Ethiopian Food, Medicine and Healthcare Administration and Control Authority

Inspection Manual for Inspectors

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Chapter One
Introduction

1.1. Background

The government of Ethiopia has been working to strengthen the regulatory system at national level. Providing comprehensive regulation of all matters related to safety and quality of pharmaceutical products is crucial. The regulation of medicines involves, among other things, inspection of medicine outlets which include manufacturers, importers, wholesaler, distributors and retail outlets.

Conducting inspection activities is important in ensuring that medicines and other 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 medical products.

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, during and after inspections. The manual highlights general conditions and other pertinent requirements that are necessary for carrying out medicine outlets inspections.

1.2. Objectives of the manual

To guide inspectors on how to carry out inspection so as to determine effectiveness and efficiency of the regulatory system in implementing planned inspection activities for improving the quality of inspection services.

1.3. Scope of the manual

This manual shall apply to inspection activities concerning medical products including medicines, cosmetics and medical devices at all levels of distribution channels. However, the detail of inspection process may vary depending on the scope of the pharmaceutical facilities to be inspected.

1.4. Terms and definitions

In this manual, the following terms and definitions shall apply, unless the context otherwise requires.

Authority: the Ethiopian Food, Medicine and Health Care Administration and Control Authority

Inspection: A Systematic and independent examination to determine whether quality activities and related results comply with the planned arrangement and whether these arrangements are implemented effectively and are suitable to achieve the objectives.

Inspection team: two or more inspectors conducting an inspection.

Inspector: any person appointed by the authority to perform inspection activities pursuant to this proclamation No. 661/2009.

Lead inspector: an inspector who is assigned with the responsibility of leading an inspection team carrying out inspection of a specified Pharmaceutical establishment site.

Medical products: Includes medicines, medical devises and cosmetics and other health products.

Chapter Two
Medicine inspection

2.1. What is inspection?

Inspection is a systematic and independent examination to determine whether quality activities and related results comply with the planned arrangement and whether these arrangements are implemented effectively and are suitable to achieve the objectives. To inspect is to look closely at something, especially to check that everything is in good order and ensure that it meets certain prescribed or known standards and specifications.

Thus, medical products inspection is the act of examining or looking closely at all the attributes of the products and the condition of all the facilities and/or premises as well as the personnel that deal with products. This helps ensure companies are meeting Ethiopia's safety, effectiveness and quality requirements. The inspection activities are meant to safeguard and promote the health and safety of the patient and public. This will be reinforced through enforcement of laws and regulations. Inspectors shall give emphasis on how inspections are operated as describe in the laws, inspection guidelines or manuals, procedures, work instructions, checklists or any other quality documentation.

Furthermore, though the inspection may vary depending on the scope of the inspectee, the inspections shall cover all areas where inspection activities are carried out such as manufacturing, import and export, wholesale, transportation, storage, distribution, selling, compounding and dispensing of medical products.

2.2. Objectives of inspection

The objective of conducting a medical products inspection is to ensure that the products, either locally manufactured or imported, meet set quality requirements to ensure the safety and health of patients; and the public health at large. A medical product inspection also looks at the premises in which products are stored and services are provided to ensure the facility as well as personnel meet established standards.

2.3. Scope of the inspection

The inspections shall cover all areas where inspection activities are carried out including all documents relating to the control of medical products such as databases, files, reports and other related documents as well as personnel working in the facility.

2.4. What needs to be inspected

Establishments associated with the medical products supply and distribution chain should be inspected regularly. This includes;

- Entry and exit ports
- New premises or facilities for manufacture, import, export, wholesale, store and retail outlets. This is before licensed (pre-approval) and after being licensed (post approval).
- Overseas pharmaceutical manufacturing facilities before approved and post approval

2.5. Types of inspection

In general term inspection can be classified as post and pre-licensing inspections. Recognizing this, there are five types of inspections, as outlined and described below:

1. Routine inspection
2. Concise inspection
3. Follow-up inspection
4. Special inspection
5. Investigative inspection

2.5.1. Routine inspection

Routine inspection is a full or comprehensive review/inspection of all aspects and components of the pharmaceutical establishments including medicine retail outlets, distributors, wholesalers, importers, exporters or manufacturer etc. This form of inspection is applied for new pharmaceutical establishments; when an establishment is applying for permit to a permit to extend its scope of operations beyond that for which it was originally licensed; has made important changes in its key personnel or moved to new premises or is changing premises; or has not been inspected for a long time; or when there is information of serious gaps/deficiencies/lapses. This type of inspection should be announced.

2.5.2. Concise inspection

Concise inspection is the evaluation of limited aspects relating to compliance within a facility. A limited number of compliance requirements are selected by the inspector to serve as indicators of the overall compliance to the standard by organization. It is generally reserved for establishments that have been previously inspected with a view to assessing standards of GxPs including good pharmacy practice, Good storage Practice and Good Distribution Practices. The outcome of the inspection helps in the proper assessment of establishments for compliance with the set standards.

The inspectors must also identify and evaluate any significant changes that might have been introduced by the establishment since its previous inspection. A concise inspection is conducted under the following circumstances:

- Where an organization has a consistent record of compliance with set requirements through routine inspections in the past
- Where a sample of aspects can be taken as a good indication of the overall level of organization's compliance with the relevant standard
- If the concise inspection uncovers evidence that the level of compliance has fallen, however, a more comprehensive or full inspection should be performed soon after the concise inspection

These inspections can be announced or unannounced.

2.5.3. Follow-up inspection

A follow-up inspection is referred to as a re-inspection or a re-assessment of the facilities. It is normally carried out to ensure that corrective measures have been undertaken following advice and notice given during a previous inspection. Where 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 risks associated with the nonconformance, adequate time to rectify the defect should be provided. The follow-up inspection is limited to specific non-compliances that have been observed.

2.5.4. Special inspection

A special inspection is used to assess the performance of a new establishment whose scope of operations was previously unknown. A special inspection is undertaken to conduct "spot checks" which could focus on one product, a group of related products, or

a specific operation etc. A special inspection is conducted under the following circumstances:

- When complaints have been made about a specific product/organization that suggests there may be defects/non- compliance
- When specific information need to be gathered, or specific operations of the organization's need to be investigated.

The inspection should be unannounced.

2.5.5. Investigative inspection

This type of inspection is undertaken to deal with specific complaints received about gaps or non-compliance with standards of professional practice or performance of new establishment whose scope of operation was previously unknown, complaints, product failure or recall. Such inspection may be focused on one product, a group of related products or specific operations such as mixing, sterilization, labelling, compounding, dispensing practice, storage practice and procurement etc. The inspection should be unannounced.

2.6. Frequency of inspection

Every licensed pharmaceutical institution which manufacture, store, transport, distribute, handle or dispense medicines will be inspected at least once every year as routine inspection program. The regulatory body may implement risk based inspection approaches to make efficient use of the available financial, human and time resources where they are most needed. Thus, those pharmaceutical institutions which demonstrate constant compliance over certain period (as it is determined by the regulator) of time may not be subjected for yearly routine inspection. For premises with a good record, less frequent inspection may be needed but where contravention is often noticed, the inspection should be more frequent.

2.7. Levels of inspection

The levels of inspection take into account the existing inspection administrative set up from national, regional to the local district regulatory bodies. Each level can carry out inspection as per the legal mandates given by law. However, the regulators can conduct inspection based on agreements made among the federal and regional regulatory bodies whenever deemed to be necessary.

Chapter Three

Major areas to be inspected

During conducting inspections every inspector shall verify and ensure the following areas are compliant with the national legal requirements.

Personnel

Ensure that the personnel employed or working in the licensed institution is as per respective regulatory requirements for personnel qualification for the concerned institutions/establishment. Check the adequacy of qualified personnel against the work load, competency of the personnel, training (induction and on job training related to the work assigned), training programs & records, health and hygiene practices, and professional ethics and discipline.

Premises

Ensure that the premises of the medicine establishments are complaint as per the national regulatory requirements and international practice as it applies. Check the following areas such proper and adequate storage facility, proper sanitation and hygiene practice, proper dispensing/dispatch facility, proper record keep facility, proper maintenance practices and proper security etc.

Source of supply

While conducting inspections in medicine establishments, inspectors must ensure that only medicines and health products registered or those which have got waiver by EFMHACA must be procured, stocked, sold, dispensed or transferred by the medicine establishments including the retail outlet. Such products must have been procured or sourced from known sources.

Storage

Inspectors shall ensure that medicines and health products held in inventory are in the manufacturer's original pack and meet labeling requirement as stipulated by EFMHACA, or any other guidelines/regulation recognized by EFMHACA. The products shall be stored according to the Good Storage Practice Guidelines of EFMHACA. For example, off the floor and protected from heat, direct sunlight, moisture, adverse temperature, insects, rodents, and contamination etc.

Moreover, inspectors shall ensure that damaged or expired medicines found in the medicine establishments have been recorded, sealed, quarantined, and labeled with red ink with the statement "Expired/damaged medicines— Not for sale". Expired and damaged medicines and health products shall be disposed under the supervision of the EFMAHCA and/or appropriate regulatory body based on the medicines disposal guidelines of EFMHACA.

Dispensing procedures

Inspectors shall verify dispensing records to ensure that dispensers dispense only medicines and health products registered and approved by EFMHACA. 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 the Good Dispensing manual of EFMHACA. furthermore, inspectors shall verify that dispensers use dispensing tools such as dispensing trays to dispense tablets and capsules to avoid contamination and cross-contamination.

Complaint handling

Check whether there is mechanism for handling of customer complaints e.g. procedures

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 national regulatory requirements and other national relevant laws. Check for availability of standard operating procedures (SOPs).

Self-inspection/internal audit

Check the presence of approved self-inspection procedure (SOP)and schedules; and review self-inspection results if any.

Reference materials

Depending on the need of the medicine establishments, each facility shall have and maintain for easy reference the following books:

- National drug policy
- Proclamations, regulations and appropriate directives
- Pharmacy code of ethics

- National list of medicines including registered medicine lists, national essential medicines and other lists as appropriate
- National standard treatment guidelines and Good dispensing practice manuals
- Directive for disposal of pharmaceutical products and other appropriate directives

Chapter Four

Conducting inspection

4.1. Planning for inspection

Before conducting inspection, the team shall be responsible for planning of inspection following an approval of the work plan and budget. The planning for inspection shall include preparation of an annual inspection plan based on the approved budget and available resources.

When preparing an inspection plan (schedule), the following points should be considered:

- Map and group the establishments to be inspected based on their location in the same geographical location so that single trips can be organized
- The number of hours or day(s) required to inspect one establishment and all establishments located on the same geographic location
- The availability of budget at that time
- Risk-based inspection approach that focuses on, for example, certain high-risk medicines.
- Reported market (public) complaints

The inspection plan shall include names, postal and physical addresses of the establishments, type of inspection, proposed date of inspection, and names of inspectors. The inspection shall be carried out by at least two inspectors. The work plan shall be approved by the Director or appropriate person for inspection.

4.2. Preparing for 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:

- Review previous inspection and audit reports
- Inspection tools such as checklist, guidelines, and sampling kits etc.)
- Arrange traveling logistics and weather forecast
- List (names and address) of premises to be inspected
- Registered medicine lists, national essential medicines and other lists as appropriate

- Official communication with the establishment (depending on the type of inspection)
- Inspectors identification card
- Stationery supplies (pen and inspectors writing book)
- Full-time transport
- Approved budget to undertake the inspection
- Any other tool depending on the type and nature of inspection

4.3. Conducting an inspection

Upon reaching the premises where the inspection is to take place, the team shall make a courtesy call to the respective authorities or person in charge of the facility or the management of the facility:

- Introduction of the inspectors
- Inspectors must present their credentials
- explain the purpose of the inspection
- requesting for an officer to accompany the inspection team during the inspection if necessary
- ask for assistance where needed
- Use diplomacy, tact, and persuasiveness to acquire the necessary information and all necessary inspection details.
- 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.

During the actual inspection, inspectors shall conduct the inspection systematically using the appropriate inspection checklist. Inspectors shall record their findings and observations accordingly. At least two inspectors, one being the lead inspector, shall constitute the inspection team. During the actual inspection, the inspectors shall scrutinize inspection reports, inspection data etc.; check whether inspection guidelines, checklist, working procedures are followed; sampling of areas to be inspected as appropriate; on site verification (inspection, taking sample, action taken, advice and recommendations); and prepare a brief report. If any samples have been taken for testing, furnish a receipt for these samples to the person from whom samples are taken.

Inspection may include 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. Samples should be collected as per the laboratory requirements. Inspectors shall also be trained on techniques for sample collection.

4.4. Post-inspection briefing

This is an activity that takes place after inspection has been carried out. The objective of this stage is generally to convey inspection findings/observations in brief to the inspected establishment. Inspectors are required to provide both positive and negative findings. Adopt a courteous attitude in calling attention to the practices or conditions observed at the time of inspection.

Any suggestions for improvement may also be communicated. The findings shall be filled in a corrective action form which shall be signed in duplicates by the inspectors and inspected establishments indicating the major non-conformances, suggested corrective measures and the time frame. One copy shall remain with the inspected establishment.

4.5. Inspection report

A final report need to be prepared which should incorporate all findings. Inspection report should be written immediately after completing the inspection. The compilation and submission of the report should take not more than three working days on completion of inspection.

Chapter Five

Inspection report

An inspection report shall be written immediately after completing inspection. The compiled report shall be submitted to head of inspection within three working days upon completion of inspection. The head of inspection shall make sure that the inspection report is sent to the inspected facility within 15 calendar days after receiving the inspection report. Regulatory action(s) taken 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.

5.1. Contents of the audit inspection report

In spite of the type and format of the audit inspection report, the report should contain the following information;

5.1.1. Title of the report

- Name of institution
- Name of inspectors
- Name and signature of the person approving the report
- Heading of the report indicating place, date and duration

5.1.2. Acknowledgement (optional)

An appreciation of the contribution and participation of groups of people, stakeholders and individuals involved in one way or another during the inspection

5.1.3. Acronyms

List of abbreviations commonly used in the report.

5.1.4. List of figures and tables, as appropriate

Title of figure/ tables and pages to locate them

5.1.5. Table of contents

List of topics and pages to be located

5.1.6. Executives summary

5.1.7. Introduction

- General overview
- Scope of inspection

- Purpose of inspection
- Methodology

5.1.8. Main body of the report

- Situation analysis, needs, services and systems
- Observations/Findings
- Analysis of the findings

5.1.9. Conclusion and recommendations

Name of inspectors and Signature: Names and signature of inspectors participated in that inspection

5.1.10. Appendices, if required

List of tools used.

Chapter Six

Inspectors competencies

Inspectors with only the knowledge of inspection techniques may understand the technical requirements for an effective inspection yet may not be effective inspectors. They must not only present themselves professionally but also demonstrate the ability to apply their knowledge and skills effectively

6.1. Qualification and training of inspectors

Inspectors shall be appointed by the regional regulatory body. The inspectors shall have the qualifications necessary to effectively take part in the inspection of medicine establishments. These qualifications shall be based on the following;

- Academic education
- Training
- Work experience

6.1.1. Academic Education

Pharmaceutical establishment inspectors should normally be pharmacists who have work experience in in different areas of pharmaceutical discipline. The possibility of having part-time inspectors with special knowledge as part of inspection teams may also be considered if deemed necessary and these inspectors should sign declaration for conflict of interest. The inspectors shall have a minimum of bachelor degree in pharmacy and appropriate work experiences.

6.1.2. Training

To be competent in carrying 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 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 regulatory body or other national and international organizations

6.1.3. 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:

- S/he has been involved in inspection of pharmaceutical outlets for 2-3 years.
- S/he has demonstrated competence in communication skills and report writing.

Such experience will be taken into consideration when planning for and conducting pharmaceutical outlet inspection.

6.2. Resource management

Proper preparation in the inspection planning stage can eliminate many delays in the inspection performances. To make efficient use of resources, the inspectors must plan the inspection on several levels i.e. inspection director, inspection team leader, lead inspector and inspectors level.

6.3. Conflict resolution

The most effective method of solving conflict is to take steps to reduce conflict occurrences. The lead inspector may establish ground rules, for the inspection team, for communication, interaction and performance of the inspection teams before the inspection process. This will help the inspection team to reduce conflicts during the inspection by eliminating misunderstandings, remaining open minded and flexible.

Conflict may develop at any time during inspection process. The best course of action for the team is to temporarily stop the inspection and allow a cooldown period before proceeding and avoiding or smoothing the issue.

6.4. Other competences

The inspectors should also have competences on communication techniques, interviewing techniques, presentation techniques and process verification (verify by examination of records, documents or interviewing) and validation techniques.

Chapter Seven

Code of 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.
- Perform duties tactfully, honestly, and impartially to avoid circumstances that may lead to conflict of interest.
- Protect and promote the interests of this/her organization to the best of his or her ability and knowledge, recognizing that the organization has placed trust and confidence in him or her.
- Make every effort to uphold, maintain, and improve the integrity and reputation of the regulatory body and the government of Ethiopia
- Maintain confidentiality whenever accessing confidential information as a result of inspection.
- 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.
- Strive to acquire new knowledge and skills continuously and use them effectively.
- 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 his/her organization 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 his/her organization.
- Not use his or her position for personal gain.
- Conserve his/her organization's 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 your organization before engaging in outside employment or activities or seeking or negotiating for employment that will directly conflict with the duties or interests of the regulatory body.
- 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 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.