, record review and semi- structured interview guide questionnaire were used for data collection.

Results: The response rate was 25(92.6%) for the retails; 6(24%) pharmacies and 19 (76%) drug stores. The total area of the premises varies from $30m^2$ to $56.5m^2$ for Pharmacies and $22.75m^2$ to $56.0m^2$ for drugstores. Majority (92%) of retails have functional refrigerator, but only 15(60%) has functional refrigerator thermometer. Only 10(40%) retails have Stock card and/or Bin cards; even 4(40%) didn't have for all products and 6(60%) of retails didn't register stock movements on time. Only 12(48%) of the retails were kept the prescription with/out registration either separately or not. Only 13(52%) of the licensed professionals were available at the date of visit. In 15(60%) of the retails there was accumulation of expired drugs, stored from 3 months up to 11 years.

Conclusions: Based on this study, we conclude that; majority of the drug retail outlets do not satisfy the minimum requirements set by the regulatory authority of the country. The concerned regulatory bodies also do not strictly monitor the requirements, irrespective of their allegation on the products stocked and the service provided by the DROs. We also recommend the concerned stakeholders to improve or prevent the non compliances of DROs through stringent regulatory action, follow up inspection, training and accountability rule.

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List of Abbreviations/Acronyms

ADRs	Adverse Drug Reactions
BPR	Business Process Reengineering
DROs	Drug Retail Outlets
EFMHACA	Food, Medicine and Healthcare Administration and Control Authority of Ethiopia
EML	Essential Medicine List
EPRDF	Federal Democratic Republic of Ethiopia
FIFO	First in First Out
FIP	International Pharmaceutical Federation
FMOH	Federal Ministry of Health
GDP	Good Distribution Practices
GSP	Good Storage Practice
GDP	Good Dispensing Practice
HC	Health Center
Hrs	Hours
HSDP	Health Sector Development Program
IPLS	Integrated Pharmaceuticals Logistics System
LME	List of Medicines for Ethiopia
LMICs	Law and Middle Income Countries
M	Meter
Cm	Cent meter

M^2	Meter Square
MSH	Management Sciences for Health
NDP	National Drug Policy
NF	National Formulary
NGO	Non-Governmental Organization
NPS	Narcotics and Psychotropic Substance
NTG	National Treatment Guideline
OTC	Over-The- Counter
PFSA	Pharmaceuticals Fund and Supply Agency
PSI	Pharmaceutical Society of Ireland
PRB	Prescription Registration Book
RDV	Rural Drug Vendor
RHBS	Regional Health Bureaus
PI	Principal Investigator
SDSs	Special Drug Shops
SPS	Strengthening Pharmaceutical System
SPSS	Statistical Package for the Social Sciences
STG	Standard Treatment Guidelines
TGL	Treatment Guideline
W/Showa	West Showa
WHO	World Health Organization

1. Introduction

Countries introduce extensive laws and regulations to safeguard the health of their public. Regulatory bodies also established at different level to oversee the implementation of laws and regulations through which they can control the pathway of drugs pass from point of manufacturing to the final users and with the concern of the relevance of information on medicines (MSH, 2012).

Thus, regulation in drug supply chain encompasses: inspection of products at the port of entry, control of distribution and sales activities. Regulation also includes registration and licensing of pharmacy professionals and licensing and inspection of pharmacy facilities. Without efficient regulation at each step in the supply chain, the products may loss the intended quality and leads to drug resistant and death of the users (Dalberg and MIT-Zaragoza, 2008).

However, there are numerous challenges in drug regulation, including the cost of the products and the stakeholders involved in the system are among the other issues. Thus, people may not only suffer from the lack of drugs but also medical products of inferior quality and irrational use of drugs (MSH, 2012). Therefore, to insure rational use and proper handling of drugs, it is mandatory to control carefully all the activities throughout the chain (WHO, 2011). Hence, the World Health Organization (WHO) recommended that monitoring and assessing the pharmaceutical sector are vital to determine if the key pharmaceutical objectives are met or not. The recommendation aimed in assessing the people have access to essential medicines, these medicines are safe, effective and good quality and they are used correctly (WHO, 2017). Yet, the status of noncompliance of these laws and regulations is used not only to take action against those violate it, but also to verify the causes of the problem (MSH, 2012).

In a health care system supply and distributions of medicines is a crucial issue among others. If the supply is not properly carried out it may affect cost, quality and availability of the products for the users (Ariane et al., 2011). Since, the way medicines purchased, distributed and managed in the health system determines availability and/or access of medicines (WHO, 2007).

To manage medicines accordingly professionally qualified, well trained and competent personnel should be available both at the facilities and regulatory positions. In addition, possible action

should be taken for forecasting, selection, quantification, procurement, distribution and use of medicines to make the supply chain efficient and sustainable (Iqbal M.et.el., 2017). With this concern, availability of trained and sufficient number of pharmaceutical personnel is one of the pillars and needs special attention to attain the national and hence the global health goals (Ministry of Health and Social Welfare, 2009).

The pharmaceutical sector in Ethiopia is reguleted by Food Medicean and Health Adminstrative and Control Autherity of Ethiopia (EFMHACA) and the Regioanal Health Breoues (RHBs) or city health bureaus based on the proclamation 661/2009. That is the regulation of trans-regional suppliers (manufucterers,importers and wholesalers/distrubiters) is for EFMHACA.The regulation of the drug retail outlets (DROs) and licensing of the concerned professionals is the mandate of regional health bureaus (RHBs) or city health bureaus based on the directive sate by FMHACA. In some instance, the regional health bureau also outsources some of the regulation activities to the woredas and town health offices. For instant, the inspection and renewal of the retail competence license is the mandate of these bodies. The regulation is based on the directives, gidelines and standerds set by EFMHACA (Federal Negarit Gazette, 2010).

The pharmacy service in the community settings in Ethiopia is provided by drug retail outlets (DROs) including: pharmacies, drug stores and rural drug vendors (RDV) run by a pharmacist, druggist and pharmacy technician respectively who is dually registered and licensed by concerned body. The premises for the DROs are required to have rooms for dispensing, storage, and compounding (only for pharmacy retails). However, the size of the rooms and the types of medicines handled varies among the DROs; increases from RDV through drug stores to pharmacies (FMHACA, 2013).

Hence, this study was conducted to assess the compliance of the community DROs in Ambo Town to the minimum standard for retails regulation set by EFMHACA with respect to the premises, personnel, stock management, documentation, and expired drugs management system.

2. Statement of the Problem

The private retail pharmacy sector is the major source of health care system for the majority of the people in low and middle-income countries (LMICs). However, the studies done in LMICs showed that, the legislation and regulation of the retail out lets in most of the countries is insufficient. Even in same case, it is controversy to the health goals with considering only access and affordability of medicines (Lowe and Montagu, 2009). In addition, community pharmacy professionals are the back bone of primary health care and easily accessible to the community. Their task is extended globally. Therefore, countries set laws and regulation to control the services of these drug retails through establishing requirements for personnel, premises, equipment, processes, cost and working hours (WHO, 2019).

The minimum standard required is determined by the local situations based on pharmacy practice environment and profession objectives (WHO, 2011). However, in most LMICs the enforcement of the regulations is difficult or impossible, due to inadequate regulatory capacity and the fragmented nature of pharmaceutical retail markets (Lowe and Montagu, 2009). Furthermore, studies showed that such inefficient regulation of health care system in LMICs are potentially serious; including enhancing inequities, weakening of public sectors, augment un ethical activities and poor quality care (The Nossal Institute for Global Health, 2011).

Pharmacy retails are the last bridge from the manufacturer to the final users in the supply chain. Therefore, medicines stocked in the retails should be in the same quality, safety and efficacy as their manufacturing specifications. To achieve this goal for the safety of users', regulations and intended guidelines should complied (PSI, 2018).

To maintain the original quality of pharmaceutical products, every party active in the distribution and supply chain must comply with the applicable legislation and regulations. Consequently, each activity should be done in line with the principles of Good Storage Practice (GSP), Good Distribution Practices (GDP) and Good Dispensing Practice (GDP) as applicable (FMHACA, 2015). In contrast, poor supply chain management is one of the common problems concerned with the supply and distribution of pharmaceuticals (Ariane *et al*, 2011).

To perform these practices accordingly and efficiently professionally qualified and ethically competent personnel are obligatory. FMHACA proclamation 661/2009 art 33(1) also prohibit the health professional to practice without having a professional practice license issued by the appropriate body (Federal Negarit Gazeta, 2010). Controversially, the cross sectional study conducted in private DROs in Ambo Town, the current study area, by 2014, revealed that out of 18 dispensers working at these settings, 5(27.8%) were not qualified professionals (Jimma et al., 2015). The W/Showa Zonal Health Office supervision had done in 2017 also indicate the presence of non-professional practicing in the private DROs by renting professional license (W/Showa Zonal Health Office unpublished report).

The pharmacy retails must follow the proper stock control procedure, within intended environment and facilities (PSI, 2018). Assessing the condition of products handled and relevance of service provided by these retails is a fundamental issue to maintain the intended quality of the products stocked and to improve the service provided by the retails (WHO, 2019). Some guidelines also point out that, the handling and storage of drugs by the retails are some indicators of the quality of drugs dispensed to patients. These indicators are evaluated at the dispensary and store rooms at private drug retails and public retails/warehouses (MSH, 2012).

Therefore, this work was done to identify the compliance of community DROs in Ambo Town with the minimum regulatory requirement set by regulatory authority of Ethiopia. That in turn indicates how the service the drug retails provided is maintained the safety, efficacy and quality of the products and relevance of the information to the users. It can also serve as an input and alarming for the regulatory bodies at different level. Moreover, the results from the study will also serve as pilot study, since there is scarce of such regulatory base study done at the primary facility level in the country.

3. Literature Review

3.1. Overview of drug supply chain system

Access to health care including essential drugs is a fundamental human right (MSH, 2012). The supply and access to quality and affordable drugs may not covered by governments' budget alone. So far, the health care system in LMICs usually comprises four sectors; public, faith-based, employer-provided and private. Every of these sectors try to cover the need of the population based on the local laws and regulation (Dalberg and the MIT-Zaragoza, 2008).

If favorable business conditions are available, the private sector drug retails can invest. Therefore, governments could promote the sector and create conducive environment for their participation. Simultaneously, countries tried to set standards and prepare guidelines for licensing professionals and retails by introducing pharmaceutical laws and regulation and establishing the regulatory authorities that oversee laws and regulations. Yet, in most cases countries lack these regulatory resources or infrastructures to monitor the safety, quality and rational use of drugs (MSH, 2012).

One study showed that, most people in developing countries get their medicines from retail drug sellers and often conceder as the most convenient source. Because they assumed as medicine is affordable prices and consult the pharmacists on medication and the physician they should visit (Rakib, 2015). Although, there is insufficient number of both qualified pharmacy professionals and drug retail outlets in developing countries. In some countries also there is the imbalance between the available qualified pharmacy professionals and the retails; more retails than the available professionals in most cases (MSH, 2012). Consequently, dispensing of drugs might be done both in public health facilities and private drug retail outlets by non pharmacy professionals. In Ethiopia, like other countries, the service is provided by public (hospitals, health centers, etc.), NGOs and community (private) pharmacy facilities (FMOH and WHO, 2002). The government of Ethiopia also focused to collaborate with the private health sectors as one of the strategies to achieve the improvements of public health stated in HSDP (Health Sector Development Program). The available data also showed that, the private health sector could be

the major source of outpatient care and nearly 90 % drug outlets are for-profit drug stores in the country (FMO, 2013).

One survey done in Ethiopia indicated that, some of the reasons for preference of private sectors by users include proximity of a health facility to the patients, availability of medicines, good counseling by health workers, short waiting time, qualification of staff and the facility accepted patients in the waiver system (FMOH, 2017).

Despite the facility where the dispensing takes place or who does it, irrational dispensing may results in serious problem mostly on health or economy. Therefore, the dispensing personnel play a crucial role in the therapeutic process. However, training and supervision the dispenser has received may determine the competency of these dispensing personnel, in addition to other factors (FMOH and WHO, 2003). For example, one assessment done in Dhaka city, Bangladesh revealed only 4% community pharmacists informed the patient about the dose, drug name , precautions and side effects of drugs and only 2% pharmacists informed about storage condition (Abdur, 2015). Another study done in the same country, in different city, Rajshahi city revealed that, about 22.70% of drugs have sold without a prescription. Out of these items dispensed without prescription, 66.2% were dispensed by clients request and 33.8% by the dispensaries recommendation. The type of drugs prescribed per prescription was highly variable, ranging from2 to 5 medicines per a prescription (Saha and Hossaim, 2017).

However, improving the services provided and products supplied by the retails can contribute to improvement of public health. Therefore, it is recommended that, drug retails should access to quality drugs and skilled dispensing professionals and also regulation should be enforced. To improve access and rational use of medicines especially for underserved areas (MSH, 2012).

Inspection is considered as a quality assurance method, through which the implementation of laws and regulations and compliance of professional and/or ethical standards are evaluated. The aim might be either the drug retail out lets or the professionals (WHO, 2019). For these and related reasons, in Ethiopia the concerned regulatory authorities introduce regulation. However, the enforcement might be weak or impossible due to lack of resources (PFSA, 2015). The regulatory body, primarily, Ambo Town Health Office and others at different level most

probably inspect the DROs periodically and/or based on the urgency of situations (Federal Negarit Gazette, 2010).

3.2 The premise of the drug retail outlets

The primary criteria for granting a drug retail license are the qualifications of the technical personnel and the adequacy of the premises, materials and equipment (Ratanawijitrasin & Wondemagegnehu, 2002). Pharmaceuticals store room needs care more than a room that provides a space for storage of anything else. For instance, the wall of the DROs premises shouldn't be constructed from soil, wood, grass and steel covers, but should be painted with washable materials and have intended height. The floor of the premise should construct from cement, clay or wood. The floor and walls should be smooth, free of recess and easy to clean (FMHACA, 2013) (Wafula et al., 2014) (FMHACA, 2015).

Countries determine the required average or minimum size of the premises based on the local situations. In Europe for instance, the dimensions of the pharmacy retails varies in relation to the size of population they serve. The average size of the retails varies from 470m^2 (in Denmark) to 60m^2 (in Italy) which serves an average of 18,000 and 3563 population respectively. However, the number of staff also increases as the size of the retail increases, and hence with the number of population served (Taylor and Harding, 2005).

EFMHACA also determined the minimum standards for the design of the premises of the DROs used to maintain the labeled quality, safety and efficacy of the product stocked by the retails. Consequently, the dimension of the premises also have minimum standard based on their purposes and the verities of items stocked. The minimum area of the dispensing and store rooms and hence the total area of DROs premises vary based on the level of the retails. Generally, for pharmacy retails it is 25m^2, 16m^2 and 41m^2 for dispensary, store and total premises area respectively and a compounding room of 9m^2 (optional, not a mandatory). Likewise, for drug store it is 22m^2, 12m^2, and 34m^2 for dispensing, store and total area of the premises respectively. However, the design, type of construction materials, the height of the wall and other facilities are similar for all irrespective of their level of retails (FMHACA, 2014).

3.3 Stock Management

Unless drugs are stored and distributed properly as labeled by their manufacturer, they might be physically deteriorated and chemically decomposed. It affects the intended potency and results in the degradation of ingredients (MSH, 2012). Thus, proper storage helps in safekeeping of pharmaceuticals to avoid damage, expiry and even theft. So, customers can be assured that they have received intended quality products. That ensures the physical integrity and safety of products and their packaging, throughout the various storage facilities along the supply chain system, until they are dispensed to clients (PFSA, 2016).

The premises temperature should be monitored regularly as guidelines recommend, with special attention for noticeable temperature variations areas like near the heaters, windows or lights. The temperature should be recorded and approved periodically by the concerned personnel for their compliance with the required conditions. These records should be kept by the facilities for the intended period as a proof for a consignment or if any deviations happen for stoked products (PSI, 2018).

A cold storage facility (refrigerator) is vital for storage of some susceptible drugs and vaccines to maintain the shelf-life and quality of the products. However, the storage of these products outside the intended temperature ends up with irreversibly damage of the products (MSH, 2012). Moreover, food and drinking items, but not medical foods, and even drugs for personal use should not be stored with these drugs in a refrigerator, to prevent cross contamination (PSI, 2018).

Generally, extreme temperatures, light, freezing or humidity may cause deterioration of medicines. Heat affects most medicines, especially liquids, ointments, and suppositories. Some medicines that are light sensitive, such as injections, spoil very quickly when exposed to light. Humidity can spoil tablets and capsules because they easily absorb water from the air, making them sticky and causing them to deteriorate. All products need to be kept in their original packaging, containers or boxes following the storage instructions given on the labels of the manufacturers (MSH, 2010).

Therefore, efficacy, safety, stability, quality and the shelf-life of drugs stocked determined by how drugs managed in the facilities. Hence, storage areas should be designed to achieve the necessary storage conditions. The retail outlets premises environment should possess: appropriate temperature, sufficient lighting and optimum humidity management system. They should also possess materials for cold storage facilities, adequate shelves and lockable cabinet to maintain the quality of the products and to protect undue effects. The premises should be clean and dry, ventilated and free from accumulated waste and vermin and maintained within acceptable temperature limits. Pharmaceutical products should be stored off the floor, walls and ceiling as well as suitably spaced to permit cleaning and inspection. Pallets and shelves should be kept in a good state of cleanliness and repair (Ministry of Health Care & Nutrition, 2008) (EFMHACA, 2012) (USAID‖ DELIVER PROJECT, 2014).

One study done in Kathmandu and Kaski districts of Nepal on the standards of physical premises of drug retails revealed less compliance to the requirements. The study was including about cleanliness, ventilation, protection from physical environment, dimensions and storage facilities. The result indicate that physical premise of most pharmacies were not in line with a good pharmacy practice requirements of codes on sales and distribution of drugs in the country (Poudel and Ishii , 2016)

FMHACA also standardize the minimum distances as from shelves to the wall, shelve to shelve, shelves away the ceiling and the foot (base) of shelves from the floor is 30cm, 50cm, 100cm and 20cm respectively. For the free movement of personnel, ease of cleanness and control of stock in the premises. The distance from the entrance door to the dispensing table is also not less than 1.5 meter for the convenience movements of users and to protect direct sunlight from the stock products (EFMHACA, 2018).

Inventory Control System helps in forecasting the amount of stock needed and time of supply. Thus, efficiently controlled inventory system helps in preventing or minimizing over stock, shortage, wastage and expiry of drugs among others (PFSA, 2016). Stock record card and bin card are used by the retails to control their stock movement. Data from these cards include the amount and date of both issued and received which are used for determine the amount of products to be ordered. It is a must that responsible personnel should have both stock and bin

cards for all products and each dosage forms separately. The movements of the stock also registered timely and kept as a proof for the intended period of time (PFSA, 2015).

Received products should be registered on time of delivery, which describes the type, amount, quality, batch/lot number, expiry date, received date and the supplier name. These records kept for a period equal to the shelf life of the products plus one year (FMHACA, 2015). Conversely, even studies done in public health facilities in different parties of the country showed less usability of the cards. For instance, the study done in West Hararghe Woredas health storerooms in 2014 showed only 40% of the facilities have and use both cards properly*(Gizat and Samson, 2014).* Another study conducted in public hospitals in Addis Ababa City in the same year revealed that , only eight out of ten (80%) of the hospitals' pharmacies had Bin card and Stock card (Bethlehem G, 2014).

The expiry date tracking chart is used for systematic and regular checkup of expiry date of stocked pharmaceuticals by the premises. Products with short expiry date would be separated and followed. Expired, patient returned and products with quality defects should be separately stored and marked as products for destruction. However, any expired medicines should not be stored for the period of greater than six months in the facility (FMHACA, 2015).

3.4 Pharmacy Personnel

Pharmacy professionals that practice in the community (drug retail outlet) are easily and mostly accessible to the public. They ensure the supply of appropriate products; dispense prescription and non-prescription drugs with appropriate counseling, provide drug information to health professionals and the community, participate in health program promotion. They also serve as a bridge to other health professionals in primary health care (WHO, 2019).

Quality of health workers in general is a determinant of the health status of a population. Health care resources especially medicines might be used inappropriately and wasted if not managed by adequately trained and motivated health workers (FIP, 2009). However, pharmacy professionals are primary visited professionals in community DROs and the last step to serve patients in hospitals (Stenson et al., 2001). So, they are the front line professionals in managing rationally and efficient utilization of the health care items in general and pharmaceuticals in particular.

Traditionally, pharmacy professionals' primary responsibility is stocking, distributing and maintaining quality of medicines dispensed. Currently, their role is mainly focused toward advising other health care providers, counsel patients and monitoring medicine use. They serve as link between the prescribers and users and safe guarder of drugs supply system (FMHACA, 2012). Therefore, legally qualified pharmacy professionals have indispensable role in prompting pharmaceuticals care in particular and public health in general. Relatively, the professionals considered that the users take appropriately prescribed, most effective, safest and with possible users compliancy to the medicines. Generally, when one conceder their professional responsibility, pharmacy professionals are the unique contributors of their patients pharmaceutical therapy and quality of life (PFSA, 2015).

However, the Federation International Pharmaceuticals (FIP) 2009 report shows many countries worldwide experience a shortage of pharmacists and distribution imbalances within countries. African countries also have both low densities of pharmacists and pharmacies. That indicates, the scarce of both access to essential medicines and qualified professional who manage the medicines. Even the report shows that, several countries have many times more pharmacies than pharmacists and vice versa. The former is diminishing the issue of appropriate supervision of pharmaceutical services. For example, the density of pharmacists varies greatly between countries ranging from 0.04 (Chad) to 18.88 (Malta) per 10,000 population (FIP, 2009). One pilot study done by 2012 in WHO member countries shows; the total number of pharmacies in each 9 of study countries ranges from as low as 27 in Suriname to as high as 7,000 in Pakistan (Ashigbie, 2011).

Another assessment done in Tanzania also revealed that there is shortage of pharmaceutical personnel and their distribution is skewed. Until August 2009 there were 5241 pharmacies totally in the country but only 1506 pharmacy personnel. Even in Dar Es Salaam alone, the largest city in the country, there were about 560 pharmacy personnel but 750 pharmacy facilities. Which mean only 29% the retails would be staffed, indicating that, pharmaceutical services were provided by unqualified personnel in over 70% of premises (Ministry of Health and Social Welfare, 2009).

The assessment of pharmacist's workforce done in Ethiopia by 2013 also showed that, like other countries in the world. The study showed both non-uniform distribution among regional states and low density of the professionals in the country (2.38 per 100,000 population).The highest density was in Addis Ababa, the capital city and the lowest was in Afar which was 29.88 and 0.66 pharmacists per 100,000 populations respectively (Gebremedhin and Teferi, 2013).

Besides the limitation of their number and non-uniform distributions, some studies showed that, the licensed/authorized professionals also not frequently or regularly available on their working place. The study done in Kenya specialized drug shops (SDS) shows that 54% of the professionals have not available during study time and provide service by non-authorized persons (Wafula et al., 2014). Another study done in Nepal also indicated only 58.2% of the retails have authorized pharmacy professionals to dispense drugs (Poudel *et. al*., 2016). Similarly, the study done in Ambo town DROs, by 2014 showed that, from those eighteen DROs available in the town, five of them licensed professionals was not available, indicating that the service was provided by nonprofessionals (Jimma *et. al*., 2015).

On the other hand, the available skilled and knowledgeable pharmacy personnel are the determents of the supply chain and the quality of the pharmacy service in general. However, PFSA point out that, various supportive supervisions and surveys had been done in Ethiopia showed that, the availability of sufficient number of competent and compassionate pharmacy professionals is still a challenge issue. For the case, FMOH, RHBs and PFSA have been providing different supportive supervisions and capacity building activities to enhance supply chain management system and rational use of medicines (PFSA, 2016).

The type and quantity of drugs used or stocked by any facility is determined by the capacity of staffs available to use the drugs efficiently. However, to perform their activities properly, different types of reference materials related to prescribing, dispensing and storage of the products must be available and accessible on regular base to the pharmacy professionals and all staffs (Rutta, 2015).

3.5 Medicines Waste Management and Disposal system

While trying to address the availability and accessibility of sufficient amount of drugs to the users some drugs may be expired or damaged before used. In addition, medicines returned from users and medicines with quality problem may stock for some time as unsafe products. These socked products are in general known as medicine waste. These medicine wastes by themselves may not harmful. However, the lack of safe handling and timely and safe disposal of these wastes can be a serious problem to the environment and the public (FMHACA, 2012).

Moreover, the health of the public and the environment should be protected from any risks associated with medicines wastes and unsafe disposal. EFMHACA (regulatory body) mandated medicines wastes should be managed and disposed by those who generated them. EFMHACA is responsible to ensure the safe disposal of medicines waste and provide certificate for those who dispose as stated (Ejigu et, al., 2012).

Expired pharmaceuticals by themselves do not represent a serious threat to public health or to the environment. However, unsafe disposal of these products is dangerous if results in contaminating water supplies or other sources, accessed to scavengers and children due to insecure land fill. On the other hand theses expired drugs may be stolen from the stock and diverted to the market and misused. Nevertheless, most pharmaceuticals past their expiry date become less efficacious and a few may develop a different adverse drug reaction profile (WHO, 1999).

Records show that, the huge accumulation of medicine wastes from time to time in Ethiopia. For different reasons; including lack of efficient pharmaceutical management practices, clear directives for disposal and the shortage of appropriate disposal facilities. For instance, one study showed the national averages for presence of expired drugs were 8%, 2% and 3% in health facilities, regional drug stores and private drug retail outlets, respectively by 2003 (FMOH and WHO, 2003). Even after this time, there were also the accumulations of these wastes in public and private health facilities, which occupy large portions of storage areas. Yet, few facilities tried to dispose, but in unproven and dangerous method, which may affect the environment and the public (FMHACA, 2012).

Considering these situations, about medicines waste management and disposal practice, FMHACA formulate the medicines waste management and disposal directive in accordance with Article 55 (3) of the FMHACA Proclamation No.661/2009(Federal Negarit Gazette, 2010). Accordingly, medicines waste should not be stored for more than six months and disposed based on the disposal guideline procedure, by the facilities that generate the waste or getting approval and authorizing of disposal from the appropriate organ (FMHACA, 2011).

However, after the development of waste management manual, one study done by 2014 in Amhara National Regional State showed the availability of the health care wastes. Which including pharmaceuticals, in both public and private hospitals, but also segregation was not practiced in all hospitals. The common waste treatment method used by hospitals was incineration. However, the incinerators used were found to be inefficient because of faulty design, construction and operation. All public hospitals had open pits in their backyards that were used for the final disposal as burial or open incineration, while private hospitals were mixing their healthcare waste with the municipal solid waste (Esubalew T., 2015).

Not only safe disposal of these wastes but also recording and reporting of medical wastes is important for the future planning on infrastructure, logistics and manpower and purpose of monitoring the compliance to the medical waste management guideline (USAID‖ DELIVER PROJECT, 2014) (DRA, 2014).

3.6 Recording, documenting and reporting system

Documentation is a must in well-organized information system. Some references state as; in pharmacy the absence of documents implies that no activities have been done. The assigned professionals are responsible and accountable for every activity done in their facilities. Hence, the documents are considered as a proof of transactions in a system. In the area of pharmaceuticals care the necessary requirements include: documents related to the license of personnel and retail, products stocked and dispensed, recorded temperatures and information related to expired drugs. Therefore, documentation is a must in the drug retail outlets to evaluate the service they provide to the community (Shane and David, 2009).

Better information ensures better uses of resources, which are often in scarce. For example, in drug supply chain the available information are crucial in determining the amount of drugs to be ordered or supplied. Determining stock level by itself minimizes or prevents the probability of stock-out and over stocking of products. Stock information is also critically for the decision makers at the upper stream, to determine the quantity to be supplied or purchased (Logistics, 2008).

For example, in most of the WHO European Countries regulations and legislation require that community pharmacies maintain records of medicines dispensed from a prescription and/or the medicines compounded. For example, in Austria the regulation lists the information to be recorded for medicines compounded in a community pharmacy and medicines dispensed by the pharmacy (WHO, 2019).

FMHACA also recommend that records should be kept for each delivery which include the description of the items, quality, quantity, supplier, date of receipt, assigned batch number and expiry date. Such records should be retained for a period equal to the shelf life of the incoming materials and products and plus one year. The receipts for requisition, receiving of items as well as the prescription registration book should be kept properly (FMHACA, 2015).

Proclamation no 661/2009 obligates all health professional to fully record and health institution to ensure the records of personal health information are kept and maintained properly in a confidential way, unless it is requested for a legitimate purpose authorized by law (Federal Negarit Gazette, 2010). Some guidelines also recommend that documentation demonstrates both the accountability of the pharmacist and gives value to the pharmacist's services (PFSA, 2015).

One of the records is concerning a prescription, which should be recorded and documented as proof of transaction between the patient and the dispenser. Prescriptions can therefore be traced back if any need arises. All dispensing units should have a standardized Prescription Registration Book (PRB) for recording every drug dispensed to a patient. If a computerized registration is used that is preferable to be printed on paper as a backup. The PRB should be filled during dispensing time or as soon as possible. Filled prescription also should be kept as a receipt; prescriptions for narcotic and psychotropic substances should be kept for 5 years and other

prescriptions for 2 years. Thereafter, they should be disposed carefully in the presence of appropriate body. Regular reports on medicine consumption and prescribing pattern from patient PRB should be prepared and report to the appropriate body timely. Information obtained from prescription registration book could be used for further planning and efficient utilization of resource. The report on physical inventory shall be documented (FMHACA, 2015).

The practice may far from the legislation. For example the assessment done in Nepal shows that only 67.2% of the pharmacy outlets were found to maintain narcotics/psychotropic record and of them only 14.7% of the pharmacy outlets had updated the record (Poudel et. *al*., 2016)

Another issue concerning drug related report is adverse drug reactions (ADRs) information, although less focused yet. Pharmacy professionals and prescribers can tackle the information than other health professionals because of their frequent and more approached to the users. In Ethiopia, like other country, pharmacy professionals have the duty and responsibility to report ADRs to the concerned body by using yellow card printed and supplied by FMHACA (FMHACA, 2014).

One pilot study in WHO member's countries showed doctors reported ADRs in all the countries where mandate to report ADRs followed by pharmacists, pharmaceutical companies, nurses and consumers respectively (WHO, 2012). The study done in Bangladesh on drug retail outlets also shows 35.5% of the respondents disclosed that they had experienced ADRs, and 51.7% of the respondents were not familiar with the existence of an ADR reporting body. This is due to different reasons including lack of: knowledge of reporting, reporting forms, motivation to report and professional environment to discuss about ADR among other factors. Totally, no respondent community pharmacist was found to be involved with ADRs reporting (Rakib et al., 2015).

Generally, recording and documenting activities are used to assure availability of data by different bodies and for various proposes like for validation, review, statistical analysis, ensure the successors and to perform the activities sustainably. It may also use to ensure the quality and consistency of processes or activities throughout the service provided (ORHB, 2014).

4. Objective of the Study

4.1 General objective

- To assess the regulatory compliance of drug retail outlets in Ambo Town, W/Showa, with respect to regulatory requirements of EFMHACA.

4.2 Specific objectives

- To assess the premises of DROs based on the minimum requirements
- To assess stock management pattern of the DROs
- To assess the level of personnel's practicing in the DROs
- To assess the registration and documentation practice by the DROs
- To assess waste drug management and disposal system by the DROs.

5. Materials and Methods

5.1. Study area

Ambo is one of the biggest towns in W/Showa Zone, Oromia Regional State of Ethiopia. The town is located 116km to West of Addis Ababa, the capital city of Ethiopia. The town has currently a total population of 96,251. There are different public (governmental) and community (private) health facilities found in the town. These facilities include two public hospitals (Ambo General Hospital and Ambo University Teaching Referral Hospital), two public health centers, one zonal pharmaceutical store, thirty two private clinics (21 medium clinics and 11 primary clinics), twenty-seven community drug retail outlets (6 pharmacies and 21 drug stores). The west Showa Zonal Health office and the Ambo Town Health Administration also located in the town (Data from W/Showa Zone Office).

5.2. Study design and period

A descriptive cross-sectional survey was conducted from April to May 2019 on community DROs in Ambo Town. The data collection was mainly focused on detail assessment of issues like; the structure and the dimensions of rooms, arrangements of shelves, availability and functionality/updating of equipment and materials, the personnel practice in the retails, stock and expired/waste drugs management system by the retails. Through review of available records/documents, measuring dimensions of premises, observation of available equipment and materials and interview of heads (licensed professionals) of the DROs on the issues by using guiding questioners.

5.3. Study population

5.3.1. Source and study population

All private DROs in the Ambo Town provide service during the data collection period and the licensed professional (head) of all drug retail outlets who gave consent for the study and participated in the study.

5.3.2. Sampling and sample size determination

All private DROs in Ambo Town provided pharmacy service during data collection period and licensed professional (head) who were willing to respond were included in the study.

5.4. Data collection and management

5.4.1. Survey team and data collection period

The data were collected by fourth year advance pharmacy program students of Rift Valley University. The data collectors were trained on the aim of the study, the study procedures, data collection instruments and were give a brief explanation on research ethics. Data collection time was from April to May 2019.

5.4.2. Data collection instruments

A combination of interview guide, observation checklist and measuring instruments (meter) were used. To collect data on the DROs about issues on the dimensions of the premises, stock management system, available pharmacy professionals, waste drugs handling and disposal methods and documentation and reporting activates. The data collection tool was developed by compiling the ORHB inspection check list with some guide lines and it is presented in the annex part.

5.5. Data quality assurance

Pre-test was conducted with the data collector in Kudus Gabriel Drug Store, one of Guder Town's private DROs, which is about 12km from Ambo Town, on the day of training given to data collectors. The PI also checked the completeness of collected data and the accuracy of measurements and their unit of measurements after each collection. The collected data was summarized and entered in to epi info on the same day of the data collection.

5.6. Data entry and analysis

The collected data was manually checked for completeness and consistencies before entered into the computer. The collected data was entered by epi info 7 and re-cleaned and analyzed using the Statistical Package for the Social Sciences (SPSS) version 21.0 software. Descriptive statistics like mean, frequency and percentages was determined. The findings will be published in scientific journals.

5.7. Ethical Consideration

Ethical approval was obtained from the Ethics Review Board of the School of Pharmacy, Addis Ababa University on by the reference number ERB/SOP/97/04/2019. Research support letter was

also written from the Department of Pharmaceutics and Social Pharmacy to the studied DROs. Permission was secured from all responded DROs prior to conduct the study. After, participants were well informed concerning the purpose of the study. They were also assured about the confidentiality of the information obtained in the course of the study; that participant facility identifier was not used during the data collection and the result would be reported as a general. They were also informed that they have a right to terminate the interview at any time and skip any questions. Finally, their willingness was again asked to participate in the study.

6. Results

A total of twenty five (92.6%) community drug retail outlets (DROs) available in Ambo town were studied; among these 6(24%) were pharmacies and 19(76%) were drug stores. However, the head of the two (7.4%) drug stores (2 of the DROs) were not interested to participate in the study. All of the DROs involved in the study were private DROs except the Ethiopian Red Cross Association Pharmacy Ambo Branch. Besides, the licensed pharmacy professionals or the available dispensing personals were interviewed. All personals working in DROs were volunteer to respond for our request except the head of one pharmacy retail that was not volunteer to show the storeroom.

6.1. Premises related issues

The average years of the DROs serving the community was 7.16±4.81 years (range 1 to 17 years). The usual average working hours of the DROs were 12.6±4.52 hrs (Min 8hrs, max 24hrs) per day.

Majority of the DROs (84%) responded that they were inspected this year but the rests, two of each level, didn't inspected this year (in the past 10 months) at all. They were responded that their facility had been inspected at different frequencies annually; once (36%), twice (36%), 3 times (20%), 4 times (4%) annually and one was established at the end of last year.

All the DROs were displayed their name and level of their retail in front of their facility but one drug store displayed a level which is above the legally allowed level for it. All the DROs have original or copy of the retail pharmacy business certificate; only 20 (80%) of the DROs were displayed in their dispensary room but the rest, four drug stores and one pharmacy, were not displayed (**Table** 1).

The DROs on estimate located from 10m to 1000m (median= 300m) from the public health facilities (hospital, health center, etc.) and adjacent to 600m (median= 100m) from private health facilities (clinics). Five of these (20%) of the DROs, were located in the same compound (fence) or adjacent to the private clinics and most of those were owned by the owner of the private clinics.

Almost all (92%) of the premises walls' were constructed from brick or stone; however, the rest 2 (8%) from wood and soil (mud). Similarly, almost all floors of the facilities (96%) were constructed from cement and concrete and 1(4%) from wood. All of the DROs have roofs' ceiling, sufficient light in their dispensing rooms and premise constructed (elevated) in a way that protects the entrance of flood (table 1). The ceilings are made of different materials; plastic (4%), chip wood (32 %), some textile type (12%) and the rest were concrete (52%), which were the ground floor of the buildings (of G+1 or more). Twenty one (84%) premises store rooms were in a way of preventing entrance of insects but the other 4(16%) was not preventing. Likewise, 21(84%) DROs were having toilet with water supply, which was not directly opened to the dispensing room except in one pharmacy (**Table 1**). When we observed; most of them were out of the facilities and in common use with living rooms, clinics, collages, hotels and other renter or families, and in separate place or room with water supply. From this point it is easy to say that the retails do not have their own toilet with water supply, rather it is possible to say that the retail had toilet and water supply in common with someone else.

Table 1: Some premises related requirements of the community DROs in Ambo Town, Ethiopia, April to May 2019.

Requirements	**Yes**	**No**
Retail title/trading name clearly displayed near public entrance	24(96%)	1(4%)
Certificate of retail business displayed at the premises	20(80%)	5(20%)
The retail inspected this year	21(84%)	4(16%)
Toilet with water supply available	21(84%)	4(16%)
The room preventing entrance of insects	21(84%)	4(16%)
Store room has sufficient light	22(88%)	3(12%)
The room has ceiling	25(100%)	0(0%)
The building is in a way protecting entrance of flood	25(100%)	0(0%)

Drug store mentioned above its level

The height of the walls for premises ranged from 2.20meter to 3.50meter (mean=2.79±0.34). Among these, the height of the wall for eight (32%) DROs'; 2(33.3%) pharmacies and six (31.6%) drug stores was less than 2.6m .The height was similar for both dispensing and store rooms.

In the survey, the measurement results also reviled that, the dispensing room areas of pharmacy retails range from 21.7m^2 to 31.5m^2 (median=26.42m^2). In other way, half of the dispensing room area of the pharmacy retails was greater 25m^2 while the rests 50% were below. For drug stores the dispensing room areas range 12.5m^2 to 32m^2 (median=20.0m^2). Similarly, greater than half (63.2%) of drug stores dispensing rooms were below 22m^2, which is the minimum standard, but the rest (36.8%) exceeds 22m^2. Only two 2(33.3%) of the pharmacies had a compounding room of 9m^2 each but without any compounding equipment and materials. However, the rests have neither compounding room nor materials. In other word, none of the pharmacy retail has compounding materials and preparing extemporaneous preparations. The storerooms mean area of pharmacies and drug stores were 26.64±3.98m^2 (min 21.7m^2, max 31.5m^2) and 13.86±3.41m^2 (min 8m^2, max 24m^2) respectively. The storeroom area of four (66.7%) of the pharmacy retails were great or equal to 16m^2, which is the minimum standard, and the rest one didn't allow to measure the store room. The storeroom areas of four (21%) drug stores were less than 12m^2.

Generally, the total area of the pharmacy premises vary from 30m^2 to 56.5m^2 (mean=42.67±8.79m^2) and for drug store retails from 22.75m^2 to 56.0m^2(mean=36.47±8.74m^2). Two (33.3%) pharmacy and eleven (57.9%) drug store premises total areas were less than 41m^2 and 34m^2 respectively, which is the minimum standards, including preparation/compounding room (figure 1 and 2).

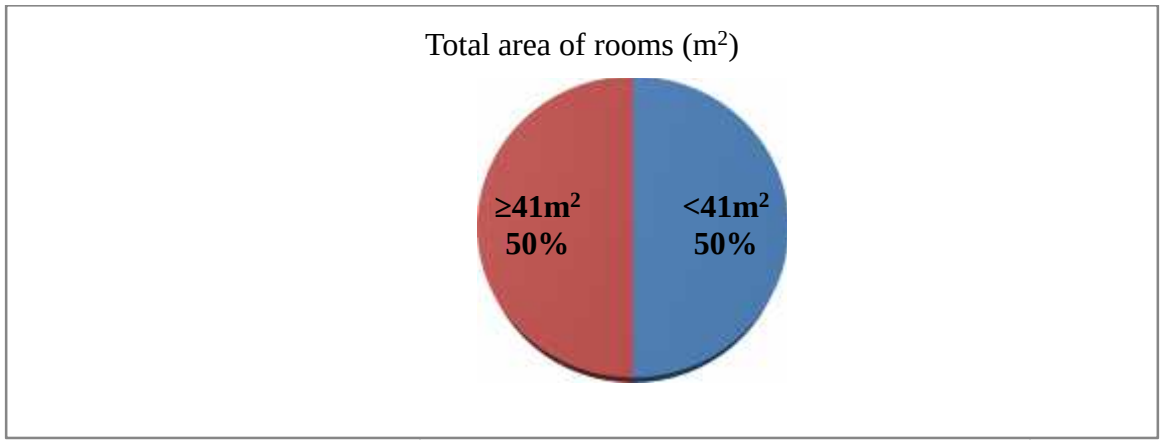

Figure 1: The total area (m^2) of the community pharmacy premises in Ambo Town, Ethiopia, 2019.

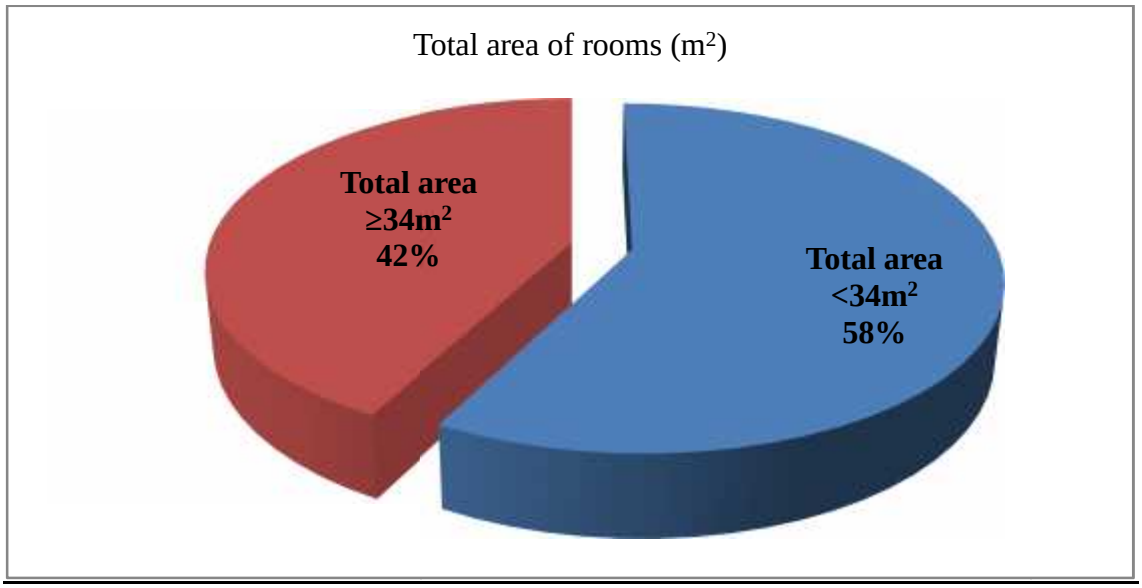

Figure 2: The total area (m^2) of the community drugstore retail premises in Ambo Town, Ethiopia, 2019.

6.2. Stock management pattern by the drug retail outlets

The study result showed that, in all DROs dispensing area (room) were separated from the storage space within the same room (building). Accessible to dispensing area was strictly controlled only in 18(72%) of the study DROs but the remaining 7(28%) of them, 3 pharmacies and 4 drug stores, didn't restricted the entrance of other person than permitted personnel. In the

dispensing room, only 9(36%) of the DROs, 3 pharmacies and six drug stores, had counseling area. However, all the DROs have chairs and tables for waiting, staffs and writing purpose in the dispensing room. The sources of prescription for all DROs were hospitals, health centers and private clinics. Arrangements of drugs in all the DRO were based on pharmacological classification.

Regarding the storeroom, only eighteen (75%) of the DROs had self-contained storeroom. However, in the rest one quarter (25%) of the DROs, store rooms' were not self-contained, had connection with other rooms through window or door. In storerooms, less than half, 10 (40 %), store some drugs on floor, pass way and/or streets. Moreover, nine (36%) DROs stored medicine with other items including cocked foods, cosmetics and household materials in either storeroom or dispensing room.

All the DROs storerooms were protected from direct sunlight and dry during the study period. The retails were protected from dust, free of pests and cemented/smooth except one pharmacy and one drug store (8%) for each requirement. Of all, one drug store roof was not protecting the entrance of rain/moisture. One drug store (5.3%) and 2(33.3%) of the pharmacies didn't have adequate light in their store room. Three of the DROs, two drug stores and one pharmacy storeroom did not have adequate ventilation.

Concerning the hygiene of the premises; in majority (92%) of DROs the dispensing room shelves were clean and hygienically maintained; however, in 2(8%) (One pharmacy and one drug store) were not clean during data collection time. In the storeroom, majority (76%) of DROs shelves (palates) were clean and hygienically maintained, i.e. free of dust, insect and pests, but in six (24%) of them, 2 pharmacies and 4 drug stores, were not clean during data collection time. In dispensing room ceilings, walls and paintworks were in a good state of repair in 18(72%) but not in 7(28%) of them. Almost in the same number of DROs, 21(84%), storeroom ceilings, walls and paintworks were in a good state of repair but not in 4(16%) of them. Two drug stores were completely not clean. The dispensing rooms of few retails (2 drug stores) were not clean and one drug store's room floor (dispensing and store) and another one drug store's storeroom were not cemented. However, all the DROs rooms (both dispensing and store) were dry (no water retained on the floor, wall or ceilings) during data collection time.

Another issue concerned was, the distance of the shelves in the premises from the building and each other. From the table 2 (below) the height of shelves/pallet above the floor for 56% of DROs were 3 to 10cm and for the rest 15 to 20cm. The distance between shelves in the facilities were range from no distance between shelves in six (24%) and 2m in 2 (8%). In dispensing rooms, the average distance from the entrance door to the dispensing shelves was range from 1.0m to 4.0m.

Table 2: Arrangements of shelves in community DROS in Ambo Town, Ethiopia, April to May 2019.

Measurements	**(Min, Max) value**	**Mean ± SD of the Value**	**Standard**
Height of shelves/pallet above the floor (cm)	(3.0, 20.0)	11.3±4.9	20
Distance between shelves (m)	(0.0□, 2.0)	0.4±0.56	0.5
Distance of the shelves from the wall (cm)	(0.0, 100)	12.8±20.73	30
Distance of the shelves from the ceiling (cm)	(5.0, 150)	71.0±35.19	100
Distance from the entrance door to dispensing table/shelve (m)	(1.0, 4.0)	2.3±0.79	1.5

□Distance 0.00= Adjacent or no distance between

In the study following the premises, we observed availably and functionality of the necessary equipment used for storage and safety of products stocked in the retails. Accordingly, 23 (92%) of DROs were having functional pharmaceutical refrigerator, where as one drug store had non functional refrigerator and another one drug store did not have it at all. Of those having

refrigerator only 15(60%) had functional refrigerator thermometer and the rest did not have at all. Almost half (52%) of the DROs did not have functional fire extinguisher, i.e. 10(40%) have but not functional (the ex. expiry date is passed, etc.) and the rest 3(12%) have not it at all. Twenty-four percent of the DROs, two pharmacies and four drug stores, did not have functional wall thermometer (fig 3).

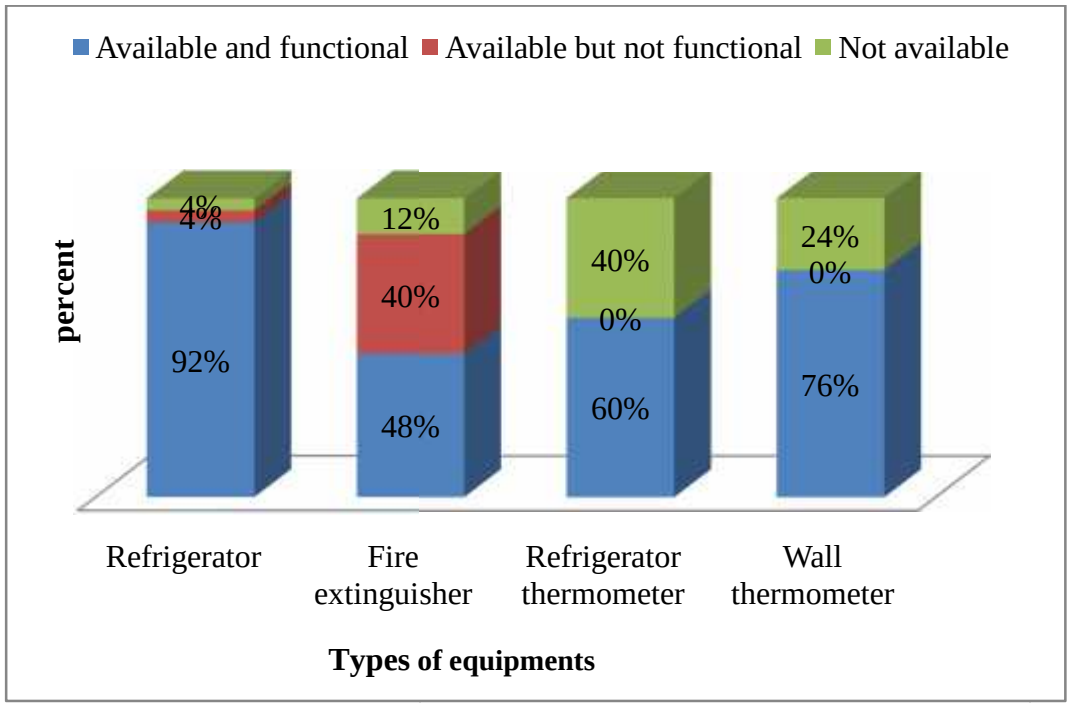

Figure 3: Available and functionality of necessary equipment for storage and safety in storerooms of community DROs in Ambo Town, Ethiopia from April to May, 2019.

Regarding the equipment used for dispensing purposes in the DROs (from the figure 4 below) 66.7% (4 out of 6) pharmacies and 89.5% (17 out of 19) didn't have counting try for counting tablets and/or capsules. Nevertheless, all facilities/ retails did have a spoon. Half of pharmacies and 3(15.5%) drug stores did not have medicine envelop and they use any sort of paper as medicinal package. Twenty two (88%) of the DROs didn't have labeling material for the drug they sold. Instead, they might write the instructions/advice on the primary or secondary package of the medicines or counseling orally only. Three (50%) of the pharmacies and 14 (73.7%) of the drugstores did not have adult weight and height scale and 23 (92%) of the DROs also did not have infant weight scale. However, only two drug stores, owned by those who had clinic

facilities in addition to drug retails, had it. Even among those having an adult weight and height scale, twelve of them didn't have height measurements, but only weight measurement. Out of the total DROs 7 (28%) of them, majorities were drug stores (6), didn't use sales ticket for the drugs they were selling.

With regard to available reference materials, only 3(12%) of the retails had OTC drug list and less than half (40%) had National drug Formulary and NTG. Only one pharmacy (4%) had ADRs reporting manual and two pharmacies (8% of the retails) had written SOP for dispensing (fig 4).

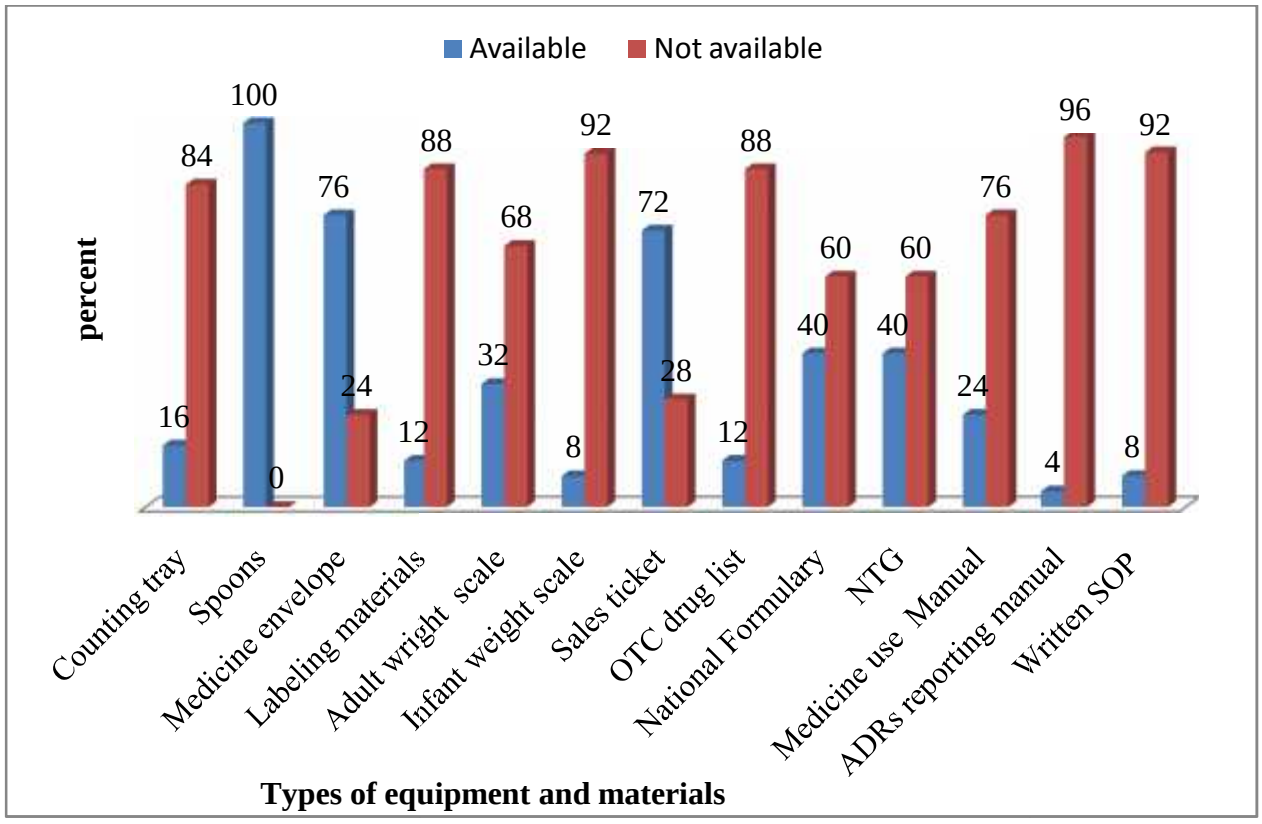

Figure 4: Types of equipment and materials available in dispensing room of community DROs, Ambo Town, Ethiopia, from April to May 2019.

6.3. Recording, reporting and documenting practices by the drug retail outlets

In this section, we focused on the available materials for recording of activities, extent of their updating/use, documentation and then when necessary, their reporting practice. The result

showed, only less than half of the DROs (40%), three pharmacies and seven drug stores, had Stock card and Bin cards. Of these, 20% (both owned by clinic owners) had only Bin card (only for store movement control) and the rest 60% did not use both at all. Even, among those having stock card and/or bin cards, 40% of the DROs (4 drug stores) didn't have for all products and 60% (six) of those DROs didn't register/ fill received or issued items (stock rotation) on time.

Only 6(24%) of the DROs have a temperature-monitoring chart for recording the daily room and refrigerator temperature. All these retails measure and recorded the room temperature morning and afternoon on daily base. Yet, only 4(66.7%) of those recorded the temperatures of the room, keeps it as a document for the period of fifteen months 1(25%), 2 months 2 (50%) and one month 1(25%). Even, only16%, two from each level retails, measure and recorded the temperature of the pharmaceuticals refrigerator daily. Only half of those, one pharmacy and one drug store, kept the recorded temperature for only fifteen and two months respectively. Almost all (91.3%) of those having refrigerator had been used for storage of drugs according to the manufacturer's label. However, one-pharmacy was found storing food items in refrigerator, and another drug store was store drugs over congested including the door of the refrigerator.

Based on the response of the respondents and in our observations; only two pharmacies (8% of the total retails) dispense drugs based on the types of prescription intended i.e. narcotic and psychotropic drugs on the special prescription and other drugs on ordinary standard prescription. The other retails (all drug stores and 66.7% of the pharmacies) could either dispense both types of drugs on the same prescription or without prescription, like OTC drugs.

Only 8(32%) of the DROs were having prescription registration book (PRB) to register dispensed drugs to the users. Of these, only one of the retail had separate PRB for NSPs drugs and other drugs prescriptions registration book (log). From those having PRB only 6(75%) of them register the dispensed drugs on PRB timely (update it) and the other 2(25%) retails didn't register for the last 6 months to one year.

Less than half (48%) of the retails were kept prescriptions after registration or without registration separately (NPS prescription and others). However, 9 (36%) retails keep separately NPS prescription in lockable cabinet but the rest 3(12%) did not keep in lockable cabinet.

Majority (28%) of the DROs stored/kept both of prescription since the establishment of the facility, from six to seventeen years. Controversially, few (8%) did not keep (return to the patient, dispose with other wastes or use as packaging for drugs) but had been serving for five to seventeen years. The duration of prescriptions kept by the retails is similar for both types of prescriptions. That is 3(12%) DROs are those established in recent years hence store 1 to 2 years, 3(12%) for one year, 6(24%) for two years,4(16%) of the retails for the period of their establishment mines one year (3, 4 and 5 years respectively),7(28%) starting from their establishment(six to 17 years). None of the DROs reported the disposal of any prescription to the concerned regulatory body.

None of the DROs was submitted regular report to the appropriate regulatory body and no regulatory body asked the retails report about consumption and stock of controlled (NSPs) drugs.

Related to ADR reporting, except few (8%) (one pharmacy and one drug store), the DROs had no ADRs reporting form, even these two had only one or two copies as a sample, as one of a regulatory requirements. In addition, all of the pharmacy personals available during data collection time did not have any training related to ADR reporting. Only 7 (28%) of the personnel had a chance to contact a patient with drug allergies, but none of them reported the case to the concerned body.

From figure 5 (below) only one drug store (4%) use drug receiving form only to control the stock movement and the form updated because of its purpose. From those who had expiry-tracking chart, only four percent updated it, the others two use/had it only as the regulatory requirements. Those DROs having physical inventory form were who submit annual income report to Inland Revenue for tax pay purpose and did physical inventory annually at the end of the physical years. Those DROs having expired drug disposal form report the available expired drugs to the regulatory body. None of the DROs had Patient allergic card at all.

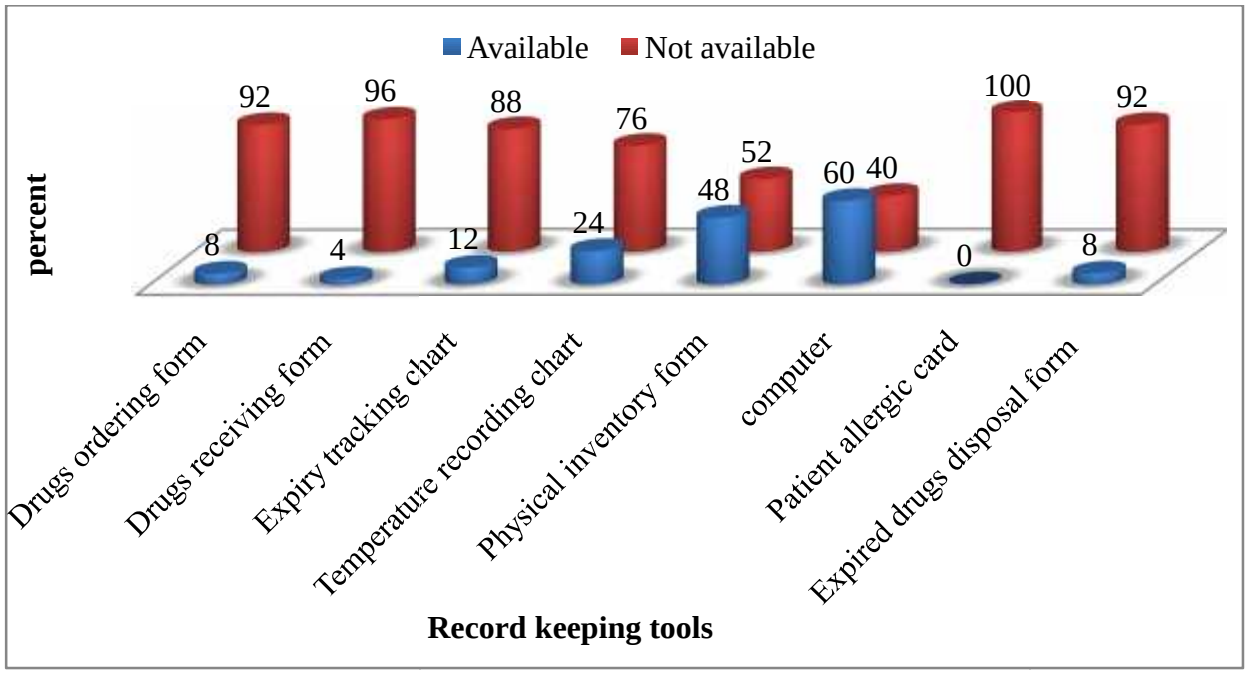

Figure 5: Material available for recording and documentation in Ambo Town community DROs, Ambo, Ethiopia, 2019.

6.4. Pharmacy personnel

Here we assessed legal and professional status of personnel's available for dispensing during data collection time, the renewal status of their professional license and number of personnel practice in the retails through observation of their available data and interview. From those licensed pharmacy professionals 20 (80%) were male and 5(20%) were female druggists. Almost half (52%) of the licensed pharmacy professionals; 3(50%) of pharmacists and 10 (52.6%) of druggists, were available during data collection time and interviewed. Eleven (55%) of male and 2(40%) of female were present during data collection time. However, the other retails were without legally licensed professionals, we observed their available data and interview the available dispensing personnel. Based on their response, the mean age of the responded professionals is 36.2±5.41 (N=20) years and with an average service year of 10.02±4.68 years (N=22).

Only 6(24%) of the professionals/interviewed personnel wear white clean gown, and only one druggist (4%) use the tag during data collection time. All of the licensed professionals including

those who were not available during data collection time had renewed their professional license in the last two years and the trade license of the DROs were also renewed for the study year. Only 48% of the DROs (4 pharmacies and 8 drug stores) have assistant licensed personnel. But, different number of assistants; 83.3% of them (4 pharmacies and 6 drug stores) had one assistant and the rest two drug stores (16.7%) had 2 assistant professional. A total of 9 (36%) licensed professionals, half of the pharmacists and six of the druggist, were on education (regular, weekend, distance, summer, etc, programs). Of these on education licensed professionals, 5(55.5%) of the retails didn't have assistant licensed pharmacy professional/s. Those DROs having no assistant professionals responded that they can close the retail when they (licensed professional) are not available.

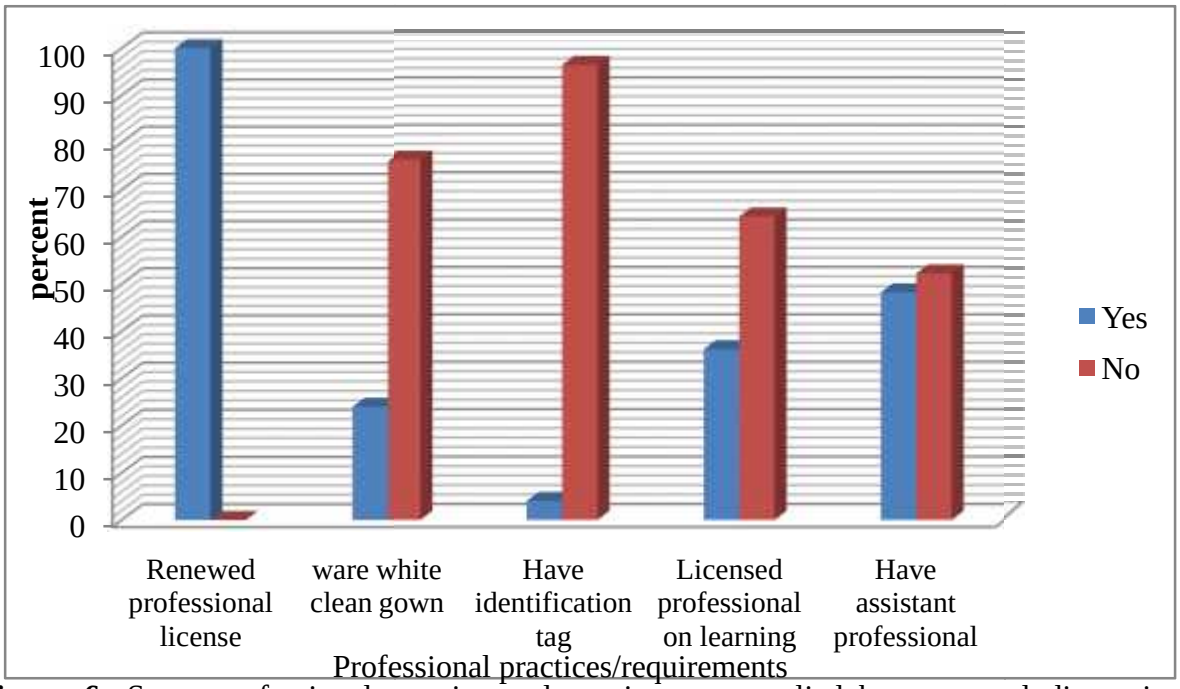

Figure 6: Some professional practice and requirements applied by personnel dispensing in community DROs of Ambo Town during data collection time, from April to May 2019.

Despite the fact that all the DROs were provide service to the community during data collection time, only 13 (52%) of the licensed professionals were available during data collection time. But, 2(8%) of the DROs provide service by non-licensed personnel and/or non-professionals; including par timers (governmental employees), 2(8%) clinical nurses and 2(8%) level II TVET (technical and vocational education and training) pharmacy technician students (non or sub-

pharmacy professionals) and 3(12%) of them by non-professionals (families, casher, etc.). Those who were pharmacy professionals responded that they had renewed their professional register license in the last three years (from 2009 E.C to 2010 E.C).The others available licensed professionals responded that they close the retail whenever they are not present. One druggist was rented his/her professional license in one of the DROs and employed as full-time worker in other retail, in the town. The DROs have different number of personnel including the licensed pharmacy personnel, assistants professionals, cashers and others 4(12%), 3(20%), 2(28%) and one personnel (40%) of the retails respectively.

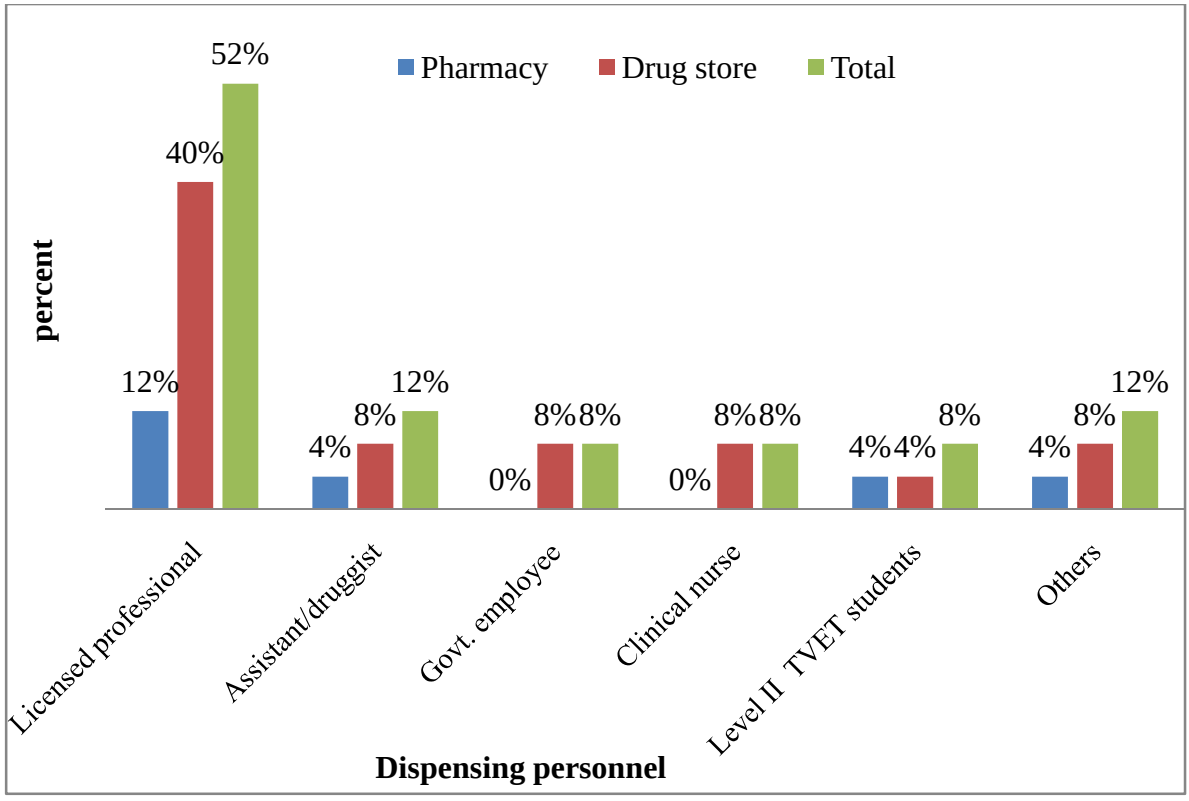

Figure 7: Dispensing personnel in Community DROs during data collection time Ambo Town, Ethiopia, April to May 2019.

6.5. Expired drugs management and disposal system of the DROs

In 60 % of the DROs (5 pharmacies and 10 drug stores), there was an accumulation of waste/ expired drugs available during data collection time. However, only in one pharmacy (6.7%) the expired products were segregated from each other. The DROs stored/accumulated these expired

drugs for an average of 2.9±3.4 years (from three months up to eleven years); most of them stocked it since their establishments.

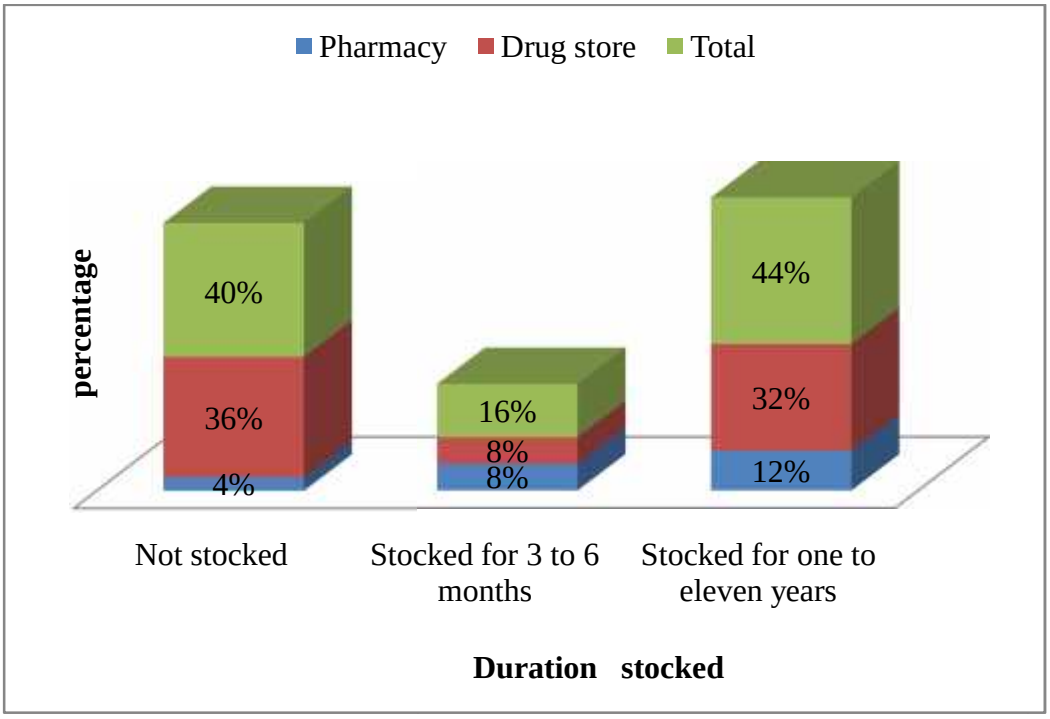

Figure 8: Duration of expired drugs stocked in community DROs in Ambo Town, Ethiopia, April to May 2019.

Again when asked about their past practice of expired drug disposal system, only 6 (24%) DROs responded that they had ever disposed expired drugs in the past time. Of all these disposed the expired drugs, only 50% of DROs (Two drug stores and one pharmacy) were disposing/ burn in the Ambo Health Center disposal facility and secured permission and conformation from Ambo Town Health Office. Nevertheless, the other 50% were disposing by different mechanism without reporting to the concerned regulatory body. That is, two drug stores burned it in an incinerator of the clinics and one DRO burned it on filed on a time without the regulatory body permission. However, only four DROs had a document related to disposed drugs like lists of disposed drugs and letters of application to the regulatory bodies (West Showa Health office and Ambo Town Health Office).

Regarding the availability of expired/waste drugs disposal facility by the drug retail outlets; all responded that they do not have it. But, all responded that they had other waste disposal facility which is used for the disposal of packaging materials, waste papers, cartons, etc. When we observed that, all had it, but in common use with other organization, business retails or living rooms, like that of latrine and water supply. Finally, the DROs response how to dispose available or going to be expired drugs were two basic plans. Accordingly, all the three drug stores 3(12%), owned by the clinic owners, were planning to use the clinic incinerators as expired drug disposal facilities. Nevertheless, the rest 22(88%) DROs planned to refer the expired drugs or drugs to be expired in the future to other health facilities to dispose.

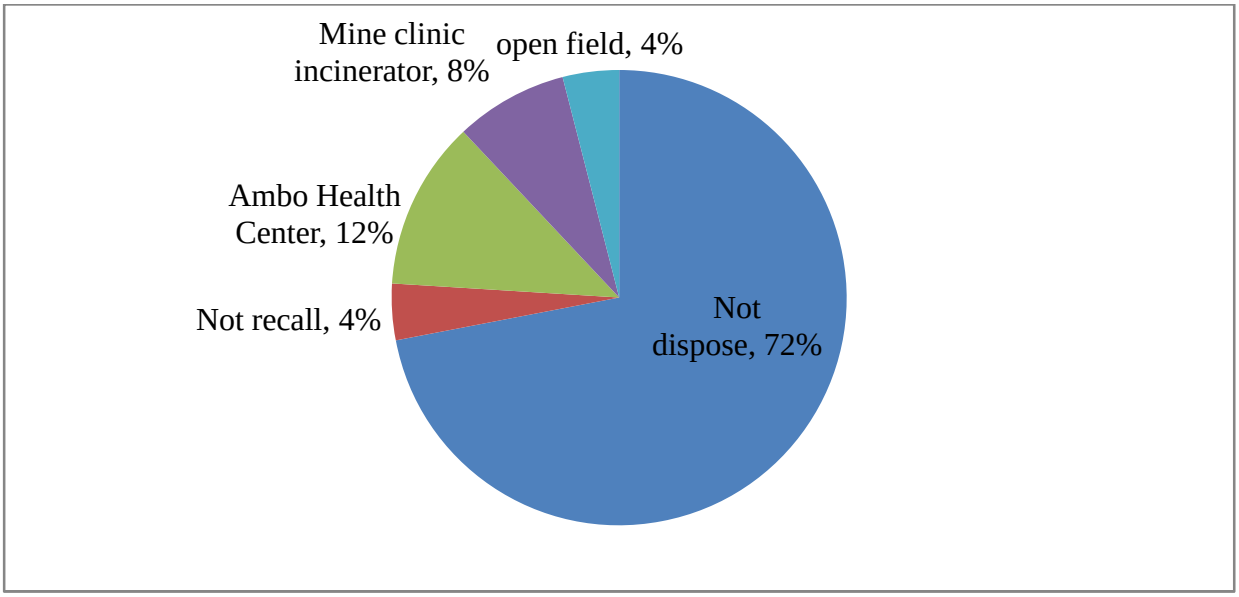

Figure 9: The dispensing personnel response of expired drugs disposal practices by community DROs in Ambo Town, Ethiopia, 2019.

7. Discussion

If standards for pharmaceutical premises exist in a country, they should define the minimum requirements to operate a drug shop as the regulation (MSH, 2012).In this study, we also tried to assess the compliance of community DROs in Ambo Town with the minimum standards set by the regulatory body.

Before all, the facility should be easily accessible to the public and possess retail license. Pharmacy regulation mandated that; the name and level of the retail should clearly display in front of the retail. The copy of certificate of the retail pharmacy business should also be displayed/hanged were it is clearly seen in the dispensing room (EFMHACA 2014). Accordingly, the entire DROs well displayed the title of their DROs name and level of the retail written in combinations of three languages namely; Afan Oromo, Amharic and English almost respectively in front of their facility clearly. However, one drug store (4%) stated above its level, which is not only confusing the community but also against the regulation. Besides, 20% of DROs were not displayed the certificate of the retail pharmacy business at the premises, but all have it unlike that of the Nepal retails which showed 6.7% of the study pharmacy retails didn't have at all (not registered)(Poudel et al., 2016). It was less than half of the study done in Kenya SDSs by 2014, in which 44% wasn't displayed (Wafula et al., 2014). Again it is less than those displayed in Pakistan drugstores, which was 34.7% (Shah et al., 2016).

Five of these (20%) DROs were located in the same compound (fence) or adjacent to the private clinics. Most of those are owned by the private clinic owners. This distance seems ease of access to the retails for the community. Nevertheless, the EFMHACA regulation do not permits to establish any private drug retail in any types of health service providing institution/facility, but without limitation of the distance between them. The premises should be also self-contained and not to be connected with other service providing rooms through window or door (FMHACA, 2015). Even, Oromia Regional Health Bureau currently do not allow establishment of any DROs in a radius of 100m from any health service providing facility, both private and public health providing facilities (letter written from ORHB to all zones in the region on 12/03/2012 E.C by the reference number of BEFO/AHITQTFFWO/GO-18/1501).

As far as the dimensions of each room of the premises have their own allegation on the product stocked and services provided, they are the primary requirements to grant a retail business license. EFMHACA also standardize the number and dimensions of the rooms needed based on the level of the retails and the purposes of the rooms (EFMHACA, 2013). However, the result of our study showed that the height of the wall of 2(33.3%) of pharmacies and 6(31.6%) of drugstores is less than 2.6m which is the minimum requirement. It indicates that there is less chance for the free circulation of the air in the room and hence the case for probability of the increment of room temperature. Majority (87.5%) of them having wall height under the minimum requirement were those retails serving for six years and above.

The current study also showed that, variations among the areas of rooms were not only based on the minimum standard but also a considerable variation among similar level DROs and hence the total areas of the premises. Accordingly, half of the dispensing room areas of the pharmacy retails were below $25m^2$(with the least $21.7m^2$) and greater than half (63.2%) of the drugstores' dispensing room area were below $22m^2$ (12.5 to $21.20m^2$), which is the minimum standard requirements. The store room area of only 4 (66.7%) of the pharmacy retails great or equals $16m^2$, of one pharmacy was $10.20m^2$ which is 36% less than the minimum area required. The store room area for drugstores range from 8 m^2 to $24m^2$; four (21%) of them had lessen $12m^2$ while the rest had greater or equals to $12m^2$ which is the minimum standard mentioned above.

In other way, the total area (the sum of dispensary, store and compounding rooms) of the pharmacy premises were vary from $30m^2$ to $47.5m^2$ and for drug store retails from $22.75m^2$ to $56m^2$. Generally, 3 (50%) of pharmacy and 11 (57.9%) of drug store premises total areas were less than $41m^2$ and $34m^2$ respectively, which is the minimum standard (FMHACA, 2013). In other words, the total area of the pharmacy and drugstores were up to 26.8% and 33.1% respectively below the minimum standard area sated by FMHACA.

However, the dimension of the premises should be measured and evaluated prior the retail gained the retail business license but they have been provide pharmaceutical services in these substandard rooms since their establishment. It shows that not the non-compliance of the retails but also the negligence of concerned regulatory bodies due to some factors which need further investigations.

In this study 23(92%) of DROs were having functional pharmaceutical refrigerator which was more than in Pakistan drugstores and Kenya SDSs which were only 75.6% and 12% respectively (Wafula et al., 2014) (Shah et al., 2016). However, one of the retail use nonfunctional refrigerator for regulatory requirement only. Of those, having refrigerator only 15(60%) has refrigerator thermometer but it is much greater than that found in Pakistan drugstores, which was 1.4% only (Shah et al., 2016). A pharmaceuticals refrigerator without measuring thermometer means not the fridge temperature is monitored and adjusted or coincides with the temperature required for products storage label. Hence, it is difficult to tackle or trace if any temperature deviations will happen during the storage of the product.

During this assessment majority of the retails who have refrigerator use refrigerator for storage of drugs only as labeled by the manufacturer. Yet, two of the retails use in opposite manner; one pharmacy store food items in refrigerator and another drugstore was over congested the refrigerator including the door of the refrigerator which occludes the free movement of the air inside.

When we count the available fire extinguisher almost all (92%) of the DROs have it. However, when actually observed, 10(40%) were not functional (the ex. expiry date is passed, etc.). It shows that almost half of the respondent DROs did not had fire extinguisher at all or had nonfunctional fire extinguisher eventhogh it is also one of the regulatory requirements to get a drug retail business license. Guidelines recommend fire extinguisher would be available, accessible, and functional. From this study, one can argued two things; first, the owner and/or personnel didn't well understand the use of the equipment. Secondly, that regulatory body who inspected the retails and give the license to the facility didn't consider not only the functionality but also the availability of fire-extinguisher.

Not only considering the regulatory requirement but also for their purposes materials for dispensing aids should available. But, the availability was only 8%, 16%, 32% and 76%, for infant weight scale, counting try, adult weight scale and medicinal envelop respectively, other than the spoon which was the only 100% available (fig. 4). This shows that the DROs did better improvement regarding weight scales when compared with the study done by 2014 on these retails which showed none of them had all types of measuring scale (Jimma et al., 2015).

For the pharmacy professionals it is also necessary to have some reference materials related to their practices for proper selection and storage of drugs, good dispensing practice, to obtain updated information, registration and documenting. In this part of the current study, we focused on the availability of some reference materials, which the professionals may use routinely in their practice to promote rational use of drugs. During our observation the availability of these reference materials was not greater than 40% for each. However, almost all the assessed reference materials are those published and updated by the regulatory body of the country, FMHACA. Therefore, none availability of these materials might be related with some reasons: either due to the carelessness of the professionals or lack of sufficient supply by the concerned body.

One of the essential documents is those related with stock management data. Since a good inventory control makes ordering and managing pharmaceuticals easier (MSH, 2012**).** One of the instruments used as a backbone in DROs is stock card and bin cards, either in software or in printed-paper. However, the current study showed that less than half of the DROs 10 (40%) was having Stock card and/or Bin cards. Even, two of these (both drug stores owned by clinic owners) had only Bin card (used for control movement of items in store) and the great majority (60%) didn't use both at all. Of those having stock card and/or bin card 40% of the DROs (4 drug stores) didn't have for all products and 6(60%) of those DROs didn't register/ fill received and/or issued items on time. When summarized, only 4(16%) of the total drug retail out lets have the cards and properly register received and/or issued items on time.

Ideally, all should have the cards and register stock movements on time. The current result showed that it is difficult to trace if any problems happened and even if the retails had been stocked illegal products or not. On other hand, it is difficult whether the inspecting regulatory body focused on this issue because majority of those DROs having no stock and bin cards were responded that, they had inspected one to three times annually and even 12(48%) of them inspected in the study year. It was almost the same number for both those retails whose licensed professionals available and not available during data collection time. Therefore, it is also another issue which needs further investigation for the reason why the cards neither used by the retails nor thoughtfully controlled by the concerned regulatory body.

EFMHACA recommend measuring both refrigerator and room temperatures twice daily and recording it on prepared temperatures monitoring chart (EFMHACA, 2018). Nevertheless, only 6(24%) of the DROs have a temperature monitoring chart and had been recording the measured temperature twice daily. Even, from these only 16% (two from each level retails) measure, recorded and keeps the temperature of the pharmaceuticals refrigerator. However, they had been keep the documents for the period not exceeds fifteen months; for one to 2 months 3 (75%) and fifteen months 1(25%). But, guidelines recommend that all monitoring records should be kept for at least up to the shelf-life of the stored product plus one year for review. Failure to monitor and record temperatures accurately can mean that health professionals may be unaware of these potential effects on medical product **(**EFMHACA, 2015). The result also shows not only the professionals improperly monitor the temperatures but also the concerned regulatory body or inspectors are also passing over it.

Not only based on the blameless responses of the respondents but also in our observation during data collection time; only two pharmacies (8% of the total retails) dispense drugs based on the types of prescription intended. It means that narcotic and psychotropic drug on the special prescription and other drugs on ordinary standard prescriptions. The other retails (all drug stores and 66.7% of the pharmacies) could either dispense both types of drugs on the same prescription or without prescription all types of drugs. Another study conducted in Addis Ababa private retail pharmacies by 2016, similar to the current study, showed that both the dispensing professionals and the data collector observations witnessed that drugs sold without intended prescription drugs. All the respondent professionals also complain that weak regulatory mechanism as one of the major reasons for nonprescription sales of antibiotics (Gebremedhin and Mirgissa, 2012).

One study done in Dhaka city, Bangladesh, by 2015 also shows 82% of antibiotics and 80% NSPs drugs sold without prescription, according to the professional response (Rakib et al., 2015). Another study done in, another city Rajshahi, Bangladesh by 2017 again indicates 22.70% of all drugs were sold without a prescription in private pharmacies (Saha and Hossain, 2017).

Whatever the situations looks like in the studies done so far, including the current study. The country's regulation controversially mandates any dispenser of medicine may not dispense medicines without prescription issued in accordance with medicine prescribing procedures,

except OTC medicines. But also, the retails have the duty to record and document the dispensed prescriptions for the intended time in a secured way (Federal Negarit Gazette, 2010).

FMHACA also mandated all dispensing units to have a standardized Prescription Registration Book (PRB) for recording dispensed drugs timely and kept properly (FMHACA, 2015). Controversially, only 8(32%) of the DROs had PRB to register dispensed drugs. Of these, only a single retail had separate PRB for NSPs drugs and other drugs. From those have PRB, only 6 (75%) of them (24% the DROs) register the dispensed drugs on PRB timely (update it). The rest other retails 2(25%) didn't register for the last 6 months to one year. The availability of PRB is even ten percent less than the result from Kenya SDSs which was 42% (Wafula et al., 2014). EFMHACA also recommend preservation of records on what medicines and products have been issued is one of the most useful techniques to ensure quality in dispensing (FMHACA, 2012).

When irrational handling (preserving) of prescriptions is compiled with the selling of drugs without the legal prescription, mentioned above, it is easy to see that the degree of the prevalence of irrational use of any types of drugs. Especially, it is a clear picture that shows great opportunity to sell both NSPs and antibiotics which are vulnerable to addiction and micro-organism resistance respectively. In addition it is difficult for evaluating the service or product provided to the users. With this regard, it also needs further investigations and urgent interventions to fill this huge gap, especially by looking through the country's situations.

The ADR reporting form collects basic information about the patient, the medicine, the adverse reaction, the action taken, and the outcome (PFSA, 2015). In this study, insignificant number, 8 % (one from each level) DROs had one or two copies of ADR reporting form, as a one of a regulatory requirements. None of the respondents had been taking training on ADR reporting. However, seven (28%) of the personnel were contacted a patient with drug allergies. However, none of them reported the case to the concerned body like the community pharmacist respondents of one of the Bangladesh city by 2015 (Rakib et al., 2015). This may be due to the lack of awareness. It shows that the regulatory body of the country also hadn't been focused on ADRs monitoring, hence not providing training and supplying ADR reporting form for the professionals. Since, these two activities are the duties and responsibilities of the regulatory body of the country (FMHACA, 2014).

Dispensing practice plays a central role in the provision of rational medicine use (EFMHACA, 2012). Thus, lack of trained staff in drug dispensing outlets can lead to inappropriate dispensing of medicines and irrational use (Ariane at.al, 2011). Therefore, in this study we focused on the dispensing professionals rather than the process since they are the determinant factor over the practice. However, during data collection time, almost half (48%) of the licensed pharmacy professionals were not present. Nevertheless, all of them were providing service by; their assistants (12%) and non-legalized or non-health professional persons (36%). Even, from those nine licensed professionals currently on education four of them neither available during data collection time nor have an assistant licensed professional. Beside, only 12(48%) of the DROs have one or two assistant licensed professional. It is somehow less than the study done in Bangladeshi by 2015, in 64% shops, pharmacists worked alone (Rakib, 2015).

One druggist was rent his/her professional license in one of the DROs and work/employed as full-time worker in other retail in the town. That is a chance to work for those non authorized persons in the retail that serve by renting his/her license. It is one of the magnified indicator toward the weakness of the concerned regulator body (inspectors) or the relation of the regulatory body with the professionals or/and the retails.

It is almost similar with the cross sectional study conducted in private drug retail outlets in Ambo Town, the current study area, in 2014. Which revealed that, out of 18 dispensers working at these settings, during visit, 5(27.8 %) was not professionally qualified (without having any college diploma or university degree) (Jimma et.al, 2015). It is also almost relative to the study conducted in Nepal in which 42.8 certified dispensing personnel absent (Poudel et al., 2016). However, it was much less than another assessment done in Tanzania; in which the service was provided by unqualified personnel in over 70% of premises (Ministry of Health and Social Welfare, 2009).

According to proclamation 661/2009 art 39(3) medicines should be dispensed by medical professional who is dually registered and licensed by concerned regulatory body and for those assistant professionals to practice/work under the management of those authorized professionals. It is a punishment with an imprisonment of two to five years and a fine of 50,000 to 100,000 Birr (Federal Negarit Gazette, 2010).

In any type of health institutions there is a chance for a product to be wasted or become useless by any means including expiration, inefficient management, over stoke, environmental situations, quality issues, etc. In this study, we focused not on the case of wastes rather we focused on the way of their management and the disposal mechanism of these waste/expired products in the study DROs.

During the current study period expired drugs were stored in 15 (60%) of the study DROs; 5(83.3%) of pharmacies and 10 (52.6%) of drugstores. Nevertheless, all store by separating from other usable products without label as 'products to be disposed'. The DROs store/accumulate these expired drugs from three months up to eleven years (range= 10.75 years). Briefly speaking, 4(26.7%) of DROs for the period of 3 to six months in line with the regulation and 11(73.3%) of DROs from one to eleven years which is a great contrary to the regulation. Most of them stocked it since their establishments. It may end up with the use of the products and occupying store area then may push the owners to use the unsafe disposal to relief their space. Nevertheless, the regulation and some guidelines recommended these wastes should be disposed from three to six months of their expired/waste date (FMHACA, 2011), (US AID‖ DELIVER PROJECT, 2014).

EFMHACA also witnessed that only limited number of facilities disposed expired drugs and this few facilities were dispose in unsafe way before the adoption of waste management guideline in 2012 (FMHACA, 2012). The study done in Amhara National Regional state by 2014 also showed the accumulation and improper disposal of health care waste, including pharmaceuticals wastes both in public and private hospitals respectively (Esubalew, 2014). This study again reflected that, the situation is almost similar in the study retails as it was before the guideline developed by FMHACA. It is the indicator of the gap on training of waste management and disposal for both the concerned regulatory body and pharmacy professionals/ the owners.

In other way it is clear that, from their response, in the rest three (12%) of the DROs drugs had been not expired or not wasted throughout because of either their efficient stock control or loss of memory or fear of responding that the retail may dispose illegally. It needs further investigation and we recommend so.

8. Strengths and limitations of the study

1. Strengths of the study

- It was a survey done on entire, rather than using the sample retails in the town; hence, its result is precisely the representative of the community retails in the town.
- We used different techniques; interview, physical observation and measuring.
- We cross check the practice that have been done by different regulatory bodies for long period of time.

2. Limitations of the study

- Hence, a limitation of such types of studies, in most cases results compared with standards.
- The study didn't assess all regulatory issues like product and process.
- The prospective of regulatory body and patient/clients wasn't included.
- May be recall biases on issues like disposed expired drugs and frequency of inspection.
- The data was collected only during working hours not include weekend, holy day and off working hours.

9. Conclusions

The DROs should meet the entire regulatory minimum required standards to get license of the retail and serving the community. Nevertheless, none of the retails meets all the minimum requirements and most of the DROs do not fulfill majority of the requirements set by EFMHACA.

The total area of greater than half (52%) the DROs premise is below the standard, even up to 33.1%. Likewise, the height of the walls of 8 (32%) of the DROs are below the standard. Five (20%) of the DROs, are located in the same compound or adjacent to the private clinics. These are some of the indicators of the pre- licensing of the retail inspection mal-practice activity.

The stock management patterns in the DROs were almost poor; because of not only the unavailability and non-functionality of the stock management materials and equipment but also improper use of them by the professionals. It was compiled with poor hygiene of the rooms and shelves in the DROs. The data management system was also negligible almost in all retails; some of the data either not recorded and kept at all or stocked over the intended time.

Because of 48% licensed pharmacy professionals were not present during data collection time; they were providing service either by their assistant or illegal personnel. Except few the majorities of the DROs, either stored beyond the intended period (for 2.9±3.34 years) or had been dispose expired dugs in unsafe way.

Based on this study, we conclude that; majority of the drug retail outlets do not satisfy the minimum requirements set by the regulatory authority of the country. The concerned regulatory bodies also do not strictly monitor the requirements, irrespective of their allegation on the products stocked and the service provided by the DROs.

10. Recommendations

Based on the study findings we would like to forward the following recommendations for the respective stakeholders, for the future improvement or correction of the issues assessed.

- **Policy makers**

- If accountability rule could prepared for the concerned regulatory bodies.
- It is best if further assessments would be done on the proportion of available pharmacy personnel and pharmacy facilities in the country as whole.

- **Education**

- It is better if some of the issues like standards, reporting, recording, etc incorporated in the pharmacy education curriculum.

- **Practice**

- Have to facilitate pre- professional registration training on the gaps for the professionals.
- It is better if regulatory body cross checks the requirements and takes necessary corrective measures.
- Pharmacy professionals should use updated reference materials and secure professional ethics.

- **For further study**

- To assess possible case of the problems and the magnitude of the problems in different woredas, zones, regions and hence at national level.
- To assess product and process related issues.

11. References

Ariane MC, Andreas S, Aissatou D, Christopher HH, Sheila D (2011). Private Sector Pharmaceutical Supply and Distribution Channels in Africa: A Focus on Ghana, Malawi and Mali; HNP discussion Paper.

Ashigbie P. G (2011). Phamaceuticl Regulation: Atwelve Country Study: A P harmaceutical Assessment Management and Policy Practicum (PAMP) Report; Boston University School of Public Health, Boston, USA.

Bethelehem G (2014). Assessment on the implementation of Hospital Reform Guideline with reference to Pharmacy service in Addis Ababa, A thesis submitted to the Department of Pharmaceutics and Social Pharmacy, Addis Ababa University, Addis Ababa, Ethiopia.

Dalberg Global Development Advisors and the MIT-Zaragoza International Logistics Program (2008).The Private Sector's Role in Health Supply Chains: Review of the Role and Potential for Private Sector Engagement in Developing Country Health Supply Chains. Technical partner paper 13.

DRA (2014). Guideline for Disposal of Pharmaceutical Waste. 1st ed. Kingdom of Bhutan.

Edmealem E. and Hailu T. (2014). Development of the National Minimum Standards for Healthcare Facilities in Ethiopia. A Milestone for Country Ownership and Sustainability of Best Practices, p 9-12.

EFMHACA (2011). Medicines Waste Management and Disposal Directive. Food, Medicine and Healthcare Administration and Control Authority of Ethiopia. Addis Ababa, Ethiopia.

EFMHACA (2013). Guideline for Medicine retail outlets Licensing and Regulation System, Amharic Version. Addis Ababa, Ethiopia.

EFMHACA (2014). Guideline for Adverse Drug Events Monitoring (Pharmacovigilance*).* Third ed. Addia Ababa: Food, Medicine and Healthcare Administration and Control Authority (FMHACA) of Ethiopia.

EFMHACA (2012). Manual for Medicines Good Dispensing Practice. Second ed. Addis Ababa, Ethiopia.

EFMHACA (2015). Guidelines for Good Storage Practices, Good Distribution Practices, Pharmaceutical Products Recall. 1st ed. Addis Ababa.

Ejigu E, Tadeg H and Mekonnen N. (2012). Establishment of Medicines Waste Management and Disposal System in Ethiopia: A Report on Progresses and Achievements.

EPRDF (2010). Food Medicine and Health care Administration and control Proclamation 661/2009. *Federal Negarit Gazette*, 2010; **16**:5157-91.

Esubalew T (2015). Healthcare waste in Ethiopia a study of waste generation, composition and management in the Amhara national Regional state, Ethiopia. A Dissertation submitted to the School of Graduate Studies of Addis Ababa University in partial fulfilment of the requirements for the Degree of Doctor of Philosophy (PhD) in Public Health.

FIP (2009). 2009 Global Pharmacy Workforce Report. The Hague, The Netherlands: Federation Internationale Pharmaceuticals (FIP). Available at: www.fip.org/hr. Accessed 12/4/2017.

FMOH (2017). Ethiopian Health Accounts Household Health Service Utilization and Expenditure Survey 2015/16. Addis Ababa, Ethiopia.

FMOH and WHO (2003). Assessment of the Pharmaceutical Sector in Ethiopia. Addis Ababa,Ethiopia.

Gebremedhin B. and Teferi G. (2013). Assessment of Pharmacists workforce in Ethiopia. *Ethiop. J. Health Dev* **27**(2):124-133.

Gizat M and Samson M (2014). Assesessment of pharmacuticalstore management in woreda health office of west Hararghe Zone, Ethiopia. *Int. Res. J. Pharm* ***5****(8): 642-645.*

Health Board on Global (2001). Committee on Understanding the Global Public Health Implications of Substandard, Falsified, and Counterfeit Medical Products:Countering the

Problem of Falsified and Substandard Dr. *the national academies press*, pp. 334-3313. available at: http://nap.edu/18272.

Jimma L, Biruk M, Minyahil A, Dumessa E (2015). Analysis of Dispensing Practices at Community Pharmacy Settings in Ambo Town, West Shewa, Ethiopia . *J Community Med Health Educ* **5**(1): 329.

Lowe RF and Montagu D (2009). Legislation, regulation, and consolidation in the retail pharmacy sector in low income countries. *Southern Med Review* **2**(2):35-44.

Management Sciences for Health (MSH) (2012). MDS3: Managing access to medicines and health technologies. Arlington, VA; 2012.

Ministry of Health and Social Welfare (2009). Assessment of the pharmaceutical human resources in Tanzania and the Strategic Framework. Tanzania Ministry of Health and Social Welfare, Dar es Salaam.

Ministry of Health Care & Nutrition Government of the Democratic Socialist Republic of Sri Lanka (2008). Manual on Management of Drugs. Second revision, Sri Lanka.

Mir JI, Mohammad IG and Parvez AD (2017). Medicines Management in Hospitals:A Supply Chain Perspective. *Sys Rev Pharm:* **8**(1), pp. 80-85.

MSH (2010). Health Systems in Action: An e-Handbook for Leaders and Managers. Medford, MA.

ORHB (2014). Knowledge and Skill transfer Mechanism Guideline:For Regional Health Bureau, Zonal health departments, Town Health Officesand Woreda health offices pharmacy coordinators and officers. Addis Ababa, Ethiopia.

PFSA (2016). Pharmacy Mentoring Manual. First Edition, Addis Ababa, Ethiopia.

PFSA (2015). Ethiopia Standard Operating Procedures Manual for the Provision of Clinical Pharmacy Services in Ethiopia. PFSA in collaboration with the US Agency for International

Development's Systems for Improved Access to Pharmceuticals and Services Program. Addis Ababa, Ethiopia.

PFSA (2015). Standard Operating Procedures (SOP) Manual forthe Integrated Pharmaceuticals Logistics System in Health Facilities of Ethiopia. Second Edition ed. Addis Abab,Ethiopia,.

Pharmaceutical Society of Ireland (PSI) (2018). Guidelines on the Storage of Medicinal Products within a Retail Pharmacy Business; Version 2.

Poudel BK, Ishiia I, Khakurelc B (2016). Assessment of Regulatory Compliance in Selected Pharmacy Outlets of Nepal. *Journal of Pharmaceutical Health Services Research* **7**: 31–36

Poudel BK and Ishiia I (2016). Assessment of Physical Premises of Selected Pharmacies of Nepal. *SAGE Open Medicine* **4**: 1 –5

Rakb A, Sarwar S, Shaheda Z, Sayema K, Mamunur R (2015). A Survey of the Role of Community Pharmacists in Dhaka city,Bangladesh. *Bangladesh Pharmaceutical Journal* **18**(2): 137-141.

Ratanwijitrasin S and Wondemagegnehu E (2002). Effective drug regulation: A multi-country study. World Health Organization, Geneva.

Saha S and Hossain Md. T (2017). Evaluation of medicines dispensing pattern of private pharmacies in Rajshahi, Bangladesh. *Saha and Hossain BMC Health Services Research* **17**(36):*136.*

Shah SS. AM, Naqvi BS, Fatima M, Khaliq A, Sheikh AL and Baqar M (2016). Quality of drug stores: Storage practices & Regulatory compliance in Karachi, Pakistan. *Pak J Med Sci*.; **32**(5):1071-1076.

Shane P. D and David P. Z eds. (2009). Pharmacy Management: Essentials for all Practice Settings. 2nd Ed, Mc Graw-Hill.

Stenson B, Syhakhang L, Lundborg CS, Eriksson B, Thomson G (2001). Private pharmacy practice and regulation. A randomized trial in Lao P.D.R. Int J *Technol Assess Health Care*,; **17**(4):579-589.

Taylor K. MG. and Harding G, ed. (2005). Pharmacy Practice. 2nd Edition, University of London, London, UK

The Nossal Institute for Global Health (2011). Health care regulation in low-and middle incomecountries: A review of the literature. Health Policy and Health Finance Knowledge HUB.Working paper series number 14. Available at:w.w.w.ni.unimelb.edu.au. (Accesed 12/5/2017).

USAID DELIVER PROJECT (2014). Guidelines for Warehousing Health Commodities. Second edition. Arlington, Va.: USAID | DELIVER PROJECT, Task Order 4.

Wafula F, Abuya T, Amin A, Goodman C, (2014).The policy practice gap: describing discordances between regulation on paper and real-life practices among specialized drug shops in Kenya.*Bmc Health Services Research* **14**:394.

WHO (1999). Guidelines for Safe Disposal of Unwanted Pharmaceuticals in and after Emergencies.Geneva, Switzerland.

WHO (2011). Joint FIP/WHO guidelines on good pharmacy practice: standards for quality of pharmacy services. WHO Technical Report Series, No. 961.

WHO (2019). The legal and regulatory framework for community pharmacies in the WHO European Region. WHO Regional Office for Europe, Copenhagen.

12. Annexes

I. Questioner/observational check list for community DROs

Addis Ababa University

School of Pharmacy

Department of Pharmaceutics and Social Pharmacy, Regulatory Affairs (Medicine stream)

Verbal consent form before conducting interview

Greeting

Hello, my name is _____. I am working with the research team of the Department of Pharmaceutics and social pharmacy, School of Pharmacy, Addis Ababa University. I would like to ask you a few questions regarding your pharmacy/ drug store on regulatory issues. The interview would take around15 minutes of your time. The purpose of this study is to assess about some of the premises, your practice and professionals working in your retail. This will be helpful in regulatory situations. Your participation is completely voluntary. All your responses will remain strictly confidential. Anybody, including regulators at different level, will not have access to your responses. Your name will not appear on the interview guide (will not be recorded) and your responses will not be linked to your identity at any time. You have a full right not to participate in the study, interrupt at any time or skip any questions without a problem to you or the services you provide in the facility.

Do I have your permission to continue?

Yes _____ No_____

If yes, continue to the next page; if no, skip to the next drug retail outlet.

I. The premises

Date: _____

1. Code _____
2. Level of DRO 1/ Pharmacy 2/ Drug store 3/ RDV
3. The owner of the facility? 1/ private 2/NGO 3/ Sh.co.
4. The year of the establishment of the facility _____ E.C
5. The usual working hour of the facility _____hrs.
6. The certificate of the retail pharmacy business displayed at the premises?

   1/Yes 2/ No
7. The DRO title/trading name clearly displayed near public entrances?

   1/ Yes 2/ No
8. The facility inspected this physical year? 1/ Yes 2/ No
9. How many times inspected annually? _____
10. The wall of the DRO constructed from

    1/ brick or stone 2/ Wood and soil (mud) 3/ other (specify)_____
11. The floor is constructed from

    1/ Wooden 2/ Cement/concrete 3/ Clay 4/ other (specify)_____
12. Toilet with adequate water supply available? 1/ Yes 2/ No

    If yes, open directly into the dispensary? 1/ Yes 2/ No
13. The room (store) preventing the entrance of insects in to the facility? 1/ Yes 2/ No
14. The facility has sufficient light? 1/ Yes 2/ No
15. Does the room have ceiling? 1/ Yes 2/ No

    If yes, what is the type of ceiling? 1/ gypsum 2/ plastic 3/ cheap wood 4/ some textile type 5/ concrete 6/ other (specify) _____

16. The building level is in a way that protecting the entrance of floods (water)?

    1/ Yes 2/ No

17. The height of the wall _____meter.

18. The area of the dispensing room _____ m x _____m =_____(m2)

19. The area of the store room _____ m x_____ m=_____(m2)

20. The area of the compounding room _____(m2) (if available)

21. Total area of the rooms of the DRO _____ (m2)

22. Estimate, how far the DROs from the nearest governmental (public) health facilities (hospital, health center, etc.) _____m

23. Estimate, how the DROs far from the nearest private (community) health facilities (clinics) _____m

24. The sources of prescription for your dispensing

    1/ Hospital 2/ health center 3/ private clinic 4/ all 5/ others (specify) _____

II Dispensing and storage environment /stock management

25. Is a dispensing area separate from the storage space? 1/ yes 2/no

26. The DRO has an appropriate area for counseling of patients? 1/ Yes 2/ No

27. How is the drugs arranged on the shelves?

    1/ pharmacologically 2/ Based on the dosage form 3/No systematic arrangement

28. Dose the DRO have chairs and tables for waiting, staffs and writing purpose?

    1/ Yes 2/ No

29. Accessible to dispensing area strictly controlled? 1/ Yes 2/ No

30. Is the storage area self-contained? 1/ Yes 2/ No

31. Any medicine stored with other products? 1/ Yes 2/ No

32. Any medicine stored on floors, stairs and/or pass way? 1/ Yes 2/ No

B) Observe the storage condition/environment and fill in your finding in the following table (if yes write 1 and if no write 2)

S. NO	Parameter		Availability
1.	The store room properly ventilated		
2.	The store has adequate light		
3.	Unfit for use(damaged, expired, etc.) drugs stocked separately from usable stocks		
4.	The store free of pests		
5.	The storage space protected from	Direct sun light	
		Moisture/rain	
		dust	
6.	The floor	clean	
		dry	
		Cemented (smooth)	

1. In the dispensing room, shelves clean and hygienically maintained?

   1/ Yes 2/ No

2. In dispensing room, ceilings, walls and paintwork in a good state of repair?

   1/ Yes 2/ No

3. In the store room, shelves clean and hygienically maintained?

   1/ Yes 2/ No

4. In store room, ceilings, walls and paintwork in a good state of repair? 1/ Yes 2/ No

5. The height of shelves/pallet above the floor _____ (cm)?

6. The distance (wide) between shelves _____ (m)?
7. The distance of the shelves away from the wall _____ (cm)?
8. The distance of the shelves away from the ceiling _____ (cm)?
9. The distances from the entrance door to dispensing table/shelve _____ (m)?
10. A pharmaceutical refrigerator available? 1/ Yes 2/ No

    If yes, the refrigerator is functional? 1/ Yes 2/ No

    If yes, the refrigerator has thermometer? 1/ Yes 2/ No

11. The DRO have fire-extinguisher? 1./ Yes 2/ No 3/ Yes, but not functional (the ex. expiry date is passed)
12. The facility has functional wall thermometer? 1/ Yes 2/ No
13. The temperature in the room noted and a written record made daily?
    1/ Yes 2/ No

A) Observe the dispensing area and fill in your findings in the following table (if yes, write 1 and if no write 2)

S. No	**Parameters**		**Availability**
2.	Does the dispensary has	Counting tray	
		Spoons	
		Medicine envelope	
		Labeling materials	
		Prescription registration book	
		Adult weight & height scale	
		Children/infant weight scale	
		Sales ticket	
7	Are the reference material	OTC drug list	

	for use by the practitioner	National formulary
		National treatment guidelines
		Medicine use counseling guide Manual
		ADRs reporting manual
		Written SOP for dispensing
6	Is the floor	Dry
		Cemented (smooth)
		Clean

III <u>Recording of data and reporting system in the facility</u>

1. The facility has stock card and bin cards for control of stock rotation?

   1/ Yes 2/ No

   If yes, is it available for all products separately? 1/ Yes 2/ No

2. All received and/or issued products documented on the stock cards on time? (Observe)
   1/ Yes 2/ No

3. The DROs has temperature monitoring chart? 1/ Yes 2/ No

   If yes, does the temperature of the room measured and recorded daily?

   1/ Yes 2/ No

4. The recorded temperature keeps as document for each record?

   1/ Yes 2/ No

   If yes, for how long it is kept _____

5. The temperature of the refrigerator is measured on daily base?

1/ Yes 2/ No

6. The recorded temperature kept as document? 1/ Yes 2/ No

   If yes, how long it is kept _____

7. See products available in the refrigerator and check whether they stored as the manufacturer label range of temperature. Write if any deviations observed _____

8. Drugs dispensed based on the types of prescription intended?

   1/ Yes 2/ No

9. The facility has prescription registration book (PRB)?

   1/ separately for NSP and other drugs

   2/ only a single PRB for both types of drugs

   3/ not have PRB

   If yes, dispensed prescriptions timely registered on PRB after each dispensary? (Cheek)

   1/ Yes 2/ No

10. Prescriptions keep separately (NPS and other drugs)? 1/ Yes2/ No

    If yes, NPS prescriptions kept separately in lacked cabinet? 1/ Yes 2/ No

11. For how long prescription have been kept; (observe with maximum time kept)

    1. NPS prescriptions _____

    2. Other prescriptions _____

12. Are you submitting regular report to the appropriate regulatory organ regarding consumption and stock of controlled drugs? 1/ Yes 2/No

13. Have you been reporting the disposal of prescriptions to concerned regulatory organ yet?

    1/ Yes 2/ No

14. The DRO has ADRs reporting form (yellow card)? 1/ Yes 2/ No

15. The pharmacy professional take training on reporting of ADRs? 1/ Yes 2/ No

16. Have you ever contacting patient with ADRs? 1/ Yes 2/ No

If yes, would you report the case to the concerned body? 1/ Yes 2/ No

Check if appropriate recording system is in place and fill in the following table (write 1 if yes and write 2 if no)

S. No	Record keeping form/tool	Available	Updated
1.	Drugs ordering form		
2.	Drugs receiving form		
3.	Expiry tracking chart		
4.	Temperature recording chart		
5.	Form for making physical inventory		
6.	computer		
7.	Patient allergic card		
8.	Expired drugs disposal report form		

IV <u>Pharmacy professionals</u>

1. The sex of licensed professional _____age_____
2. The service year of the licensed professional? _____
3. The dispensing personnel wear white clean gown 1/ yes 2/no
4. The dispensing personnel have identification tag 1/yes 2/no
5. The licensed/authorized pharmacy professional renew his/her professional license?

   1/ Yes 2/ No

   If yes, how long it is _____(observe)
6. The licensed professional being currently on education (weekend, summer, regular, night, etc.)? 1/ Yes 2/ No

7. The DRO have assistant professional? 1/ Yes 2/ No

   If yes, how many _____

   If no, who is practicing/ serving/dispensing when the licensed professional is not available on work? (Specify)_____

8. The licensed professional available during data collection time?

   1/ Yes 2/ No

   If no who was dispensing during the data collection time? _____

If dispensing person was professional, had professional registered license? (Observe)

1/ Yes 2/ No

If yes, specify the year renewed/registered _____ (E.C)

V <u>Handling of expired/waste drugs</u>

1. Is there any stocked expired/unfit drug available? 1/ Yes 2/ No

   If yes, dose these expired/unfit products stored separately from usable stocks? (Observe)

   1/ Yes 2/ No
2. Do these products segregate from each other? 1/ Yes 2/ No
3. For how long these unfit products have been stored? _____
4. What are your plan /measure to dispose these waste/ unfit products?

   1/ to report to the nearest regulatory body then wait for their action

   2/ the facility have its own disposal facility and dispose its own

   3/ another option (specify) _____
5. Have you ever disposing expired/unfit products previously?

   1/ Yes 2/ No

   If yes, did the regulatory organ give permission and participate in the disposal of the products? 1/ Yes 2/ No
6. Does the reports of disposed product submitted to concerned regulatory organ?

   1/ Yes 2/ No

   If yes, did the regulatory organ provide you the certificate of disposal?

   1/ Yes 2/ No

7. Do documents related disposed expire products document and available?

   1/ Yes 2/ No (If yes observe)

8. The facility has expired and unfit for use drugs and supplies disposal facility?

   1/ Yes 2/ No, but returned expired drugs to suppliers 3/ refer to other disposing institution (specify) _____

   If yes, observe and specify the type _____

Thank you!

II. Ethical clearance paper from ERB of Addis Ababa University School of pharmacy

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Addis Ababa University

School of Pharmacy
Ethical Review Board

ቀን May 29, 2019
Date
ቁጥር ERB/SOP/97/04/2019
Ref. No.

To: **Admasu Gulu**

School of Pharmacy

Re: **Ethical Clearance**

It is to be recalled that you submitted a study proposal entitled "***Regulatory compliance of private drug retail outlets in Ambo town West Shewa Oromia Region Ethiopia***" for ethical approval by the School's Ethical Review Board (ERB). The Board thoroughly reviewed the proposal based on its operational guidelines and found it to fulfill all ethical requirements stipulated in the guidelines. This is, therefore, to inform you that the proposal is ethically approved for implementation.

With best regards,

Arebu Issa

Chairperson, ERB

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