	Title: Guideline for Pharmaceutical Inspection	
Rev No: 02	**Doc No: PBSL/GL/010**	Version no. 03
Issue date: 15 May 2024	**Effective date: 17 May 2024**	Approved by: Registrar

Adopted By PBSL	
Start of public Consultation	
End of public Consultation	
Agreed by QMS committee	
Approved by Board	

Pharmacy Board of Sierra Leone

PMB 322

Central Medical Stores Compound

New England Ville

Freetown

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EXECUTIVE SUMMARY

ACKNOWLEDGEMENT

1.0 Introduction

An essential part of any medicine control system is the provision of an inspection body with the responsibility and authority to inspect all of the pharmaceutical activities such as research, development, manufacture, control, distribution, and supply of medicines. Qualified and experienced drug inspectors in a regulatory authority constitute an indispensable component of the inspection system.

Inspection is the act of looking closely at something to ensure that it meets certain prescribed or known standards and specifications. It is simply the act of looking closely at something to check that everything is in good order.

Drug inspection is the act of examining or looking closely at all the drug attributes and the condition of all the facilities that deal with drugs. The main objectives of drug inspection are to ensure that drugs and related supplies, either locally manufactured or imported from outside the country, meet set standards of quality. It is aimed at ensuring safety of the patients and members of the public by monitoring of quality throughout the distribution chain onto utilization. This is assured by enforcing drug laws and regulations governing distribution, compounding, imports, exports, storage, and use of drugs.

2.0 OBJECTIVE

The main Purpose of Inspection is to ensure the availability of good quality drugs entering and circulating the market.

3.0 SCOPE

Different categories of business associated with drug supply and the distribution chain should be inspected regularly. These includes Ports of entry, Manufacturing facilities, Wholesalers and Retailers of Pharmacies, Drug Stores, Patent shops, Chemical Stores, Veterinary stores (both established and new ones before they are licensed).

4.0 SPECIFIC REQUIREMENTS

4.1 Types of inspection

1. Pre-approval Inspection. This is an inspection generally intended for a new establishment which has applied for permit to operate a pharmacy practice or has changed premises or wants to extend scope of operation. This inspection should be announced.

2. Routine inspection: This type of inspection is generally carried out for already approved and operating pharmaceutical establishment. It is usually done every 3 months or when the establishment has not been inspected for a long time (1-2 years). It can also be done in cases where the establishment has made important changes in its key personnel or where an establishment has a history of non-compliance with Good Manufacturing Practice or Good Distribution Practice. The inspection may be unannounced.

3. **Special/Investigative Inspection** This type of inspection is undertaken to deal with specific complaints received about lapses or non-compliance with standards of professional practice or performance of new establishment. Such inspection may be focused on one product, a group of related products or specific operations such as mixing, sterilization or labelling. The inspection should be unannounced.

4. **Concise inspection.** This is reserved for establishments that have previously been inspected with a view to assessing standards of

good pharmacy practice. The outcome of the inspection will help in the proper assessment of the establishment. Evidence of unsatisfactory pharmacy practice performance observed during concise inspection should trigger a more comprehensive inspection. The inspection will be done at least twice a year and should preferably be unannounced

4. **Follow–up inspection.** This is normally carried out to ensure that corrective measures have been undertaken following advice and notice given during a previous inspection. The inspection should be unannounced.

4.2 SPECIFIC INSPECTION APPLICABLE TO INDIVIDUAL ESTABLISHMENTS

Inspectors when going for inspection should make sure that they do a fully comprehensive inspection. This should include the following:

1. Importer

- All drugs accompanied by import documents such as bill of lading, export authorization, product licence and batch certificate
- Controlled drugs also accompanied by export authorization certificate or export declaration, whichever is applicable
- Imported drugs are in original packs, except for drugs imported in bulk for repackaging and/or manufacturing drug formulations.

2. **Retail and hospital pharmacy**

- Compounding of drugs carried out by or under the supervision of a pharmacist
- Quality of raw materials used in compounding complies with pharmacopoeial specifications
- Dispensing of prescription drugs carried out by or under the supervision of a pharmacist

- Entries of dispensed prescription drugs made in prescription book and for controlled drugs in controlled drugs book
- Prescriptions for prescription drugs retained on premises for periods provided in the drug laws
- dispensed drugs labelled appropriately with name of drug, name of patient, name and address of pharmacy, clinic or hospital, instructions for using the drugs and, where appropriate, warning labels
- Counselling of patients on use of dispensed drugs
- Adequacy of containers for dispensed drugs
- Personnel observe high standard of personal hygiene and wear clean protective clothing
- Dispensing area clean, adequate and has necessary equipment
- Walls in dispensing area easily cleaned
- Quality of extemporaneous preparations
- Sources of drugs sold and supplied from the pharmacy
- Suitable cabinets for storage of controlled drugs and poisons.

3. Hospitals, PHU's Mental Homes

- Sources of drugs used, supplied and administered
- records of controlled drugs used, supplied and administered
- storage facilities and security for controlled drugs.

4. **Unauthorized markets**

- Investigate sources of drugs in the unauthorized market
- sample drugs for quality assessment
- seize drugs in the unauthorized market.

4.3 GUIDE ON HANDLING COLLECTED SAMPLES

It is very important to ensure that collected samples follow the procedure for collection, handling and transfer to the National Pharmaceutical Quality Control laboratory.

Types of Collections

- Adverse reaction samples are generally compromised samples that have seals that have been broken. These materials include products associated with unexpected illness or deaths.
- Products that are reported to be ineffective are generally a group of findings, not a single incident.
- Suspicious samples are generally unopened containers.
- Labeling or containers that seem incorrect.
- Routine Post Market surveillance samples—generally unopened containers.

Purpose of Keeping some samples as retain samples

- To be used as evidence in a legal proceeding and must be protected to have status in court.
- To be made available only to individuals on a need to access.

End of Retained samples

The retained samples can be destroyed only after it is determined that the evidence will not be used in a legal proceedings. The collected materials are property of the government and should be destroyed at the conclusion of the findings.

4.4 QUALIFICATION OF DRUG INSPECTORS

Inspectors should normally be pharmacists who have work experience in community and/or hospital pharmacy. Where persons other than pharmacists are employed as drug inspectors, they should be adequately experienced in drug control affairs and suitably trained in inspection functions. Every Inspection team should be led by a Pharmacist. The

possibility of having part-time inspectors with special knowledge as part of inspection teams may also be considered if deemed necessary.

The inspector should:

- Advise on whether applicants and premises should be issued license to engage in drug related activities.
- Ensure that all licensed premises and authorized persons adhere to existing laws and regulations.
- Ensure that counterfeit and substandard pharmaceutical products are not found in Sierra Leone. Inspection should be held regularly. Premises should be inspected at least once every 6 months. Where problems are frequently noticed, the inspection should be carried out more frequently (e.g. every three months). For premises with a good record, less frequent inspection may be needed.

When inspecting establishments, the inspector will use the appropriate references. The method of inspection will be laid down in the SOP for inspection and checklist for inspection which also contains the requirements for a specific type of establishment.

4.5 Attributes of an inspector

An inspector should possess the following attributes:

- Good knowledge of pharmacy, laws and regulations to be enforced.
- Good command of technical terms and excellent communication skills.
- Awareness of the probable methods of using forged or false documents for transactions in pharmaceutical preparations and skills in determining the genuineness of documents presented for examination.
- Maturity, honesty and integrity.

- Responsible conduct which commands respect.
- Willingness to accept challenges.
- Ability to organize their own work with minimum supervision.
- Ability to assess facts quickly and take rational and sound decisions without delay.
- Ability to assess character and honesty of persons being interviewed.
- Good public relations image with key personnel/pharmacists in charge of premises while remaining firm, fair and resolute.
- Ability to hold discussion with company management at the completion of inspection.
- Ability to motivate other inspectors.
- Commitment to hard work and long hours.
- Ethical approach to any potential conflict of interest.
- Have good eyesight.
- Always be presentable and have a pleasant character.
- Ability to adopt new work and assignment.
- Be punctual.

4.6 DO'S & DON'TS FOR INSPECTION

- Exercise confidentiality: do not reveal to a third party findings/observations regarding your work.
- Make accurate reports of the facts observed.
- Be courteous and demonstrate poise and competence in your work.
- Refrain from expressing personal views; such remarks or opinions may be interpreted as official.
- Do not lose temper when abused or accused.
- Do not miss single object, correspondence, record, accounts book, chit, rough book, or other relevant papers, which may prove to be material evidence in establishing conduct, transactions, circumstances, and so on of the establishment being inspected.

- Do not fail to mention or record all items seized.
- Full details and descriptions of the incriminating articles or circumstances for which a charge will be opened (in case of intention to institute legal charges) should be recorded with witnesses present and signatures of responsible persons should be on the seizure document.

4.7 PROCEDURES FOR DRUG INSPECTION

(a). During inspection of facilities the following must be done

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

2. Present credentials (your identity card) and explain the purpose of your visit.

3. Use diplomacy, tact, and persuasiveness to acquire the necessary information and all necessary inspection details. Use the standard operating procedures (SOPs)/Inspection Checklist to achieve this.

4. 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.

4. 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.

6. If any samples have been taken for retrieval, testing or further investigation, furnish a retrieval form for the samples to the person from whom samples are taken.

7. Testing of Pharmaceutical using TruScan RM when necessary.

(b) At the Port of entry

- Organoleptic Inspection of the product is performed
- Testing with the TruScan RM

(c) During post-marketing surveillance SOP for Inspection of Pharmaceutical outlets must be followed

4.8 Organisational aspects

All inspectors should be employed or nominated by the Pharmacy Board of Sierra Leone, which ensures the following aspects.

- A job description which describes the duties of the inspector and proper reporting procedures to the Distribution Chain Inspection department.
- Regular meetings of inspectors to ensure uniformity of approach in which experiences on the job are exchanged to enhance the performance of inspectors.
- Inspectors should work according to a work plan and to SOPs.
- Inspection report should be in four parts:
    1. Sent to the Registrar, through the HoD-DCI, with date of inspection and general information on the area/establishment inspected
    2. description of the inspection activities undertaken, including analytical data of sample taken.
    3. observations in the form of Premises, Professional, Product and Records.
    4. Recommendations.
    5. Attachment of Retrievals
    6. Copy of Report sent to the the Inspection and Enforcement department.

Inspectors in the regional offices should submit weekly reports to the Headquarter office whilst inspectors in the Headquarter office should submit daily reports.

The existence of unauthorized markets for the distribution of drugs possesses considerable health hazards. The inspectors in the regional offices with the assistance of task forces (if necessary) can investigate the extent of the unauthorized markets, the types of drugs distributed and supplied, and the sources of the drugs. All unauthorized markets for drugs should be prohibited through effective inspection activities. The inspector should also investigate the sources of supply of suspected counterfeit or substandard pharmaceutical products. The type of product on sale should also be investigated.

4.9 Cooperation with other agencies:

The inspector will be expected to interact and cooperate with other interested parties such as:

a) industrial, community and hospital pharmacists,

b) management and supervisory staffs of pharmaceutical establishment and hospitals, medical practitioners , dentists, veterinarians, nurses, midwives and other health workers,

c) public analysts,

d)drug law enforcement officers including the police and customs,

e) officers of port authorities, clearing agents at the ports importers and exporters,

f) members of the public

g)staff of department of pharmacy in the college of health science,

h)foreign drug regulators authorities

4.10 Independence.

Inspectors should never depend on the hospitality of the facility to be inspected for example for inspection costs and transport.

5.0 GLOSSARY

None

6.0 REFERENCE/INFORMATION SOURCES

When inspecting establishments, the inspector will use all appropriate references, the method of inspection as laid down in the SOP for inspection and checklist for specific type of establishment. The inspection SOPs will be in the format of a checklist. The reference/information sources to be used by inspectors should include existing Pharmacy and Drugs Act and the guideline for licensing, GMP, Good distribution practice, Good pharmacy practice, promotion of pharmaceutical products.

7.0 ANNEXES

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