Republic of Liberia Ministry of Health and Social Welfare

Liberia Medicines and Health Products Authority

ACCREDITED MEDICINE STORES (AMS) INSPECTION MANUAL

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A.T.C Building, Opposite J-mart Furniture & Showroom
Randall, Street, Monrovia
E-mail: contact@limhra.org

CONTENTS

Foreword

Medicines are vital goods for any health care delivery system. Therefore, one objective of the national medicine policy is assurance of the safety, quality, and efficacy of the medicines circulating in the market. An essential part of any medicine control system is the provision of an inspection body with the responsibility and authority to inspect some or all of the activities involved in research, development, manufacture, control, distribution, sale, and supply of medicines. Qualified and experienced drug inspectors constitute an indispensable component of the inspection system.

Drug inspectors serve as the eyes and ears of the medicine control authority and should be the front lines in maintaining the identity, quality, purity, and strength of medicines manufactured and marketed in any country. In this respect, drug inspectors have an important role in protecting and promoting public health by ensuring that medicines and medical supplies circulating in the market meet safety and quality standards. Succinctly, the inspector's job is law enforcement. A drug inspector is empowered by the law, at all reasonable times, to enter any premises that is on the register or any premises in which he or she has reasonable cause to suspect that the law has been or is about to be contravened. The functions and duties of the Liberia Medicines and Health Products Regulatory Authority (LMHRA) in relation to ensuring safety, quality and effectiveness of medicines are stipulated in section 2 of the LMHRA Act, 2010.

Drug inspectors should perform their duties according to the guidelines. This manual has been prepared to guide inspectors while preparing for and performing Accredited Medicine Stores (AMS) inspection activities. It also serves as a reference document for drug inspectors before and during AMS inspections.

Managing Director
LMHRA

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Acronyms and Abbreviations

AMS	Accredited Medicine Store
LMHRA	Liberia Medicines and Health Products Authority
MSH	Management Sciences for Health
PBL	Pharmacy Board of Liberia

Definitions

- *Medicines* means any substance or mixture of substances intended for use in—
    - the diagnosis, treatment, mitigation, or prevention of a disease, disorder, abnormal physical or mental state, or symptoms thereof, in man or animal, or
    - restoring, correcting, or beneficial modification of organic or mental functions in man or animal.

- *Authority* herein means the Liberia Medicines and Health Products Regulatory Authority, established under Part I, Section 1, of the LMHRA Act, 2010.

- *Dispense* means to give or prepare and give (especially a medicine) out; to deal out.

- *Dispenser* means one who is trained and licensed or registered to dispense (medicines). Practically**,** one who, though not a (graduate) pharmacist, is trained to prepare and distribute, to a patient, a course of medication on the basis of either an oral or written prescription; to manage stocks and to maintain records of same of drugs and nondrug therapeutic items; and trained in the procurement of drugs and nondrug therapeutic items.

- *Pharmacy* means a shop wherein medicines are sold conventionally under the superintendence of a licensed pharmacist; also a hospital dispensary. *Pharmacy*, as a profession, is that science that deals with the recognition and isolation of drug substances (in the case of plant-derived medicines); the synthesis of drugs (in the case of synthetic drugs); the compounding, storage, and dispensing of drugs; and the imparting of drug information to both the prescriber and the patient, and so on.

- *Pharmacist* means a holder of a degree or diploma in pharmacy from a recognized higher (usually a tertiary level) institution of learning and who is registered or licensed to practice pharmacy.

- *Pharmaceutical personnel* means anyone licensed to practice any aspect of pharmacy proper or of subpharmacy (a pharmacist or a dispenser, respectively).

- *Pharmaceutical product* means a pharmaceutical dosage form (i.e., the raw active ingredient made into a particular dosage form).

Chapter 1. Introduction

1.0 Background

The Liberia Medicines and Health Products Regulatory Authority (LMHRA) was established under the Liberia Medicines and Health Products Act, 2010, to provide for comprehensive regulation of all matters related to safety and quality of medicines and health products.

The regulation of medicines involves, among other things, inspection of medicine outlets, which in Liberia include wholesale pharmacies, retail pharmacies, and the current medicine stores (potential Accredited Medicine Stores, or AMSs). Conducting inspection activities is very important in ensuring that medicines and health products circulating on the market meet the prescribed safety and quality standards. To achieve this goal, inspectors need to be provided with sufficient knowledge and skills, working tools, and ample time to exert their expertise in observing, investigating, and reaching conclusions on the quality of a particular medical product.

This manual has been prepared to guide inspectors in preparing for and performing various types of inspection activities. It also serves as reference document for inspectors before and during inspections.

The manual highlights general conditions and other pertinent requirements that are necessary for carrying out AMS inspections. It comprises three principal chapters. Chapter 1 introduces the inspection concept, types of inspections, and the code of ethics and conduct for drug inspectors. Chapter 2 describes the legal requirements and standards for AMSs, which include personnel, premises, and quality of products (medicines) to be dispensed from AMSs, record keeping and documentation, and recommended references. Chapter 3 describes the AMS inspection and refers to planning and conducting inspection; qualification, training, and experience required for inspectors; sample collection; and report writing.

Various working tools have been included in this manual to help inspectors comprehend matters related to AMS inspection. The manual is expected to help inspectors conduct AMS inspections with integrity and diligence.

1.1 Introduction to Drug Inspection

This chapter describes what inspection is, what needs to be inspected, what the different types of inspections are, what is the code of ethics and conduct for inspectors, and what is expected of inspectors. It is important for inspectors to review this chapter, especially during the preparatory phase of inspections.

1.1.1 What Is Inspection?

To *inspect* is "to look closely at something, especially to check that everything is in good order." Inspection is, therefore, the act of looking closely at something to ensure that it meets certain prescribed or known standards and specifications.

In relation to drug inspection, this involves the act of examining or looking closely at all the medicine's attributes and the condition of the facilities or premises dealing with medicines. The objective of conducting a drug inspection is to ensure that medicines and related supplies, either locally manufactured or imported from outside the country, meet set quality standards to ensure patients' safety and the public health at large. A drug inspection also looks at the premises in which medicines are stored and services are provided to ensure the premises meet established standards.

Safety of medicines can be ensured by enforcing medicine laws and regulations governing manufacturing, compounding, distribution, importation, exportation, sale, storage, and use of medicines.

1.1.2 What Needs to Be Inspected?

To ensure the quality of medicines entering or circulating in the Liberian market, the following establishments associated with the medicine supply and distribution chain should inspected regularly—

- Ports of entry
- New premises or facilities for wholesale and retail pharmacies and Accredited Medicine Stores* before they are licensed
- Operating wholesale and retail pharmacies
- Operating Accredited Medicine Stores*
- New local manufacturing facilities before they are licensed and after being licensed
- Overseas pharmaceutical manufacturing facilities before they are approved to import medicines to Liberia

1.2 Types of Inspection

Generally, there are five types of inspections, as outlined and described below—

1. Routine
2. Concise

* The scope of this manual is the inspection of the Accredited Medicines Stores.

3. Follow-up
4. Special
5. Investigative

1.2.1 Routine Inspection

Routine inspections are generally intended for a new establishment (new premises) or for an establishment that has applied for a permit to extend its scope of operations, made important changes in its key personnel, moved to new premises, or has not been inspected for a long time. The inspection should be announced (communicated in advance) except when an inspection has not been conducted for a long time, when an unannounced inspection would be the norm.

1.2.2 Concise Inspection

Concise inspections are generally for establishments that have been previously inspected with a view to assessing standards of good pharmacy practice. The outcome of the inspection helps in the proper assessment for compliance of the establishment with the set standards. These inspections can be announced or unannounced.

1.2.3 Follow-Up Inspection

A follow-up (also referred as reinspection or reassessment) inspection is normally carried out to ensure that corrective measures have been undertaken following advice and notice given during a previous inspection. If a time limit was given for applying the corrective measures, the inspection should be unannounced. Depending on the nature of the defect, the work required, and the risk associated with the nonconformance, adequate time to rectify the defect should be provided.

1.2.4 Special Inspection

A special inspection is used to assess the performance of a new establishment whose scope of operations was previously unknown. The inspection should be unannounced.

1.2.5 Investigative Inspection

An investigative inspection is undertaken to deal with specific complaints received about lapses or noncompliance with standards of professional practice. The inspection should be unannounced.

1.3 Code of Ethics and Conduct for Inspectors

Inspectors shall behave, conduct themselves in accordance with, and observe the code of ethics and conduct as stipulated here—

- Strive to achieve the highest ethical and performance standards in carrying out inspection activities.
- Uphold the honor and dignity of an inspector and avoid association with any enterprise of questionable character or apparent conflict of interest.
- Protect and promote the interests of the Authority to the best of his or her ability and knowledge, recognizing that the Authority has placed trust and confidence in him or her.
- Make every effort to uphold, maintain, and improve the integrity and reputation of the Authority and the Government of Liberia.
- Adhere to the laid down rules, regulations, and standard operating procedures in executing his or her functions.
- Make decisions in line with authorized standards and procedures.
- Report inspection findings truthfully and accurately.
- Assess facts quickly and make rational and sound decisions without delay.
- Maintain confidentiality whenever accessing confidential information as a result of inspection.
- Strive to acquire new knowledge and skills continuously and use them effectively.
- Perform duties tactfully, honestly, and impartially to avoid circumstances that may lead to conflict of interest.
- Conduct inspections in a manner that will ensure independence from outside influence and interest, which would otherwise compromise the inspector's ability to render a fair and impartial opinion regarding any inspection conducted.
- Promptly disclose to the Authority any interest in any business that may affect the quality or the result of the inspector's work or remediation.
- Disclose fraud or abuse of power and corruption to the Authority.
- Not use his or her position for personal gain.
- Conserve Authority property and not use it for private gain.
- Not solicit, force, or accept bribes from a person whom the inspector is serving, has already served, or will be serving either by doing so in person or by using another person.

- Not receive presents in the form of money, entertainments, or any service from a person that may be regarded as geared toward compromising the inspector's integrity.

- Seek prior approval by Authority, before engaging in outside employment or activities or seeking or negotiating for employment that will directly conflict with the duties or interests of the Authority.

- Endeavor to avoid any actions that create an appearance or circumstance of violating the law or ethical standards as determined by the perspective of a reasonable person with knowledge of the relevant facts.

- Be committed to work hard and for long hours.

- Avoid the use of rude and abusive language.

- Maintain personal hygiene and dress in respectable attire in accordance with acceptable norms of the office.

Chapter 2: Legal Requirements and Standards for Accredited Medicine Stores

Every inspector while conducting AMS inspections shall verify and ensure the following AMS legal requirements have been met—

2.0 Personnel

Inspectors shall verify and ensure that every operating AMS is supervised by a dispenser who meets the following minimum qualifications: high school graduate who has successfully completed an AMS dispenser training course approved by the LMHRA/PBL. Inspectors shall verify the correctness of dispensers' particulars on the dispensing certificate issued by the PBL, a copy of which must be conspicuously displayed in the AMS.

Inspectors and AMS dispensers shall ensure that unqualified personnel who do not possess the prerequisite knowledge do not handle or dispense medicines.

Inspectors may, if deemed necessary, verify the contract between the proprietor and the dispenser to be sure that there are agreed terms and conditions of employment between the two parties.

2.1 Premises

2.1.1 Location

When conducting an inspection of new premises, inspectors shall make sure that the location and address of the said premises is the same as indicated in the application form for establishing an AMS submitted to PBL. Inspectors shall also verify to ensure that criteria stipulated in regulations, such as local demand, need for service, and distance from another operating AMS or retail pharmacy, have been met before conducting inspections of new premises.

2.1.2 Premises Requirements

(a) Inspectors shall when conducting final inspections of new premises ensure the premises meet the following minimum requirements—

- Premises are geographically and structurally permanent.
- Premises have roofs and ceilings that are made from leak-proof materials.
- Premises are well protected from entry of rodents, birds, vermin, and pests.
- Premises have adequate space to carry out primary functions of storage, dispensing, and sales.

- Premises have doors and windows that are well secured to prevent theft and unauthorized entry.
- Shelves have glass or cleanly finished wooden counters, and the main door is a glass door for safety.
- Premises have adequate ventilation and lighting (fan, air conditioner, open air, etc.).
- Premises have surfaces and floors with smooth finish that can be washed with disinfectants.
- Premises are painted with washable paint (white or any color as directed by the Authority).
- Premises have an adequate supply of water or have made provision for supply of water and soap for hand washing.
- Premises have facilities to wash hands that are clearly marked with a "wash hands" sign.
- Premises have adequate toilet facility or available public toilet facility within the premise area in clean and good working order.
- Personnel observe general hygiene in and outside the premises.
- Premises are not shared with any medical clinic, veterinary surgery, or any other business of a similar nature.
- Premises have a minimum floor length and width of 13 × 12 feet and a minimum ceiling height of 9 feet.
- A "NO SMOKING" is sign conspicuously placed to prohibit smoking in the store.

(b) Notwithstanding the minimum requirements outlined in 2.1.2(a) above, inspectors shall ensure that an operating AMS bears the following signage—

- An officially approved AMS identification logo shall be displayed to differentiate it from the nonaccredited medicine store.
- The name of the AMS and any other authorized branding conspicuously displayed on the wall or store boards shall be displayed after the final approval of the premises by the PBL/LMHRA.
- The approved list of medicines and health products to be sold in an AMS shall be displayed.
- Copies of Accreditation and Dispenser certificates shall be conspicuously displayed.

2.2 Quality of Products and Dispensing Procedures

Inspectors shall ensure that medicines and health products dispensed from AMS meet the following requirements—

2.2.1 Source of Supply

While conducting inspections in AMSs, inspectors must ensure that only medicines and health products registered by the LMHRA in accordance with the LMHRA Act, 2010, or any other written regulations are sold in the AMS. Such products must have been procured from registered wholesalers.

2.2.2 Storage

Inspectors shall ensure that medicines and health products held in inventory are in the manufacturer's original pack and meet labeling requirement stipulated in the LMHRA Act, 2010, or any other written regulations. Products shall be stored off the floor and protected from heat, direct sunlight, moisture, adverse temperature, insects, rodents, and contamination.

Inspectors shall ensure that damaged or expired medicines found in AMSs have been recorded, sealed, quarantined, and labeled with red ink with the statement "Expired/damaged medicines—Not for sale" by the AMS dispenser.

Expired and damaged medicines and health products shall be disposed of under supervision of the LHMRA at the AMS owner's cost.

2.2.3 Dispensing Procedures

Inspectors shall verify dispensing records to ensure that AMS dispensers dispense only medicines and health products registered and approved by the LMHRA for sale in AMSs. Among other things, inspectors shall scrutinize the records to verify whether medicines are dispensed against prescriptions (for prescription-only medicines), in full courses and doses, and in accordance with Good Dispensing Practices.

Inspectors shall verify to ensure that AMS dispensers use dispensing tools such as dispensing trays to dispense tablets and capsules to avoid contamination and cross-contamination.

2.3 Record Keeping and Documentation

Inspectors shall verify records and documents to ensure that all invoices and receipts for purchased medicines have been stored in the premises in an easily retrievable file for not less than the period specified by the Authority. The details of the purchase record register and the dispensing record register shall be as provided in the regulations.

Inspectors shall also ensure that each AMS keeps the following recording books—

- A special file for all correspondence related to medicines, guidelines from the PBL, the LMHRA, and other regulatory authorities
- A file for inspection reports (inspector record book) for the purpose of recording all inspections undertaken
- A book for client complaints

- A register for recording details of expired drugs
- Any other document as may be prescribed by the Authority from time to time

2.4 Reference Materials

Each AMS shall have and maintain for easy reference the following books—

- Accredited Medicine Stores approved medicines list
- National Standard Treatment Guidelines (NSTGs)
- LMHRA Act, 2010
- Accredited Medicine Dispensers Training Manual
- Accredited Medicine Dispensers Standards and Code of Ethics
- Guidelines for disposal of unfit pharmaceutical products
- Other relevant references, including Essential Medicines for Liberia, legislation, National Medicines Policy (NMP), and others as may be recommended by the PBL or LMHRA from time to time

Chapter 3: Accredited Medicine Stores Inspection

3.0 Planning for AMS Inspection

The Head of Inspection Department shall be responsible for planning of AMS inspection following an approval of the work plan and budget by the LMHRA Board of Directors. The planning for AMS inspection shall include preparation of an annual inspection plan based on the approved budget.

When preparing an inspection plan (schedule), the following criteria should be considered—

- Grouping together AMSs located in the same geographical location or county so that single trips can be organized
- The number of hours and day(s) required to inspect one and all AMSs located on the same geographic location or county
- Traveling logistics and weather forecast
- Availability of funds at that particular time because funds may depend on cash budget or cash flow
- Risk-based inspection that focuses on, for example, certain high-risk medicines
- Reported market (public) complaints
- Whether the inspection is for new premises or renewal of license

The inspection plan shall include names, postal and physical addresses of the AMS, type of inspection, proposed date of inspection, and names of inspectors. The inspection shall be carried out by at least two inspectors. The annual or work plan shall be approved by the Managing Director of the LMHRA.

3.1 Preparing for AMS Inspection

Inspectors must prepare themselves for the inspection by gathering all the necessary tools to conduct the inspection judiciously and thoroughly. The tools shall include the following—

- Application form submitted to the PBL for establishing a new AMS
- List (names and address) of premises to be inspected
- Inspection checklist for new premises

- Inspection checklist for operating AMS
- List of medicines approved for sale in AMS
- Official prior communication with the provider (depending on the type of inspection)
- Inspectors identification card
- Stationery supplies (pen and inspectors writing book)
- Full-time transport
- Payment list forms because it may be necessary to pay allowances for other co-opted inspectors different from PBL and LMHRA
- Approved budget to undertake the inspection
- Any other tool depending on the type and nature of inspection

Upon reaching the premises where the inspection is to take place, the inspection must begin with the introduction of the inspectors to the person in charge of or responsible for the premises. Inspectors must present their credentials and a notice (if any) describing the purpose of the inspection to the person in charge.

3.2. Qualification of Inspectors

AMS inspectors shall be appointed by the PBL or LMHRA. The inspectors shall have the qualifications necessary to effectively take part in the inspection of an AMS. These qualifications shall be based on the following—

- Academic education
- Training
- Experience

3.2.1 Academic Education

AMS inspectors shall have a minimum certificate in pharmacy (two-year trained dispenser) qualification. Where persons other than pharmaceutical personnel are appointed as AMS inspectors, they shall be adequately experienced in inspection of pharmaceuticals premises and pharmaceutical products and preferably trained in pharmaceutical inspection.

3.2.2 Training

To be competent to carry out inspections, inspectors shall be required to undergo training in pharmaceutical inspections. Such trainings shall provide them with knowledge and skills needed when planning for, carrying out, and reporting on inspections.

Apart from basic training, inspectors shall be required to undergo on-the-job training by senior inspector(s) such as Pharmacists. Such trainings shall involve both theory and practice of inspections and will cover inspection techniques, communication and management skills, and conducting inspections and writing reports as trainees.

Continuous training shall be provided to inspectors to keep them abreast of current knowledge and techniques in carrying out inspections. This training shall be completed through attending training programs, seminars, scientific meetings, conferences, and exhibitions organized by either the LMHRA or PBL or other national and international organizations.

3.2.3 Experience

Experience as a general concept comprises *knowledge* of or skills in or *participation* in activities or events, or knowledge or skills gained through involvement in or *exposure* to those activities or events. An inspector will be deemed experienced when—

- He or she has been involved in inspection of pharmaceutical outlets for two or three years as lead inspector.

- He or she has demonstrated competence in communication skills and report writing.

Such experience will be taken into consideration when planning for and conducting AMS inspections.

3.3 Conducting an AMS Inspection

Inspectors shall conduct the inspection systematically using the AMS inspection form (PBL/LMHRA Joint Inspection Checklist; see annex) as the checklist for operating AMSs. Inspectors shall record their findings and observations accordingly. At least two inspectors, one being the lead inspector, shall constitute the inspection team.

3.4 What Is Expected of a Drug Inspector?

During facility inspection, Inspectors shall remember the following—

- Contact the person in charge of the establishment by approaching him or her in a dignified, authoritative, and cordial manner. Avoid being arrogant.

- Present credentials (e.g., your identity card) and explain the purpose of your visit.

- Use diplomacy, tact, and persuasiveness to acquire the necessary information and all necessary inspection details. Use the standard operating procedures (PBL/LMHRA Joint Inspection Checklist; see annex) to achieve this.

- In case of refusal to undergo inspection, explain that refusing is a criminal offense and courteously discuss the matter with the owner or responsible person on the premises.
- Upon completion of inspection, meet the owner or person in charge to discuss the findings. Adopt a courteous attitude in calling attention to the practices or conditions observed at the time of inspection; make suggestions for minor corrections to be made as you perform the inspection.
- If any samples have been taken for testing, furnish a receipt for these samples to the person from whom samples are taken.

3.5 Special Instructions

The following forms, once finalized and approved by LMHRA/PBL, should be included in this manual, and shall be used to provide special instructions—

1. Observation forms
2. Sample collection forms
3. Confiscation/Quarantine forms

Chapter 4. Sample Collection and Testing

The inspection may include the collection of samples for verification of quality parameters as deemed necessary by the inspectors. Normally, the sample size should be sufficient to carry out the test for investigated parameter(s). Unless otherwise indicated by the laboratory, samples of the following sizes may be taken, depending on the dosage form of the product—

- Tablets and capsules: 100 units per batch
- Injections (single component): 20 units per batch
- Injections (combination): 20 units per batch
- Oral powders for reconstitution: 10 units per batch
- Liquid formulations: 5 bottles/units per batch

Inspectors shall be trained on techniques for sample collection.

Chapter 5. Inspection Report

An inspection report shall be written immediately after completing inspection. The compiled report shall be submitted to Head of Inspection within 14 calendar days upon completion of inspection. The Head of Inspection shall make sure that the inspection report is sent to the inspected facility within 30 calendar days after receiving the inspection report. Regulatory action(s) taken as stipulated in the LMHRA Act, 2010, shall form part of the covering letter of the inspection report.

The inspection report shall be written according to the agreed standardized inspection reporting format. Sufficient details shall be provided to allow independent assessment, comprehension, and easy decision making.

Observations made that are considered to be noncompliance with the LMHRA Act, 2010, and/or the PBL standards for Accredited Medicines Stores shall be listed in the inspection report. Where observations are included in the report, clear distinction shall be made between “compliance” and “noncompliance.”

Penalties and sanctions for violations of the LMHRA Act, 2010, shall be as provided in Part III of the Act, 2010.

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Annex: Checklist for Pharmacy Board and LMHRA Joint Inspection

REPUBLIC OF LIBERIA
PHARMACY BOARD OF LIBERIA AND LIBERIA MEDICINES & HEALTH PRODUCTS REGULATORY AUTHORITY (LMHRA)
JOINT INSPECTION CHECKLIST
MEDICINE STORES

Date: _____

S/N	Description	Notes/Observation/Response	
1	Name and address of owner	Names:	
		Street number:	
		Telephone:	
		E-mail:	
2	Name and address of premises	Names:	
		Street number:	
		Telephone:	
		E-mail:	
4	Names of Dispensers	Qualification	Cell #
	a.		
	b.		
	c.		
	Did you attend the Accredited Medicine Stores training program?		Yes ☐ No ☐
MEDICINE STORES			
	• Currently registered with PBL?		Yes ☐ No ☐
	• All medicines or health product bought locally from importer/wholesale pharmaceutical outlets?		Yes ☐ No ☐
	• Do you have receipt for all medicines purchased?		Yes ☐ No ☐
	• Have you sold medicines out of the medicine store?		Yes ☐ No ☐
	• Drug literature written in English?		Yes ☐ No ☐
	• Smooth shelves?		Yes ☐ No ☐
	• All products on shelves		Yes ☐ No ☐
	• Health products and medicines packed properly?		Yes ☐ No ☐
	• Minimum standard height 9 ft • Minimum standard width 12 ft • Minimum standard length 13 ft		Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐
	• Biological products (TAT, insulin, oxytocin, etc.) available?		Yes ☐ No ☐
	• Control drugs (phenobarbital, phenytoin, diazepam, Tremadol) available?		Yes ☐ No ☐
	• Injectable drugs available?		Yes ☐ No ☐
	• Cardiac glycoside drugs (Catopril, Enalapril, Nifedipine, Aldomet) available?		Yes ☐ No ☐

	• Diuretic HCTZ, furosemide(Lasix), etc. available?	Yes ☐ No ☐
	• Expired drugs sold on shelves?	Yes ☐ No ☐
	• Consult PBL to dispose of expired products?	Yes ☐ No ☐
	• Adequate ventilation?	Yes ☐ No ☐
	• No direct link with a bar?	Yes ☐ No ☐
	• Away from dump site?	Yes ☐ No ☐
	• Away from sewage drainage?	Yes ☐ No ☐
	• Presence of strong ceiling board?	Yes ☐ No ☐
	• Presence of acceptable lighting conditions?	Yes ☐ No ☐
	• Presence of functional cooling air conditioning system/fan?	Yes ☐ No ☐
	• Durable, easily cleanable walls?	Yes ☐ No ☐
	• Durable, easily cleanable floors?	Yes ☐ No ☐
	• Rodents or cockroaches, rats, ants, etc.?	Yes ☐ No ☐
	• Clean and disinfect outlet regularly?	Yes ☐ No ☐
	• Clean toilet with water?	Yes ☐ No ☐
	• Presence of strong grilled doors and windows?	Yes ☐ No ☐
	• Presence of only one main entrance?	Yes ☐ No ☐
	• Received complaint from customer on medicine/drug bought?	Yes ☐ No ☐
	• Presence of logbooks, ledger books. and other inventory control system?	Yes ☐ No ☐
	• Medicine reference books?	Yes No
	• Do you sleep in the medicine store?	Yes ☐ No ☐
	• Do you provide treatment (wound dressing, Injection, drip, etc.) for clients in your medicine store?	Yes ☐ No ☐
	• Internal walls painted? • External walls painted?	Yes ☐ No ☐ Yes ☐ No ☐
	• Segregated area for damaged, recalled, and expired medicines?	Yes ☐ No ☐
	General observations and comments:	
	Nonconformities Conformities	

	Recommendations:	
	Challenges:	
	Date for next follow-up inspection:	
	Name and Signature of Inspector(s)	
		Name:_____ Signature:_____ Date:_____
		Name:_____ Signature:_____ Date:_____