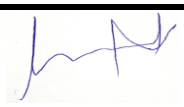
ETHIOPIAN FOOD AND DRUG AUTHORITY

INSPECTION MANUAL FOR GOOD STORAGE, DISTRIBUTION, AND DISPENSING PRACTICES

Document Number	EFDA/MN/008	Version No.	001
Date of Approval	10.05.2025	Date of Issue	15.05.2025

Document History

Version No.	Reason for Amendment	Effective date
001	Newly issued document	15.05.2025



WONDU KETELE

Branch Coordination Lead Executive Officer

May 2025

Addis Ababa, Ethiopia

1ST Edition

Foreword

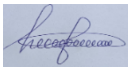
In a rapidly evolving global landscape, regulatory systems need to be stable, well-functioning, and integrated to effectively safeguard public health. The growing complexity of medical product development, the speed at which innovations reach the market, and the dynamic nature of supply chains necessitate a resilient, data-driven, and digitally empowered regulatory system, which in turn is essential to ensure the quality, safety, and efficacy of medical products throughout their entire life cycle.

The Ethiopian Food and Drug Authority (EFDA), established under Proclamation No. 1263/2021, and guided by Proclamation No. 1112/2019 and Regulation No. 531/2023, is mandated to protect and promote public health by ensuring safety, quality, and effectiveness of medical products in Ethiopia.

Despite notable progress, the regulatory landscape continues to face significant challenges, including rapid technological change, emerging public health threats, proliferation of substandard and falsified products, and capacity limitations. These challenges highlight the need for a more collaborative, transparent, and adaptive regulatory approach that upholds Good Storage, Distribution, and Dispensing Practices, aligned with international standards and national priorities.

We call upon all regulators, health professionals, stakeholders, academia, and development partners to work together in building a stronger regulatory ecosystem. A collective commitment to innovation, capacity building, and evidence-based decision-making is key to ensuring access to safe, quality and effective medical products for all.

We express our sincere appreciation to all Technical Working Group (TWG) members, institutions, experts, and partners who continue to support the mission of the regulatory bodies. Your contributions are instrumental in advancing the regulatory system strengthening efforts. As we move forward, let us reaffirm our commitment to regulatory excellence, accountability, transparency and collaboration for a healthier Ethiopia.



Heran Gerba
Director General
Ethiopian Food and Drug Authority

Acknowledgments

The Ethiopian Food and Drug Authority (EFDA) extends its sincere appreciation to all individuals and institutions who contributed to the development of this Inspection Manual for Good Storage, Distribution, and Dispensing Practices. This manual reflects the collective expertise and dedication of professionals committed to strengthening regulatory systems and safeguarding public health in Ethiopia.

The EFDA gratefully acknowledges the valuable inputs provided by participants of the national consultative workshops. Their technical insights and critical feedback were essential in ensuring the relevance, clarity, and operational feasibility of the manual.

Special recognition is given to the members of the Technical Working Group (TWG), whose active engagement, subject matter expertise, and coordinated contributions played a central role in drafting, refining, and aligning this manual with national laws, regulatory standards, and guidelines, as well as international best practices.

No.	Name	Institution
1	Getachew Genete	EFDA
2	Kidanemariam G/Michael	EFDA
3	Melaku Tileku	AAU/SOP
4	Solomon Shiferaw	EFDA
5	Assefa Mulu	AAU/SOP
6	Sisay Endale	AAU/SOP
7	Wasu Gedefaw	EFDA
8	Wendu Ketele	EFDA
9	Samuel Marie	EFDA
10	Fikrie Wondimu	EFDA
11	Muluemebet Fikadu	WHO

Acronyms and Abbreviations

AAU/SOP	Addis Ababa University/School of Pharmacy
ADR	Adverse Drug Reaction
CAPA	Corrective and Preventive Action
CES	Compulsory Ethiopian Standards
COI	Conflict of Interest
CPD	Continuing Professional Development
EFDA	Ethiopian Food and Drug Authority
eRIS	Electronic Regulatory Information System
FEFO	First Expiry First Out
FIFO	First In First Out
GDiP	Good Dispensing Practices
GDP	Good Distribution Practices
GPS	Global Positioning System
GSP	Good Storage Practices
NEML	National Essential Medicine List
NMRA	National Medicines Regulatory Authority
PPE	Personal Protective Equipment
QA	Quality Assurance
RRB	Regional Regulatory Bodies
SOP	Standard Operating Procedure
STG	Standard Treatment Guideline
TWG	Technical Working Group
WHO	World Health Organization

Table of Contents

1. Introduction

1.1. Background

The Ethiopian Food and Drug Authority (EFDA) is committed to strengthening the national pharmaceutical regulatory system to ensure the safety, quality, and effectiveness of medical products throughout their lifecycle. In line with its legal mandate under Proclamation No. 1112/2019 and Regulation No. 531/2023, EFDA regulates and oversees a range of functions, including the inspection of pharmaceutical storage, distribution, and dispensing operations.

Regulatory inspections serve as a critical tool for safeguarding public health by ensuring that entities involved in the pharmaceutical supply chain, which are importers, wholesalers, and community pharmacies, comply with applicable regulatory standards. These include Good Storage Practices (GSP), Good Distribution Practices (GDP), and Good Dispensing Practices (GDiP). Inspections are essential to preventing the entry and circulation of substandard, falsified, unregistered, unlicensed, or otherwise non-compliant medical products within the Ethiopian market.

This manual has been developed as an operational guide for EFDA and Regional Regulatory Bodies (RRBs) inspectors responsible for the regulation of pharmaceutical storage, distribution, and dispensing practices. It outlines standardized procedures, tools, and checklists for effective planning, preparation, conduct, and follow-up of inspections. It also serves as a reference document to ensure consistency, transparency, and technical rigor across all inspection activities.

1.2. Purpose of the Manual

The purpose of this manual is to provide a standardized framework for guiding EFDA and RRBs inspectors in the planning, preparing, conducting, reporting, follow-up and documentation of inspections across the pharmaceutical distribution channels. It aims to promote consistency, transparency, and accountability in inspection practices, support risk-based regulatory decision-making, and ensure alignment with national laws and internationally recognized standards. The manual further facilitates enforcement of corrective action, and enhances clear, professional communication with inspectees to protect public health.

1.3. Scope and Applicability

This manual applies to all regulatory inspections carried out by the EFDA and RRBs within the pharmaceutical distribution chain, including importers, wholesalers, and community pharmacies. It provides a structured framework for inspections to apply GSP, GDP, and GDiP requirements in accordance with applicable national laws, guidelines, and global best practices.

The manual is intended for use by EFDA and RRBs inspectors and relevant regulatory personnel involved in inspection activities. It is applicable to all types of inspections—routine, concise, special, follow-up, and investigative - conducted under EFDA's and RRB's mandate. Where applicable, the guidance herein may also be adapted by RRBs operating under their authority. Through its use, the manual aims to reinforce consistency, accountability, transparency, and quality in the planning, preparing, conducting, and follow-up of inspections.

1.4. Definitions

1.4.1. Inspection: A formal and systematic examination conducted by inspectors to evaluate whether pharmaceutical distribution channels comply with applicable laws, standards and guidelines.

1.4.2. Distribution Channel: The network of entities involved in the movement of pharmaceutical products from manufacturers or importers to the final point of sale or use. This includes importers, wholesalers, distributors, and community pharmacies.

1.4.3. Good Practices (GxP): The group of good practice guides governing the preclinical, clinical, manufacturing, testing, storage, distribution, and post-market activities for regulated medical products, such as good manufacturing practices (GMP), good distribution practices (GDP), Good Storage Practice (GSP), Good Dispensing Practice (GDiP) and other good practices.

1.4.4. Good Distribution Practices (GDP): That part of quality assurance that ensures that the quality of a medical product is maintained by means of adequate control of the numerous activities that occur during the trade and distribution process, as well as providing a tool to secure the distribution system from falsified, unapproved, illegally imported, stolen, substandard, adulterated, and/or misbranded medical products.

1.4.5. Good Storage Practices (GSP): That part of quality assurance that ensures that the quality of medical products is maintained by means of adequate control throughout the storage thereof.

1.4.6. Good Dispensing Practices (GDiP): Standards for the safe and effective dispensing of medicines, including accurate labeling, counseling of patients, and ensuring appropriate product use.

1.4.7. Compliance: The extent to which an inspectee meets the applicable legal, regulatory, and procedural requirements.

1.4.8. Non-Compliance: Any deviation from applicable laws, standards or guidelines that may pose a risk to public health or compromise the quality, safety, or efficacy of pharmaceutical products.

1.4.9. Corrective and Preventive Actions (CAPA): A system for implementing corrective and preventive actions resulting from an investigation of complaints, product rejections, non-conformances, recalls, deviations, audits, regulatory inspections and findings, and trends from process performance and product quality monitoring.

1.4.10. Distribution: The procuring, purchasing, holding, storing, selling, supplying, importing, exporting or movement of medical products, except for dispensing or providing medical products directly to a patient or his or her agent

1.4.11. Importation: The act of bringing or causing any goods to be brought into a customs territory (national territory, excluding any free zone).

1.4.12. Standard Operating Procedure (SOP): An authorized written procedure giving instructions for performing operations that are not necessarily specific to a given product but of a more general nature (e.g. equipment operation, maintenance and cleaning, validation, cleaning of premises, environmental control, sampling and inspection).

1.4.13. Storage: The storing of medical products up to the point of use.

1.4.14. Vehicles: Trucks, vans, buses, minibuses, cars, trailers, aircraft, railway carriages, boats and other means that are used to convey medical products.

1.4.15. Quality Assurance: A wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that medical products are of the quality required for their intended use.

1.4.16. Quality Risk Management: A systematic process for the assessment, control, communication and review of risks to the quality of medical products in the supply chain.

1.4.17. Quality System: An appropriate infrastructure, encompassing the organizational structure, procedures, processes, resources and systematic actions necessary to ensure adequate confidence that a product (or services) will satisfy given requirements for quality.

1.4.18. Product Recall: Removal of marketed products from the supply chain, including corrective actions for the reasons relating to deficiencies in quality, safety or efficacy, including labeling considered to be in violation of the laws.

1.4.19. Return Products: Refer to medicines, drugs, or healthcare products that are sent back to the manufacturer, wholesaler, or distributor after being supplied to a pharmacy, hospital, or retailer. These products may be returned for various reasons, but not due to a safety defect or recall.

1.4.20. Inspectors: Authorized regulatory professionals designated by EFDA or Regional Regulatory Bodies to conduct inspections of pharmaceutical distribution and dispensing facilities. They assess compliance, report findings, and enforce regulatory actions.

1.4.21. Inspection Team: A group of inspectors assigned to perform an inspection, typically consisting of a lead inspector, technical inspectors, and co-inspectors. The team may also include specialists depending on the inspection scope.

1.4.22. Medical Products: A broader category that includes medicines, vaccines, devices, diagnostics, and any item regulated for health purposes under EFDA's legal framework.

1.4.23. Observations/Findings: Non-compliances or issues identified during inspection, categorized based on severity (e.g., critical, major, or other/minor) and documented in the inspection report with recommended actions.

1.4.24. Community Pharmacy: A licensed pharmacies and drug shops that provide services where pharmacy professionals are directly in contact with patients and dispense medicines with monitoring drug therapy. Dispensing of medicines may be either on prescription order or over-the counter.

1.4.25. Importers: any person licensed by EFDA to legally import medical products from abroad into Ethiopia, in compliance with national importation laws and guidelines.

1.4.26. Wholesaler: any person who sells medical products to retailers or governmental and nongovernmental organizations or cooperatives by wholesale after having bought such products from manufacturing facilities or importers

2. Types of Inspections

Regulatory inspections of pharmaceutical distribution channels may be classified based on their timing, purpose, scope, frequency, or triggering events. These classifications support effective inspection planning, preparation, and appropriate regulatory responses across different scenarios.

2.1. General Classification

Inspections of pharmaceutical distribution channels are broadly categorized into

a) **Pre-Licensing Inspections**: These are conducted prior to the issuance of a new license or certificate of competence to importers, wholesalers, or community pharmacies. The objective is to assess whether the facility meets minimum regulatory requirements related to infrastructure, premises, documentation, qualified personnel, and necessary equipment/s to begin operations.

b) **Post-Licensing Inspections**: These inspections are carried out after a license or certificate of competence has been issued. This aims to monitor ongoing compliance with applicable standards, identify risks, and enforce corrective or preventive actions where necessary.

2.2. Specific Classification

The EFDA and RRBs recognize five specific types of inspections depending on the inspection objective and context:

A. Routine Inspection

Routine inspection is a comprehensive examination of all regulatory components of the inspectees. Routine inspections may be conducted under the following circumstances:

- When applying for a new license or renewal;
- When requesting operational expansion,
- Following significant changes such as relocation, modification of premises, or changes in the technical manager;
- When the facility has not been inspected for an extended period;
- When previous inspections or reports identify operational deficiencies

Routine inspections are generally announced in advance and cover all relevant GDP, GSP, and GDiP requirements.

B. Concise Inspection

A concise inspection is targeted inspection assessing selected aspects of Good Practices (GxP) such as GSP, GDP, or GDiP based on a set of criteria representatives of overall compliance. Circumstances warranting a concise inspection include:

a) When the facility has a consistent history of regulatory compliance from previous routine inspections;
b) When selected, indicators can reasonably reflect the facility's overall compliance level.

If a concise inspection reveals deficiencies, a comprehensive follow-up inspection should be scheduled. These inspections may be announced or unannounced.

C. Follow-up inspection

A follow-up inspection, also known as a re-inspection, is conducted to verify the implementation of corrective and preventive actions following previously identified non-compliance. It focuses exclusively on prior findings and is typically performed:

- Within a timeframe proportionate to the nature and severity of the initial deficiencies;
- Without prior notification.

Follow-up inspections are unannounced to ensure genuine correction of previously identified issues.

D. Special Inspection

A focused inspection targeting a specific product, process, or operational area (e.g., cold chain, compounding, labeling, or documentation. Special inspections are triggered by:

- Complaints from consumers, healthcare professionals, or regulatory bodies regarding the safety, efficacy, or quality of medicines.
- Product recalls or reported adverse drug reactions (ADRs) or unexpected side effects.
- Post-marketing surveillance indicating emerging risks.
- Major deviations or variations in operations such as storage, distribution, or dispensing processes.
- Traceability concerns of pharmaceutical products
- Suspicion of violations, laws and guidelines involving controlled substances
- Suspicion of handling falsified, substandard, unregistered, expired, unfit for use medicines or falsifying records, etc.
- Suspicious of failing to meet certain licensing requirements.

- Introduction of high-risk products such as biologics, vaccines, or new medicines that require close monitoring.

Special inspections are unannounced and may be limited in scope depending on the trigger.

E. Investigative Inspection

An in-depth, targeted inspection initiated in response to specific reports or allegations of non-compliance. Common triggers include:

- Complaints from patients, healthcare providers or third parties regarding substandard products or service quality;
- Product recalls or repeated treatment failures;
- Suspicion of falsified records or illegal distribution;
- Inadequate traceability of imported or redistributed products;
- Previously unknown operational scope in newly established entities.

Investigative inspections are unannounced and tailored to confirm or refute suspected violations

3. Inspector Competence and Ethics

The credibility, consistency, and public trust in regulatory inspections depend fundamentally on the technical competence, impartiality, and ethical conduct of inspectors. This section outlines the qualifications, roles, training requirements, and ethical standards governing all inspectors assigned by the EFDA and RRBs for inspections of pharmaceutical storage, distribution, and dispensing facilities.

3.1. Inspector Qualifications

Inspectors shall possess academic and professional credentials relevant to pharmaceutical regulation, including pharmacy, pharmaceutical sciences, regulatory affairs, or other health-related disciplines. Prior experience in regulatory enforcement, quality assurance, pharmaceutical inspection, or supply chain management is essential. Specialized training in regulatory science, GxP auditing, or quality systems is considered an added advantage.

3.2. Roles within Inspection Teams

To ensure effective operations, clarity of responsibilities, and quality assurance, inspectors are assigned defined roles during inspection missions based on their experience, qualifications, and the complexity of the inspection. These roles include:

- **Co-inspector**: Participates in inspections under the direct supervision of a senior inspector; not authorized to conduct inspections independently and are typically newly recruited or undergoing induction.
- **Inspector**: Fully authorized to conduct inspections independently; responsible for executing inspections in line with applicable standards and may serve as mentor to co-inspectors as part of professional development programs.
- **Lead inspector**: Leads the inspection mission and is responsible for planning, coordination, supervision, and reporting of a particular inspection; oversees team performance; and makes final inspection decision recommendations based on consensus within the inspection team.

Inspector assignments to these roles are determined based on qualifications, documented field experience, and performance evaluations.

3.3. Training and Professional Development

3.3.1. Induction and technical training

All inspectors shall complete a structured induction program before deployment. The program shall include, at least, the following components:

- Overview of the national legal and regulatory framework
- Inspection procedures and enforcement mechanisms
- GSP, GDP, and GDiP standards and guidelines
- Risk-based inspection planning, categorization, and scoring tools
- Classification of inspection findings/deficiencies (critical, major, minor)
- Documentation standards and data integrity requirements
- Use of electronic inspection platforms and reporting tools
- Inspection ethics and conflict management principles

The induction shall include supervised fieldwork and simulation-based exercises to assess readiness for field deployment.

3.3.2. Continuing Professional Development (CPD)

Inspectors are required to maintain up-to-date knowledge through CPD activities such as refresher training, technical seminars, peer exchange programs, and regional or global workshops. Participation in CPD is mandatory for eligibility for field inspection. Training records and performance evaluations are subject to periodic audit and annual review.

3.4. Conflict of Interest (COI) and Ethical Conduct

A conflict of interest (COI) arises when an inspector's personal, professional, financial, or familial interests compromise or appear to compromise their impartiality in executing inspection duties. Situations constituting COI include:

- Past or current employment, consultancy, or financial involvement with the facility being inspected;
- Personal or familial relationships with facility staff or owner of the inspected entity;
- Receipt or solicitation of gifts, favors, hospitality, or benefits from inspected parties;
- Any action that may directly or indirectly result in personal or financial gain

To preserve integrity and regulatory trust, EFDA and RRBs require that:

- All inspectors shall complete and submit a COI declaration form prior to assignment.
- Any emerging or suspected conflict during the inspection process shall be reported immediately to the immediate supervising officer.
- The designated compliance unit shall review all declarations. Where a conflict exists, the inspector shall be recused and the assignment reassigned without delay.

All COI records shall be maintained securely and treated with strict confidentiality. Failure to disclose a COI shall be treated as serious misconduct and subject to disciplinary action.

3.5. Code of Conduct for Inspectors

Inspectors should uphold the highest standards of professional conduct, legal compliance, and ethical integrity. The code of conduct shall be binding on all inspectors and shall be enforced in accordance with the applicable legal and administrative frameworks and internal regulatory procedures.

3.5.1. Principles

The following principles shall guide all inspection activities: :

1. **Integrity and objectivity:** Inspectors shall perform their duties honestly and impartially. All findings shall be grounded in verifiable evidence and applicable regulatory standards. Inspectors shall not be influenced by personal, political, financial, or professional interests in the execution of their responsibilities.
2. **Confidentiality:** Inspectors shall safeguard all proprietary, personal, or sensitive information obtained during inspections. Such information shall only be disclosed when authorized by law or mandated under official procedures of the Authority or RRBs.

3. **Professionalism and respect:** Inspectors shall conduct themselves with discipline, courtesy, and professionalism. All communications with regulated parties shall be respectful, clear, and non-confrontational, regardless of the inspection outcome or setting.
4. **Transparency and accountability:** Inspectors shall clearly present official identification, explain the legal mandate for the inspection. All observations shall be accurately documented, properly classified, and supported by traceable evidence. Inspectors are fully accountable for the accuracy and timeliness of their reports.
5. **Zero tolerance for corruption:** Inspectors shall not solicit, accept, or offer any form of gift, favor, payment, or inducement that may influence or appear to influence the inspection outcome. Any attempt to bribe or coerce an inspector shall be reported immediately through official channels. Violations will result in disciplinary action, including legal referral.
6. **Team conduct:** Lead inspectors shall ensure coordination among inspection team members, assign roles, and facilitate internal debriefings before exit meetings. All team members shall work collaboratively and uphold a unified and objective stance.
7. **Use of authorized tools and systems:** Inspectors shall utilize only approved inspection standards, checklists, electronic systems (e.g., eRIS), data entry platforms, and reporting tools. All inspection data shall be entered and stored securely in compliance with data protection and confidentiality requirements.
8. **Impartiality:** Inspectors shall avoid any relationship or situation that creates an actual or perceived conflict of interest. Impartiality requires inspectors to remain free of bias and ensure decisions are made solely on objective and technical grounds...
9. **Objectivity:** Inspectors shall disclose any real or potential conflicts of interest prior to engaging in an inspection. Such conflicts shall be resolved through reassignment or formal clearance to ensure they do not adversely influence inspection outcomes.
10. **Independence:** Inspectors shall maintain full institutional and functional independence from inspectees. Their decisions and actions shall not be subject to external control, interference, or influence. EFDA and RRBs shall safeguard this independence through structural, procedural, and administrative mechanisms.

3.5.2. Ethical Violations and Disciplinary Actions

Inspectors shall be held accountable for any violations of ethical standards, inspection protocols, or regulatory procedures. Violations may include, but are not limited to:

- Abuse of authority or misuse of regulatory powers;
- Failure to disclose conflicts of interest;
- Acceptance of gifts, favors, or bribes from inspectees that influence their decision;
- Falsification or suppression of inspection findings;
- Breach of confidentiality obligations;
- Dereliction of assigned duties.

Sanctions imposed for confirmed violations shall be proportionate to the severity of the offense and may include:

- Issuance of formal warnings or placement on probation;
- Temporary suspension from inspection duties;
- Permanent removal or debarment from the inspectorate;
- Referral to law enforcement bodies in cases involving criminal misconduct or corruption.

All allegations of misconduct shall be reviewed by disciplinary committee or another designated body. The committee shall ensure due process, impartial investigation, and transparent documentation of findings and outcomes. Disciplinary decisions shall be recorded and retained in the inspector's official personnel file.

4. Inspection Planning and Preparation

The purpose of inspection planning and inspection is to ensure that all inspections are conducted in a systematic, efficient, and risk-based manner. This section outlines the procedures for scheduling, organizing, notifying, and equipping inspection teams prior to the conduct of inspections.

4.1. Risk-Based Inspection Planning and Frequency

4.1.1. Facility Profiling and Risk Data Sources

Risk-based inspection planning begins with facility profiling. This process enables the EFDA and RRBs to understand the operational context, compliance history, and regulatory significance of each licensed pharmaceutical facility. Profiling provides the foundation for assigning risk levels and scheduling inspection frequencies in a structured and evidence-based manner.

The objective of facility profiling is to systematically gather and assess information that reflects the product risk profile, operational complexity, historical regulatory performance, and its strategic importance within the national pharmaceutical supply chain. This applies to all licensed pharmaceutical importers, wholesalers, pharmacies, and drug shops. Facility profiles shall be updated routinely to ensure that inspection planning reflects current risk realities.

Profiling relies on multiple validated sources of regulatory data. Table 4.1 below outlines the core data sources and the type of information they provide.

Table 4.1: Core Risk Data Sources for Facility Profiling

Data Source	**Information Captured**
Electronic Regulatory Information System	Facility registration details, authorized product categories, licensing status, prior inspection reports, CAPA submissions, etc.
Inspection History	Frequency of inspections, classification of deficiencies (critical, major, minor), repeat violations or compliance history
Corrective and Preventive Action (CAPA) Records	Timeliness and completeness of responses to deficiencies, effectiveness of implementation
Product Type Information	Risk profile of products handled (e.g., vaccines, biologics, narcotics, cold chain items)
Surveillance and Complaint Records	Verified complaints, product defects, adverse drug events, product recalls, and post-market surveillance findings
Enforcement History	Sanctions imposed on the facility, such as warnings, suspensions, revocations, or legal proceedings
Geographic and	Urban/rural location, regional catchment, service volume, and

Operational Data	storage/distribution capacity, remoteness, risky areas for inspection

Facility profiling is the responsibility of the inspection department or designated officers within each EFDA and RRB. Initial profiling shall be completed upon licensing or registration of a facility. Profiles shall be reviewed and updated following each inspection, or when new risk-relevant information emerges from surveillance, enforcement, or post-market monitoring activities.

All facility profiles shall be maintained and shall be supported by documentation that is time-stamped, version-controlled, and accessible to designated users. Each profile shall include written justifications for risk dimension scoring, the rationale for classification, and documentation of all updates. Profiles shall be available for review by inspection supervisors, and assigned inspectors and shall comply with national data protection and documentation standards.

4.1.2. Risk Scoring Criteria and Categories

Risk classification is a core element of inspection planning. It enables EFDA and RRBs to prioritize oversight based on the public health significance and regulatory risk posed by each facility. The risk scoring process integrates multiple dimensions to reflect both operational complexity and historical compliance. The risk profile of a pharmaceutical facility is determined by two overarching dimensions:

- **Intrinsic risk:** This dimension reflects the inherent risk of the facility's operations, based on factors such as:
    - Type and criticality of products handled (e.g., vaccines, narcotics, cold chain medicines);
    - Complexity of processes (e.g., importation, wide-scale distribution, retail dispensing, compounding, etc);
    - Infrastructure requirements (e.g., cold rooms, refrigerator, cold boxes, vaults, automation);
    - Exposure to environmental, logistical, or supply chain security risks.
- **Compliance risk:** This dimension reflects the facility's history of regulatory adherence, including:
    - Severity and recurrence of deficiencies identified during past inspections;
    - Timeliness and effectiveness of Corrective and Preventive Actions (CAPA);

- Frequency of verified complaints, enforcement actions, or regulatory sanctions;
- Responsiveness, cooperation, and transparency during previous inspections.

Table 4.2: Provisional Risk Categories for Planning Use

Risk Category	**Definition**
High risk	Facilities handling high-risk products or with significant or unresolved compliance violations. May include entities with recent complaints, enforcement, or adverse events.
Medium risk	Facilities handling moderate-risk products with some compliance concerns but no critical or repeated deficiencies.
Low risk	Facilities with minimal-risk product portfolios, a clean compliance record, and no adverse regulatory history.

All assigned risk levels shall be justified in writing and recorded in the facility's inspection profile. Profiles shall be stored in the electronic regulatory system or other equivalent mechanism, including documentation of risk criteria applied and the rationale for the final classification.

EFDA and RRBs shall maintain internal alignment by ensuring supervisory review of all provisional classifications. Inspector training and calibration workshops shall be organized to promote consistent application of these interim scoring criteria.

4.1.3. Assignment of Risk Levels (High, Medium, Low)

Each licensed pharmaceutical facility shall be assigned a definitive risk level: High, Medium, or Low based on a structured assessment of intrinsic and compliance risk factors. This classification directly informs the inspection frequency, scope, and resource allocation.

The risk level shall be used to:

- Schedule inspections in accordance with minimum frequency thresholds;
- Determine the level of inspector expertise required for each visit;
- Guide sampling intensity, documentation review depth, and stakeholder engagement;
- Flag facilities for follow-up, special inspections, or enhanced post-market surveillance.

The assignment process shall follow the following transparent and evidence-based procedures to ensure consistency.

- **Risk Dimension Scoring:** Inspectors shall assess both intrinsic and compliance risk dimensions using the structured criteria.
- **Preliminary Risk Estimation:** A provisional risk level shall be derived based on a combination of observed product sensitivity, operational complexity, and regulatory history.
- **Team Review and Justification:** The proposed classification shall be reviewed by the inspection team leader and justified with a written summary. Key supporting documents may include past inspection reports; CAPA follow-up records; complaint logs or enforcement notices; and product profiles and distribution scope.
- **Approval and Documentation:** The final risk level shall be approved by the designated supervisor at EFDA or RRB and used formally for inspection planning. The rationale shall be auditable and version-controlled.
- **Communication and Transparency:** While the assigned risk category is primarily used internally, facilities may be informed of their classification upon request, particularly if linked to adjusted inspection frequencies.

Table 4.3: Expected characteristics of risk levels and minimum inspection frequencies

Risk level	Facility characteristics	Minimum inspection frequency
High risk	Facilities handling cold chain products, vaccines, or controlled substances), or with serious or repeated compliance failures. Often subject to complaints, adverse findings, or regulatory actions.	At least three times per year
Medium risk	Facilities with moderate-risk products and generally satisfactory performance, but with historical compliance gaps requiring continued monitoring.	At least two times per year
Low risk	Facilities with low-risk products, strong infrastructure, and a consistent track record of full compliance, with no recent deficiencies or complaints.	One times per two years

Risk classifications assigned to pharmaceutical facilities shall remain valid until the next scheduled inspection or the occurrence of a verified regulatory event. However, any significant operational changes such as the introduction of new product types, issuance of an import license, substantial facility renovations or change of professionals shall immediately trigger a re-evaluation of the assigned risk level. Following each inspection, the risk classification shall be formally reviewed and updated based on the latest findings and risk indicators.

4.1.4. Minimum Inspection Frequencies by Risk Level

The assignment of a facility's risk level directly determines the minimum frequency with which it shall be inspected. This stratified approach ensures that regulatory resources are allocated based on public health risk, regulatory history, and the operational complexity of each facility. The EFDA and RRBs shall enforce these inspection thresholds as a national minimum standard. Each risk category is linked to a corresponding baseline inspection frequency, as outlined on table 4.3.

These frequencies represent the national minimum requirements. However, additional inspections may be warranted based on situational factors such as receipt of credible complaints; identification of falsified or substandard products; public health alerts or adverse event reports; and failure to implement CAPAs or deliberate non-cooperation.

All deviations from the standard frequency shall be justified in writing and approved by the lead inspector or supervisor.

4.1.5. Risk Reclassification and Update Protocols

Risk classification is not a one-time exercise; it shall be periodically reviewed and updated to reflect evolving realities within each pharmaceutical facility. The EFDA and RRBs shall ensure that reclassification is based on newly acquired evidence, operational changes, or regulatory developments. This process guarantees that inspection intensity remains appropriate to the facility's current risk profile and regulatory behavior.

Risk reclassification shall occur under the following circumstances:

- **Post-Inspection Review:** After each inspection, the facility's risk level shall be reassessed based on updated findings, compliance status, and any newly identified risks. CAPA performance, documentation integrity, and responsiveness to prior deficiencies shall be considered.

- **Operational or Regulatory Change:** Any substantial change such as expansion of services, changes in product categories (e.g., addition of vaccines or controlled substances), relocation, professional change, or licensing status modification shall immediately trigger a formal review of the risk level.
- **Public Health or Enforcement Trigger:** Risk levels shall be revised if the facility is linked to product recalls, adverse events, criminal investigations, repeated complaints, or findings from pharmacovigilance, post-market surveillance, or law enforcement bodies.
- **Periodic Risk Review:** At minimum, risk classifications shall be formally reviewed once every 12 months for high- and medium-risk facilities, and once every 24 months for low-risk facilities, even if no new inspection has been conducted.

Reclassification Procedure

1. **Initiation**: The trigger for reclassification may come from inspection reports, regulatory alerts, or facility-reported changes. The assigned inspection team lead initiates the review process.
2. **Documentation**: A Risk Profiling Form shall be completed, including the rationale for the change, supporting documentation, and proposed new risk level.
3. **Review and Approval:** The proposed reclassification shall be reviewed by the responsible supervisor or inspection unit, with approval logged into the system or form.
4. **System Update:** The revised risk level and justification shall be updated in eRIS or risk profiling form, with version control, timestamp, and link to relevant inspection or enforcement records.
5. **Facility Communication:** If the reclassification affects inspection frequency or regulatory obligations, the facility may be formally notified in writing.

4.2. Annual Scheduling and Inspection Plan Development

A structured and risk-based Annual Inspection Plan (AIP) is the cornerstone of effective inspection deployment. The EFDA and RRBs shall develop, approve, and implement a comprehensive AIP each calendar year to ensure all licensed pharmaceutical establishments including importers, wholesalers, pharmacies, and drug shops are inspected systematically and equitably.

The AIP shall reflect facility risk classifications, geographic coverage, resource availability, and coordination with other regulatory functions. It shall serve as the formal blueprint for inspection scheduling and execution throughout the inspection year.

4.2.1. Structure and Approval of the Annual Inspection Plan

The AIP to be developed should include:

- A complete list of all licensed facilities categorized by risk level;
- Assigned inspection frequencies based on risk classification;
- Scheduled inspection windows (monthly or quarterly);
- Facility-specific notes (e.g., previous deficiencies, priority concerns), when required.

The draft plan shall be reviewed and endorsed by the responsible body and disseminated to all inspection teams no later than the start of each calendar year.

4.2.2. Mapping of Licensed Facilities and Geographic Allocation

All facilities included in the AIP shall be geo-mapped by region, zone/sub-city, or woreda, and exact coordinates. Geographic mapping enables:

- Efficient route planning and travel cost optimization;
- Prioritization of remote and underserved areas;
- Monitoring of geographic coverage equity and inspection gaps.

When possible, digital tools (e.g., GIS or eRIS) shall be used to generate facility maps and optimize routing schedules.

4.2.3. Coordination with Other Regulatory and Surveillance Activities

The inspection schedule shall be harmonized with other EFDA and RRB activities to avoid duplication and enhance efficiency. These include:

- Licensing and re-licensing (renewal) operations;
- Post-market surveillance investigations;
- Pharmacovigilance and adverse event response;
- Quality alerts, recalls, and enforcement actions;
- Narcotics and controlled substances monitoring.

4.2.4. Buffer Allocation for Emergency and Unannounced Inspections

To maintain flexibility and responsiveness, a dedicated portion of inspection resources such as personnel, budget, and scheduling slots shall be reserved for:

- Emergency inspections (e.g., during product-related outbreaks or disasters);
- Triggered inspections (e.g., complaints, enforcement cases, falsified products);
- Follow-up inspections requiring expedited verification of CAPAs.

These inspections are to be authorized on a case-by-case basis by the Head of inspection unit or responsible body and integrated into the AIP as “buffer” or “on-demand” allocations.

4.2.5. Use of eRIS and Digital Systems for Scheduling and Monitoring

The AIP might be integrated into eRIS or other approved inspection management platforms. These systems shall be used for:

- Tracking inspection due dates and completion status;
- Assigning inspectors and logging outcomes;
- Generating alerts for overdue inspections;
- Visualizing inspection coverage and performance metrics.

Digitalization enhances transparency, accountability, and evidence-based planning. All updates, adjustments, and approvals related to the AIP shall be time-stamped, version-controlled, and retained in accordance with data governance policy.

4.3. Planning for Non-Routine and Triggered Inspections

Not all inspections follow the annual schedule. Certain circumstances require immediate, follow-up, or event-triggered inspections outside the regular risk-based plan. EFDA and RRBs shall ensure these inspections are conducted with due diligence, legal authorization, and clear documentation to uphold public health protection and regulatory responsiveness.

4.3.1. Follow-Up Inspections

Follow-up inspections are conducted to verify the implementation and effectiveness of CAPAs after significant deficiencies or violations identified in prior inspections.

Procedures and Standards:

- Focused strictly on the areas of non-compliance identified in the previous inspection.
- May be conducted by the same inspection team or other team.
- shall include a review of CAPA evidence, implementation timelines, and root cause mitigation.

Follow-up inspections do not substitute routine inspections and shall be recorded and classified separately.

4.3.2. Special Inspections (Product-, Process-, or Event-Triggered)

Special inspections are initiated in response to validated triggers that indicate potential regulatory or product safety risks. These may be unannounced or scheduled on short notice.

Triggers include:

- Receipt of credible complaints from patients, health workers, or whistleblowers;
- Suspicion or detection of falsified, substandard, expired, unregistered, or recalled products;
- Adverse drug event reports linked to the facility;
- Sudden changes in operations (e.g., relocation, ownership, facility modification, product type, staffing);
- Observations from market surveillance, customs interception, or enforcement bodies.

These inspections may cover specific products, processes or events (e.g., fire, flood, theft, diversion).

4.3.3. Investigative and Emergency Inspections

These inspections are conducted urgently to prevent or respond to public health threats, criminal activity, or regulatory sabotage.

Scenarios include:

- Reports of unauthorized sale or distribution of narcotics or psychotropics;
- Diversion of medicines including controlled substances or antimicrobials;
- Ongoing criminal investigation or regulatory obstruction;
- Product quality defect or adverse event investigations
- Product tampering, falsification activity, or cross-border violations;
- Natural disasters or facility emergencies affecting product safety.

These inspections are typically unannounced and may involve multiple regulatory agencies or law enforcement partners.

4.3.4. Authorization and Oversight for Unannounced Inspections

All non-routine inspections shall be formally authorized. Authorization shall be issued by the Head of the inspection unit or responsible body, using a Standard Inspection Order, which shall contain:

- Facility name and exact location;
- Nature of the trigger or justification;
- Names of authorized inspectors and team lead;
- Scope of inspection (product, process, or entire operation);
- Applicable regulatory provisions enabling the action.

Inspectors shall carry their ID and other required materials used for the inspection. Refusal of entry, obstruction, or tampering with evidence during such inspections shall trigger immediate legal and regulatory consequences.

4.3.5. Stakeholder Communication and Notification Flexibility

While follow-up inspections may be notified in advance, triggered, special, and emergency inspections are conducted without prior notice. However, inspectors shall maintain professionalism, safety, and confidentiality.

Post-inspection, EFDA and RRBs shall notify the facility of findings, CAPA expectations, and regulatory implications through official channels. Public disclosure or enforcement decisions shall follow internal communication protocols and national legal standards.

4.4. Inspection Plan and Checklist Preparation

A well-defined inspection plan and standardized checklist are essential tools for ensuring consistent and risk-based inspections across all inspectees. The inspection plan is a formal, pre-approved document that outlines the operational, technical, and procedural framework for each inspection. It ensures that inspections are objective, targeted, and aligned with both national priorities and the facility's specific risk profile.

The plan shall identify the facility by its official name, and location, and specify the type of business whether importer, wholesaler, or community pharmacy (pharmacy or drug shop). The type of inspection (routine, follow-up, special, or investigative) shall be stated, along with specific objectives such as verifying CAPA implementation, investigating a complaint, or assessing cold chain compliance.

Each actual inspection plan shall include the full composition of the inspection team. This comprises the assigned lead inspector and inspectors depending on the facility's complexity and risk focus. Roles, responsibilities, and reporting lines shall be clearly defined. All team members shall be vetted for actual or potential conflicts of interest, and declarations shall be completed and archived before deployment.

Logistical arrangements shall be finalized prior to deployment. This includes the inspection dates, expected duration, route planning, and equipment to be carried (such as temperature monitoring tools and sampling kits). Facility zones to be inspected such as receiving areas, cold rooms, quarantines, and waste disposal sites shall be pre-identified. Likewise, system-based focus areas such as inventory management,

storage, supplier qualification, adverse event reporting, staff training and documentation shall be clearly prioritized, especially where past deficiencies or unresolved risks exist.

Every inspection shall be guided by a structured checklist designed to ensure completeness, objectivity, and regulatory alignment. Checklists shall be developed in accordance with national laws, standards and guidelines. Checklists shall be adapted for the specific type, scale, and complexity of each facility.

Each checklist shall cover all essential domains, including: physical premises and layout, temperature and humidity control, documentation systems, transport and cold chain logistics, product traceability, personnel qualifications, supplier and customer verification, and waste management. Observations shall be entered digitally where feasible or on approved paper-based formats.

Checklist templates shall undergo when required and approved by the responsible body . Any updates due to changes in legal frameworks, changes in product classifications, regulatory requirements, or risk prioritization shall be incorporated, version-controlled, and disseminated to all inspection teams. Only the most current version shall be used during field inspections.

Filled checklists shall be securely archived and linked to each facility's risk history and inspection file. These tools serve not only to guide the inspection but also to inform enforcement actions, CAPA follow-up, and regulatory analytics. Their consistent use is mandatory for quality assurance and institutional learning.

4.5. Inspection Notification and Confidentiality Safeguards

In principle**,** inspections shall be conducted in an unannounced manner. When required, inspection notification might be provided to serve to formally alert a facility of an upcoming inspection, ensuring procedural transparency and allowing for appropriate readiness while preserving regulatory integrity. All inspection notifications might be issued in written or call format, either via official letter, email, call or through the eRIS, where applicable. Notifications should be issued a minimum of three (3) calendar days in advance, with flexibility applied only under exceptional circumstances in accordance with EFDA or RRB procedures.

Confidentiality shall be observed throughout the inspection process. Inspectors are strictly prohibited from disclosing inspection schedules to unauthorized individuals, even to the inspectee unless required. Likewise, facilities are required to treat all inspection correspondence as confidential and avoid selective

preparation practices. Breaches of confidentiality by any party may result in disciplinary action or regulatory penalties.

4.6. Review of Previous Inspection Reports and Risk History

Prior to each scheduled inspection, the inspection in coordination by the lead inspector shall conduct a structured review of the facility's historical regulatory performance. This process ensures continuity, facilitates risk-based targeting, and enables the inspection to focus on known deficiencies or recurring issues.

The review shall include the most recent inspection report, submitted CAPA plans, implementation evidence, and any documentation from interim or follow-up visits. Additional sources of information include official correspondence (e.g., administrative measures), the facility's current risk classification, records of product quality complaints, alerts, or post-market surveillance findings. Where applicable, changes in facility ownership, location, modifications, professionals, or scope of operation since the last inspection shall be identified and evaluated for regulatory impact.

The lead inspector is responsible for retrieving these documents using the eRIS or approved record repositories. A Pre-Inspection Summary Sheet might be completed for each facility, summarizing:

- Date and type of last inspection,
- Key deficiencies identified,
- CAPA implementation status,
- Current risk level, and
- Any enforcement history or special considerations.

Particular attention shall be given to facilities with critical or recurrent major deficiencies, missed CAPA deadlines, or ongoing regulatory actions. These facilities shall be flagged for enhanced scrutiny, and additional inspection time may be allocated accordingly.

The full set of historical documents including inspection reports, CAPA records, and the summary sheet shall be included in the inspection documents and used to inform inspection focus, checklist customization, and field strategy. Previously identified deficiencies shall be revisited during the inspection, with updated classifications and documented follow-up actions.

4.7. Pre-Inspection Team Briefing

Prior to conducting any inspection, the lead inspector shall convene a structured team briefing to ensure alignment on the scope, objectives, roles, and procedural expectations of the inspection. This step is essential for enhancing team coordination, ensuring consistency in approach, and reinforcing the integrity and professionalism of the regulatory process. The briefing should take place at least one working day before the scheduled inspection or immediately prior to deployment in the case of field visits requiring travel.

The primary objectives of the pre-inspection team briefing are to:

- Align all team members on the purpose, scope, and risk profile of the facility;
- Review the facility's regulatory history, including previous deficiencies, CAPA outcomes, and unresolved issues;
- Clarify assigned roles and responsibilities among the inspectors;
- Confirm the procedural framework, confidentiality requirements, and observation documentation standards;
- Identify logistical, safety, or ethical considerations specific to the planned inspection;
- Reconfirm internal timelines, communication protocols, and reporting arrangements during the inspection.

The lead inspector is responsible for preparing and circulating the approved inspection plan, facility risk profile, checklist templates, and key regulatory references. A summary of prior inspection findings, CAPA implementation status, and known high-risk areas should be reviewed collectively. Based on the inspection's complexity and scope, the Lead Inspector shall allocate inspection domains such as cold chain storage, documentation, personnel records, or supplier qualification to the respective inspectors.

Where applicable, technical specialists or co-inspectors may be assigned to support specific aspects of the inspection such as observation recording, sampling, or environmental monitoring. All team members shall confirm their understanding of their assigned responsibilities and be briefed on the tools or documentation formats to be used, including digital platforms or manual records.

Any known conflicts of interest shall be declared before deployment. A signed Conflict of Interest Declaration shall be collected from each inspector and filed. Inspectors are also reminded of their legal

and ethical obligations to maintain strict confidentiality concerning all facility data, documents, and verbal disclosures encountered during the inspection.

If the inspection involves travel to remote, high-risk, or security-sensitive areas, the briefing shall also cover contingency planning, transport logistics, PPE requirements, and emergency communication procedures.

In facilities with a history of unresolved major deficiencies, recent complaints, or prior enforcement actions, the team shall prioritize these areas for close scrutiny. Any such priorities shall be explicitly noted in the internal briefing records and referenced in the opening meeting agenda with the facility.

The pre-inspection team briefing shall conclude with agreement on internal communication methods, including how to handle divergent observations, internal verification steps, observation classification, and the conduct of the team debriefing prior to the exit meeting. This ensures that the inspection is conducted in a cohesive, efficient, and well-documented manner, in accordance with EFDA regulatory standards.

4.8. Final Readiness and Deployment Preparation

Final preparation before initiating an inspection is essential to ensure operational effectiveness, safety, and procedural integrity. This stage involves verifying that all regulatory, logistical, technical, and ethical requirements have been met, and that the inspection team is fully equipped and coordinated to conduct the inspection.

4.8.1. Documentation Review and Availability

Before departure, the lead inspector shall confirm that the full set of inspection documentation is complete, up-to-date, and available to all team members. The essential documents include:

- Approved inspection plan tailored to the facility type and risk classification;
- Inspection checklist;
- Most recent inspection reports, including prior findings and documented CAPAs;
- CAPA follow-up status or verification reports;
- Current risk classification profile and its justification;
- Relevant regulatory references, guidelines, and product-specific standards;
- Internal memos, complaint reports, alerts, or any surveillance intelligence regarding the facility, if available.

4.8.2. Confirmation of Team Preparedness

The lead inspector is responsible for verifying that the inspection team is fully prepared. This includes:

- Final assignment of inspection roles and responsibilities, documented on a team assignment form;
- Signed COI declarations submitted and filed for all inspectors;
- Full briefing on inspection scope, historical findings, risk focus areas, and procedural expectations;
- Alignment on internal communication protocols, documentation standards, and debriefing arrangements;
- Verification that all required tools, equipment, and documentation have been distributed and are in working condition.

If the inspection involves field deployment to remote or high-risk areas, a final safety and contingency briefing shall also be held.

4.8.3. Inspection Tools and Equipment

Each inspection team shall be equipped with the necessary tools and materials to carry out the inspection professionally and efficiently. The following shall be checked and prepared prior to departure:

- Official identification badges for each inspector;
- Printed or digital versions of inspection checklists and regulatory references;
- Sampling kits, tamper-proof labels, and chain-of-custody forms, where applicable;
- Temperature monitoring devices and other devices, where applicable. ;
- Personal protective equipment (PPE), including masks, gloves, coats, and shoe covers, as applicable;
- Laptops or tablets pre-loaded with digital inspection tools, if electronic reporting is used;
- Stationery supplies, including notebooks, pens, adhesive labels, and stamps, where required;
- Mobile phones or radios for team coordination and communication, where required.

All digital devices shall be tested, fully charged, and backed up with paper versions where needed. For inspections involving enforcement, chain-of-custody forms shall be printed and securely stored.

4.8.4. Logistical and Administrative Arrangements

When required, the lead inspector shall verify that all logistical arrangements for deployment have been finalized, including:

- Transport schedules and vehicle confirmations;
- Security clearances for restricted areas, where required;
- Per diem payments and financial clearance in line with government procedures;
- GPS coordinates or maps for facilities located in hard-to-reach areas;
- Contact details of the facility, drivers, or regional coordinators.

5. Conducting the Inspection

5.1. Opening Meeting

At the commencement of each inspection, an opening meeting shall be conducted between the inspection team and designated representatives of the facility. This meeting formally initiates the inspection process and establishes shared understanding, transparency, and cooperation.

The lead inspector shall introduce the inspection team, present official identification, and confirm the regulatory mandate, legal basis, and scope of the inspection. The objectives, duration, and focus areas of the inspection shall be outlined, including applicable national standards and relevant procedural frameworks.

Where applicable, introduce the pre-defined inspection plan, covering the inspection schedule, areas to be inspected, and expected timelines. The methodology to be employed including observation, document review, interviews, sample collection, and vertical or backward tracking shall be briefly explained. The inspectors shall also clarify how inspection findings will be recorded, categorized, and communicated throughout the process.

The facility’s representatives shall be invited to raise any initial concerns, propose arrangements, or identify operational constraints. Communication protocols shall be agreed upon, including designated points of contact, procedures for submitting additional documentation, daily feedback (if planned), and mechanisms for responding to information requests.

During the meeting, inspectors shall also outline expectations regarding access to facilities, personnel, documents, and restricted areas. Confidentiality and data protection commitments shall be reaffirmed.

The roles and responsibilities of facility staff during the inspection shall be clarified to avoid interference with normal operations.

All discussions during the opening meeting shall be conducted professionally and documented by the inspection team. A brief summary of the meeting, including participants and main points discussed, may be incorporated into the final inspection report as evidence of procedural compliance. Where appropriate, a signature or acknowledgment log may be maintained.

5.2. Conducting the Inspection

Once the inspection has commenced at the facility, the inspection team shall conduct a structured walkthrough of the premises, operations, documentation, and personnel practices, follow the predefined inspection plan while adapting as needed based on onsite realities. The inspection process shall begin with general observation and progressively narrow its focus to specific operational areas, procedures, and records.

Inspectors are expected to observe facility practices under normal operating conditions without disrupting workflow. Observation provides critical insight into the daily functioning of the premises and helps assess actual practices against documented procedures. While observing, inspectors shall pose relevant questions to staff in real time, using open-ended inquiries to elicit explanations, clarify observations, and assess knowledge and adherence to procedures. Closed questions should be avoided unless used for verification.

The following principal tracing methods are used to structure the inspection:

1. **Forward Tracing:** Begins at the goods inward or initial entry points and follows the product or documentation flow logically through the system to its endpoint, such as the dispatch area. This helps assess the continuity of physical systems and logistics.
2. **Backward Tracing:** Starts from a selected finished product or batch at the storage or dispensing area and traces its history backward through procurement, storage, and documentation. It verifies traceability and compliance based on records.
3. **Random Tracing:** Selects operational points of interest based on inspector judgment such as staff behaviors, high-risk zones, or customer service points and examines their integration within the broader system. This method is flexible but best suited for experienced inspectors.

4. **Vertical Tracking (Vertical Inspection):** Involves following a specific activity or process from initiation to conclusion, while simultaneously examining all associated records, staff actions, and physical components at each stage. This method is particularly effective for evaluating cross-functional compliance and identifying systemic weaknesses not visible through isolated observation.

Inspectors shall remain vigilant for any irregularities, inconsistencies, or deviations from documented procedures or national standards. When a potential deficiency is identified, the inspector shall "dig deeper" to determine its extent, recurrence, and impact. This includes cross-referencing records, inspecting associated equipment or storage areas, and interviewing multiple personnel involved in the activity. Inspectors shall avoid making assumptions based solely on verbal responses or appearances; all findings must be supported by verifiable evidence.

The choice of tracing method or inspection pathway shall depend on the inspection objectives, prior findings, facility risk classification, and inspector discretion. The inspection team should conduct periodic internal debriefings to review preliminary findings, recalibrate focus areas, and reassign responsibilities as necessary. These internal reviews must not delay inspection progress or interfere with facility operations.

Throughout the process, inspectors are expected to conduct themselves with professionalism, integrity, and neutrality. The inspection shall be systematic, transparent, and evidence-driven, with every observation accurately recorded in preparation for the final report and closing meeting.

5.3. Note Taking and Documentation of Observations

Effective inspection practice relies heavily on accurate, contemporaneous, and well-organized note-taking. Inspectors are expected to consistently record detailed factual information about the facility's conditions, practices, documents, and personnel responses throughout the inspection. These notes serve not only as personal memory aids but as the foundation for objective decision-making, formal reporting, and regulatory actions. Every observation that informs a finding or conclusion must be supported by verifiable evidence and documentation captured during the inspection.

Inspectors shall develop and maintain their own efficient note-taking methods that prioritize clarity, specificity, and traceability. Notes must be recorded as observations occur whenever possible. In

scenarios where immediate documentation is impractical such as sensitive interviews, restricted zones, or dynamic operational settings inspectors should rely on mental recall and document their findings promptly thereafter. The completeness and accuracy of these notes must be validated by the end of each day if the inspection needs more than one day, ensuring no relevant observation is left undocumented.

All recorded information must reflect facts directly observed or verified rather than what the facility claims should happen. Inspectors must not rely on general impressions, vague language, or undocumented assumptions. Credibility can be seriously compromised if errors or exaggerations appear in the documentation, particularly when challenged by facility management or during enforcement proceedings. For this reason, it is essential to verify details such as dates, approvals, equipment status, personnel roles, and system functions with supporting records or observations.

Inspectors may adopt a variety of recording formats depending on personal preference and situational needs. Some may choose to maintain structured rough notes that are later refined; others may use inspection checklists to systematically ensure all required areas are covered. While checklists can be especially useful for less experienced inspectors, they should be used with flexibility to allow in-depth exploration and not become a substitute for critical observation. Flow diagrams may be used to represent processes observed, identify system gaps, or map how different functions interrelate. Visual tools such as still photography or video may also be employed, provided prior permission is obtained from the facility. The use of recording equipment must be non-disruptive, discreet, and respectful of privacy and confidentiality norms.

The documentation approach chosen should never obstruct open communication or make staff uncomfortable. For example, while audio or video recordings may provide accurate visual or verbal records, their intrusive nature can inhibit honest responses. The aim is to collect comprehensive, actionable, and objective information without compromising cooperation or professional decorum.

In team-based inspections, time must be allocated before the closing meeting for inspectors to consolidate findings. Each team member must cross-check observations, clarify inconsistencies, and align positions on compliance determinations. This is particularly important when team members have inspected different parts of the facility concurrently. Discrepancies or fragmented observations must be reconciled to support a unified and coherent inspection report.

All notes and records must be handled securely, stored according to institutional policy, and remain accessible for audit trails, appeals, or enforcement reviews. They are the legal and professional backbone of the inspection process and must be treated with the same level of rigor and integrity expected of the inspection report itself.

5.4. Interviewing, Document Review, and Evidence Collection

As the inspection progresses, the inspector shall utilize multiple information-gathering methods to ensure assessment of the facility's operations and compliance. Among these, structured interviews, systematic document reviews, and careful evidence collection are the foundation of evidence-based inspection practice. These activities are conducted in tandem with direct observation and note-taking, and should align with the inspection objectives, scope, and established criteria.

Interviewing is a critical technique that complements observation and document review by enabling inspectors to understand processes in context and validate operational practices through personnel insights. Interviews shall be conducted with individuals who are directly responsible for the activities or systems under inspection, including operators, supervisors, and managers. Inspectors shall ensure that they engage the right personnel to obtain accurate and relevant information, minimizing confusion or misrepresentation. Interviews are to be conducted respectfully, during normal working hours, and ideally at the employee's regular place of duty. Inspectors should explain the purpose of the interview, clarify that notes will be taken, and seek to create a setting where interviewees can respond freely and without undue pressure. Open-ended questions are preferred, and the same question may be rephrased or asked of different staff to triangulate responses and verify consistency. Leading questions that may bias the response must be avoided. When necessary, interview summaries should be reviewed with the interviewee to ensure clarity and prevent misinterpretation. Inspectors shall thank the interviewee for their cooperation and document the interaction as part of the inspection record.

In parallel with interviews, inspectors shall conduct a thorough review of relevant documentation to determine whether documented systems, policies, and records are consistent with actual practices and regulatory expectations. Prior to the on-site visit, a preliminary review of key documentation such as previous inspection reports, SOPs, regulatory submissions, and facility-specific permits may be conducted to inform inspection focus areas. However, most document review will take place on-site, guided by the actual conditions encountered during inspection. Documentation reviewed may include

manuals or procedures, receiving records, invoices, environmental monitoring logs, temperature records, staff files, training records, equipment maintenance logs, inventory reports, and other operational records. The inspector should adjust the depth and focus of review based on the facility's complexity, risk classification, and the findings observed.

Sampling is a necessary part of both document and physical inspection. It enables the inspector to draw reliable conclusions from a manageable subset of data or processes. Random sampling may be used to assess the general quality of record keeping or operational consistency, while targeted sampling may be employed when a specific concern arises. For example, if a temperature deviation is observed in a storage area, inspectors may sample all temperature logs over the past month and correlate these with equipment calibration records and complaint reports. One-time or isolated samples are rarely sufficient to form valid conclusions; multiple samples over a defined period are recommended to detect trends or recurring issues.

Evidence gathered during the inspection must meet the standards of objectivity, relevance, and verifiability. Evidence may be derived from observations, interviews, documents, samples, or physical artifacts. It must be recorded in a consistent and structured manner. Inspectors should avoid relying solely on verbal claims or undocumented explanations, and must ensure that all findings are backed by factual, traceable sources. Only information that can be verified may be considered inspection evidence. This evidence is then assessed against inspection criteria such as national regulatory requirements, licensing requirements, and operational procedures to produce inspection findings. Findings may indicate conformity or nonconformity, or they may identify opportunities for improvement. In cases of nonconformity, the inspector shall record the evidence and ensure that the facility representative understands and acknowledges the concern. Diverging interpretations or disputes should be respectfully addressed, and unresolved points should be clearly documented in the inspection record.

Throughout the inspection, the team may hold internal discussions to consolidate emerging findings, evaluate consistency of observations, and determine whether additional interviews, documents, or sampling are needed. These reviews do not disrupt facility operations and are not substitutes for the formal closing meeting. Instead, they serve to refine the inspectors' understanding and strengthen the quality of conclusions drawn. All collected evidence shall be treated with confidentiality and integrity, and retained securely for inclusion in the inspection report and any required follow-up actions.

5.3. Closing Meeting

The closing meeting marks the formal conclusion of the inspection process and shall be conducted before the inspection team departs from the facility. This meeting is chaired by the lead inspector and is held with the appropriate representatives of the inspected facility. Its primary purpose is to communicate the preliminary inspection findings in a clear, structured, and respectful manner, ensuring that the inspectee fully understands and acknowledges the outcomes before the formal report is issued.

The closing meeting serves two key objectives. First, it provides an opportunity for the facility management to receive immediate feedback and learn directly from the inspection team's observations. This enables the facility to begin reflecting on areas of concern, good practices, and potential improvements. Second, the meeting ensures transparency and avoids surprises in the final inspection report. All significant findings whether positive or negative are openly discussed and clarified to prevent misinterpretation or future disputes.

The inspector shall begin the meeting by thanking the facility for its cooperation during the inspection. The main findings shall be presented or communicated, including any instances of non-compliance, best practices observed, and other noteworthy issues. Each finding shall be explained with reference to the applicable regulatory standard or requirement, accompanied by factual evidence obtained during the inspection. Where appropriate, findings may be categorized into critical, major, or minor observations, with emphasis on their potential impact on public health and regulatory compliance.

Participants in the closing meeting may include the inspectee's owner(s), technical leads, and relevant operational representatives. The inspection team shall use the closing meeting to agree, where applicable, on next steps regarding the submission of CAPA, expected timelines for compliance, and any conditions for follow-up inspections. Inspectors shall clearly explain that the presented findings are preliminary and subject to further internal review prior to finalization in the written inspection report.

All discussions during the closing meeting shall be professional, constructive, and solution-focused. Inspectors must refrain from providing consultancy, personal opinions, or promises regarding licensing or enforcement outcomes. The focus shall remain on factual findings, regulatory alignment, and the path toward corrective action. The meeting should conclude with appreciation for the inspectee's collaboration, and a clear explanation of when and how the final inspection report will be issued.

6. Key Inspection Areas

6.1. Import and wholesale

6.1.1. Premises and Equipment

6.1.1.1. Make visual observations, review documentation, conduct interviews, listen, take notes, and if required take samples.

6.1.1.2. Ensure the premises are suitably located, designed, constructed and maintained, to ensure appropriate operations such as cleaning, receiving, storage, picking, packing, inventory, inspection, and dispatch of medical products.

6.1.1.3. Verify that the premises and equipment are kept clean, good housekeeping is applied and cleaning agents are not possible sources of contamination.

6.1.1.4. Check the efficiency of security provided and access controlling including presence of clear instruction signs on doors to restricted areas.

6.1.1.5. Verify orderly placement and logical positioning of equipment and materials to prevent mix-ups and contamination, especially for open non-contained systems.

6.1.1.6. Check the existence of separate receiving and dispatch bays, to avoid mix-ups and contamination. The bays should protect products from weather conditions.

6.1.1.7. Verify the appropriateness of controls and segregation provided for different types of products requiring specific handling or storage conditions, such as radioactive, products containing hazardous substances, and products to be stored under controlled temperature and relative humidity

6.1.1.8. Confirm that the premises are protected from the entry of birds, rodents, insects and other animals. Check the availability of rodents and pest control systems in place.

6.1.1.9. Check the separation of toilets and washing facilities from areas where products are handled. Eating, drinking and smoking should be prohibited in all areas where medical products are stored or handled.

6.1.1.10. Verify that adequate space, lighting and ventilation is available to ensure proper segregation, storage conditions and cleaning.

6.1.1.11. Verify that storage areas are maintained within the required temperature and humidity limits, and check air condition monitoring records. Where the labels show special storage conditions are required (e.g. temperature, relative humidity), there should be a system in place to provide, control, monitor, and record the temperature and humidity

6.1.1.12. Confirm that medical products are stored off the floor, away from walls and ceilings, protected from direct sunlight, and suitably spaced to permit ventilation, cleaning and inspection.

6.1.1.13. Verify the availability of Standard Operating Procedures (SOPs) and a documented sanitation program that specifies the cleaning frequency and the methods used for cleaning the premises and storage areas

6.1.1.14. Confirm that the medical products are handled and stored in such a manner as to prevent contamination, cross-contamination and mix-ups

6.1.1.15. Ensure that medical products are stored in such conditions that assure the quality and stock are appropriately rotated following the “first expired-first out” (FEFO) principle.

6.1.1.16. Check narcotic drugs and psychotropic substances are stored in compliance with international conventions, national laws and regulations on narcotics drugs and psychotropic substances.

6.1.1.17. Verify that floors and walls are smooth and easy to clean, that corners are seamless, and that ceilings and fittings are designed to prevent the accumulation of dust and dirt

6.1.1.18. Ensure that operating areas have adequate size to prevent contamination or mix-ups.

6.1.1.19. Ensure that damaged items are removed from usable stock and stored separately.

6.1.1.20. Verify that equipment have appropriate design, adequate size, and suitable location to facilitate intended operations, cleaning, sanitation (if needed), and maintenance.

6.1.1.21. Verify that equipment surfaces in contact with product shall not be reactive, additive, or absorptive or alter quality, identity, purity, safety, or strength of medical products beyond official or other established specifications.

6.1.1.22. Review the required documents associated with importers or wholesalers available in eRIS before conducting inspection; confirm availability and adequacy of equipment; review SOPs, calibration records, and other relevant records.

6.1.1.23. SOPs for cleaning, sanitation, and maintenance of equipment are followed.

6.1.1.24. Review records for maintenance, inspection, and calibration (if needed) for automatic, mechanical, and electronic equipment.

6.1.1.25. If computerized systems are used by the importer or wholesaler, verify that the system is capable of delivering the intended outputs and results effectively.

6.1.1.26. Where the importer or wholesalers utilize electronic commerce (e-commerce), confirm that the facility defines procedures and have adequate systems in place to ensure traceability and confidence in the supply chain and products concerned.

6.1.1.27. Verify that the procedure for use of electronic transactions relating to the distribution of medical products specify the system is performed only by authorized persons with defined access privileges.

6.1.1.28. Ensure that all equipment used by inspectors is properly calibrated.

6.1.2. Personnel and Training

6.1.2.1. Inspectors should have appropriate educational qualification, experience and training relative to the scope of inspection activities undertaken.

6.1.2.2. Inspectors shall be appointed by the Authority. The inspectors shall have the qualifications necessary to effectively take part in the inspection of medicine distribution channels of the country. This includes inspection of importers and wholesalers. These qualifications shall be based on the following;

- Academic education
- Essential Skills
- Training
- Work experience

6.1.2.3. Depending on the staff composition of EFDA branch offices and regional regulatory bodies, professionals from various fields may be involved in the inspection of importers and wholesalers. However, each inspection team shall include at least one pharmacy professional to ensure the necessary technical expertise. However, the inspection team should have at least one pharmacy professional. Inspectors should possess a comprehensive understanding of national pharmaceutical laws, regulations, directives, and guidelines. In addition, they should be well-versed in relevant international standards, including those established by the World Health Organization (WHO) and the Pharmaceutical Inspection Co-operation Scheme (PIC/S)

6.1.2.4. Inspectors should have an understanding of the health system of the country, national medicines supply chain system, and risk assessment principles. Inspectors from regional regulatory bodies may be used as part of inspection teams when it is deemed necessary during the inspection of importers and wholesalers and these inspectors should sign declarations for conflict of interest and confidentiality agreement.

6.1.2.5. Inspectors shall receive continuous inspection training to gain the knowledge and skills required for planning, preparation, conducting, reporting inspections and follow-up. Apart from basic training, inspectors shall be required to undergo on-the-job training by senior inspector(s). Such training shall involve both theory and practice of inspections and will cover inspection techniques, communication and management skills, and conducting of inspections and writing reports. Those can be obtained through training programs, seminars, scientific meetings, conferences, and exhibitions organized by either the regulatory body or other national and international organizations

6.1.2.6. Inspectors should receive initial and continued training in accordance with a written training programme. The training should cover the requirements of GDP, GSP, recall procedures, product security, product identification and detection of falsified and substandard products, and supply chain integrity.

6.1.2.7. Records of training, attendance, and assessments should be maintained.

6.1.2.8. Inspectors shall demonstrate competence in planning and preparation for inspection, conducting inspection, communication and report writing. This experience will be considered when planning and assigning inspectors for supply chain inspections.

6.1.3. Storage and handling of medicines products

6.1.3.1. Inspectors should ensure that all medicines and health products in inventory are maintained in their original manufacturer’s packaging and comply with labelling requirements as stipulated by the EFDA or other recognized standards and guidelines.

6.1.3.2. Verify that products are stored in accordance with EFDA’s Good Storage Practice (GSP) Guidelines, which require keeping items off the floor and protecting them from heat, direct sunlight, moisture, dust, extreme temperatures, pests, and other sources of contamination.

6.1.3.3. Inspectors should confirm that damaged or expired medicines are recorded properly, are sealed and quarantined, are clearly labelled with the statement: "Expired/Damaged Medicines – Not for Sale"

6.1.3.4. Verified that expired and damaged products are disposed of under the supervision of EFDA, following the medicine waste disposal directives and guidelines issued by the Authority.

6.1.3.5. If the cold chain is part of the supply system, ensure its integrity should be maintained, and ensure continuous temperature logs and appropriate power backup systems consistently to maintain the required storage conditions.

6.1.3.6. Personnel

1. At each storage site (e.g. importer, wholesaler), there should be an adequate number of qualified personnel to achieve pharmaceutical quality assurance objectives.
2. Verify that personnel have received proper training in relation to good storage practice, regulations, procedures and safety.
3. Verify that all staff have high levels of personal hygiene and sanitation.
4. Personnel working in storage areas should wear suitable PPE for the activities they perform.

6.1.3.7. Storage areas

1. Verify that precautions have been taken to prevent unauthorized persons from entering storage areas.
2. Verify that storage areas have sufficient capacity to allow the orderly and segregated storage of various categories of medicinal products, including those under quarantine, approved, rejected, returned (if applicable), or recalled.
3. Verify that there is segregation of different categories of products such as expired, quarantined, recalled, damaged
4. Verify that storage areas are designed and adapted to ensure good storage conditions. In particular, they should be clean and dry and maintained within acceptable temperature limits. Where special storage conditions are required on the label (e.g. temperature, relative humidity), these should be provided, checked, monitored and recorded.
5. Verify that pallets are maintained in a good state of cleanliness and repair condition.

6. Verify that storage areas are clean, and free from accumulated waste and vermin. A written sanitation programme should be available indicating the frequency of cleaning and the methods to be used to clean the premises and storage areas.
7. A written pest control program shall be in place, using safe agents that pose no contamination risk to pharmaceutical products.
8. Verify that appropriate procedures are in place for the clean-up of any spillage to ensure complete removal of any risk of contamination.
9. Confirm that quarantine, rejected, expired, recalled or returned products storage areas are clearly marked and access restricted to authorized personnel.
10. Confirm that any system replacing physical segregations like validated (e.g. electronic system) have equivalent security. For example, computerized systems can be used, provided that they are validated to demonstrate security of access.
11. Verify that products are stored in identifiable areas.
12. Ensure that hazardous, sensitive, and high-risk pharmaceutical products (e.g., narcotics, radioactive materials, flammable or pressurized substances) are stored in dedicated areas with appropriate safety and security measures
13. Verify that the first expired/first out‖ (FEFO) principle and first-in-first-out (FIFO) principle are in place
14. Verify that storage areas are provided with adequate lighting and ventilation to enable all operations to be carried out accurately and safely.
15. Verify that periodic physical inventory is conducted in the warehouse to ensure alignment between recorded and actual stock levels, and to maintain inventory accuracy and accountability.

6.1.3.8. Storage conditions

1. Confirm that the storage conditions for pharmaceutical products are in compliance with the labelling, which is based on the results of stability testing.

6.1.3.9. Monitoring of storage conditions

1. Review the available recorded temperature monitoring data.
2. Check the equipment used for monitoring at suitable predetermined intervals and the results of such checks are recorded and retained.

3. Confirm that monitoring records are kept for at least the shelf-life of the stored product plus 1 year, or as required by national legislation.
4. Verify that the temperature mapping was done across the storage facility. It is recommended that temperature monitors be located in areas that are most likely to show fluctuations.
5. Confirm that equipment used for monitoring is calibrated at defined intervals.

6.1.3.10. Identify risks affecting product quality

1. Inspectors should ensure that risks to product quality are clearly identified and appropriate mitigation measures are proposed for each identified risk.
2. Inspectors should evaluate the effectiveness of risk mitigation measures taken by the institution

6.1.3.11. Documentation

1. Verify written instructions and records are available which document all activities in the storage areas including the handling of expired stock and product recall.
2. Check the accuracy of inventory records in storage areas and ensure such records are up-to-date, and readily accessible to ensure proper stock management and traceability of medicinal products.
3. Verify that maintaining records for each delivery. The record shall include the description of the goods, quality, quantity, supplier, supplier's batch number, the date of receipt, assigned batch number and the expiry date.
4. Ensure that Standard Operating Procedures (SOPs) for the receiving, storage, distribution, disposal, and dispensing of medicinal products are documented, approved, implemented, and regularly reviewed to ensure compliance with regulatory and quality requirements
5. Ensure that all records shall be readily accessible and available upon request.

6.1.4. Dispatch and Transport

6.1.4.1. Verify that pharmaceutical products are transported in a manner that ensures the integrity of the products is maintained throughout the supply chain as per the required storage conditions, such as temperature and humidity, are consistently preserved during transit.

6.1.4.2. Ensure that special care is exercised when using dry ice in cold chains. In addition, observing safety precautions, it shall be ensured that the product does not come into contact with dry ice, as this may adversely affect the product quality, e.g. by freezing.

6.1.4.3. Ensure temperature monitoring records are maintained and made available for review.

6.1.4.4. Ensure that dispatch and transport of pharmaceutical products are carried out only after receipt of a delivery order.

6.1.4.5. Ensure that dispatch procedures are established and documented, taking into account the nature of pharmaceutical products concerned and any special precautions that might be required.

6.1.4.6. Verify that the outside container offers adequate protection from all external influences and should be indelibly and clearly labelled.

6.1.4.7. Verify the records for dispatch are retained, stating at least: the date of dispatch, the customer's name and address, the product description, e.g. name, dosage form and strength (if appropriate), batch number and quantify, the transport and storage conditions.

6.1.5. Supplier Qualification

6.1.5.1. The inspector should ensure that supplier requirements are addressed, including capacity to meet market demand, operational and financial viability, and supply chain risk management, communication of quality and regulatory compliance, and controls for product traceability.

6.1.5.2. Verify that supplier has appropriate systems in place to prevent the introduction of falsified, diverted, or counterfeited products into the supply chain during the procurement, storage, transportation, disposal of waste, and destruction activities

6.1.5.3. Review the initial and periodic official qualification assessments are planned, scheduled and conducted on the supplier's facilities.

6.1.5.4. The inspector should review the compile supplier qualification assessment findings and assign a rating for supplier suitability (e.g., approved, conditional, rejected).

6.1.5.5. Verify that all approved suppliers are added to the qualified supplier list (QSL).

6.1.5.6. Check that periodic review of supplier performance based on quality metrics, delivery, and complaint history is available

6.1.5.7. Ensure that there are requalification audits at defined intervals or triggered by major changes/events

6.1.5.8. Verify the qualification documents, audit reports, correspondence, and agreements are maintained and ensure accessibility for inspection and internal review.

6.1.6. Documentation and Record Keeping

6.1.6.1. Verify that documents are appropriately designed, completed, reviewed, authorized, distributed and kept as required. Ensure documents are readily available.

6.1.6.2. Ensure written instructions and records are maintained for all activities relating to the distribution of pharmaceutical products, including all applicable receipts and issues (invoices) shall be available. Make sure that distributors are kept records of all pharmaceutical products received. These records shall contain at least the following information:

- Date;
- Name of the pharmaceutical product,
- Batch number,
- Manufacturer's name.
- Quantity received, or supplied; and
- Name and address of the supplier.

6.1.6.3. Verify that the procedures are established and maintained for the preparation, review, approval, use of and control of changes to all documents relating to the distribution process.

6.1.6.4. Ensure the contents of documents are clear, accurate, legible, traceable, attributable and unambiguous. In particular, instructions and procedures relating to activity that may have an impact on quality of pharmaceutical products shall be designed, completed, reviewed and distributed with care.

6.1.6.5. Verify that the documentation shall be approved, signed and dated by appropriate authorized persons, as required. It shall not be hand-written; although, where documents require the entry of data, sufficient space shall be provided for such entries.

6.1.6.6. Ensure any alterations made in the documentation are signed and dated; the alteration shall permit the reading of the original information. Where appropriate, the reason for the alteration shall be recorded.

6.1.6.7. Make sure documents are reviewed regularly and kept up-to-date. When a document has been revised, a system shall exist to prevent inadvertent use of the superseded version.

6.1.6.8. Ensure all records are stored and retained using facilities that prevent unauthorized access, modification, damage, deterioration and/or loss of documentation during the entire life-cycle of the record. Records shall be readily retrievable. Documents shall be retained for a period of 1 year after expiry of the product.

6.1.6.9. Ensure the distributor establishes and maintains procedures for the identification, collection, indexing, retrieval, storage, maintenance, disposal of and access to all applicable documentation.

6.1.6.10. Ensure records are kept either in the form of purchase/sales invoices, delivery slips, or on computer or in any other form, for any transaction in pharmaceutical products received or supplied.

6.1.6.11. Make sure that records are made at the time each operation is taken and in such a way that all significant activities or events are traceable.

6.1.6.12. If electronic copies/data are stored, ensure validation of computers and database management systems is in place.

6.1.6.13. Ensure systems exist to allow for transfer of information, including quality or regulatory information, between a manufacturer and a customer, as well as the transfer of information to the relevant regulatory authority as required.

6.1.6.14. Ensure that records relating to the storage of pharmaceutical products are maintained and readily available, and that current national regulations concerning labels and containers are respected at all times.

6.1.6.15. Verify that procedures are in place for temperature mapping, security services to prevent theft or tampering with goods at the storage facilities, destruction of unsaleable or unusable stocks and on retention of the records.

6.1.6.16. Ensure that all records are readily retrievable, and be stored and retained using facilities that are safeguarded against unauthorized modification, damage, deterioration and/or loss of documentation.

6.1.6.17. Verify that backups are maintained to prevent any accidental data loss where the records are generated and kept in electronic form.

6.1.7. Compliant and Incident handling

6.1.7.1. Verify that Complaints are recorded with all the original details. A distinction should be made between complaints related to the quality of a medicinal product and those related to distribution.

6.1.7.2. In the event of a complaint about the quality of a medicinal product and a potential product defect, ensure that the manufacturer and/or marketing authorization holder are informed without delay.

6.1.7.3. Ensure that all product distribution complaints are thoroughly investigated to identify the origin of or reason for the complaint.

6.1.7.4. Confirm that a person is appointed to handle complaints and allocated sufficient support personnel. If necessary, ensure appropriate follow-up actions (including CAPA) are taken after investigation and evaluation of the complaint, including where required notification to the authority.

6.1.8. Quality management system

6.1.8.1. Verify importers and wholesalers maintain a quality system setting out responsibilities, processes and risk management principles in relation to their activities. ensure that all distribution activities are clearly defined and systematically reviewed. All critical steps of distribution processes and significant changes should be justified and where relevant validated. Check the active participation of the organization's management, their leadership and staff in the quality system and should be supported by staff commitment.

6.1.8.2. Ensure there is documented quality policy describing the overall intentions and requirements of distributors regarding quality, authorized by the management.

6.1.8.3. Verify that an appropriate organizational structure with defined responsibilities of the personnel recorded as job descriptions are maintained.

6.1.8.4. Ensure a responsible person is appointed by the management for each distribution site, who shall have defined authority and responsibility for ensuring that a quality system is implemented and maintained.

6.1.8.5. Ensure that Senior management are engaged in all parts of the quality system including allocation of adequate resources with competent personnel and suitable and sufficient premises, equipment and facilities.

6.1.8.6. Verify that the deviations from established procedures are documented and investigated.

6.1.8.7. Ensure that the corrective and preventive action (CAPA) are taken in order to correct deviations and prevent them.

6.1.8.8. Verify that the procedures for procurement and release are in place to ensure that appropriate pharmaceutical products are sourced only from approved suppliers and distributed by approved entities.

6.1.8.9. Ensure that inspection, auditing and certification of compliance with a quality system (such as the applicable ISO series, or national or international guidelines) by external bodies are recommended.

6.1.8.10. Verify that the procedure is in place to ensure a safe, transparent and secure distribution system which includes product traceability throughout the supply chain.

6.1.8.11. Ensure procedures are in place to ensure document traceability of products received and distributed, to facilitate product recall.

6.1.8.12. Ensure that parties involved in the supply chain are identifiable depending on type of product.

6.1.8.13. Ensure that measures are in place to ensure that pharmaceutical products have documentation that can be used to permit traceability of the products throughout distribution channels from the manufacturer/imported to the entity responsible for selling or supplying the product to the patient or his or her agent. Records including expiry dates and batch numbers shall be part of a secure distribution documentation enabling traceability

6.2. Community Pharmacy

6.2.1. Premises and Equipment

6.2.1.1. Design, Layout and Facilities

1. Check that the pharmacy is self-contained and secure, with a single designated entry and exit point
2. Check that the entrance to a premise is in good condition and clearly marked, and display the pharmacy’s name along with visible signage indicating operating hours.
3. Ensure the entrance is easily accessible to the public and in a location that supports effective service delivery.
4. Make sure that the pharmacy is located at a minimum distance of 100 metres from other community pharmacies and health facilities.
5. Check that both the external and the internal areas of the premises are well maintained and properly decorated, and that all fixtures and fittings meet acceptable standards.

6. Examine the construction quality to confirm it effectively prevents the entry of dust, direct sunlight, pests, moisture, and flooding. There should be no visible cracks, leaks, discoloration, or structural damage.
7. Check that the walls, floors, and ceilings are clean, undamaged, and constructed from smooth, washable, and impermeable materials.
8. Verify that the community pharmacy is clearly separated from any other business and ensure that the pharmacy is not located within residential buildings or in areas that may pose a risk to public safety.
9. Verify the availability of all essential rooms in a pharmacy, including a dispensing room (minimum 25 m^2), a storage room (minimum 16 m^2), a counseling room (minimum 4 m^2), an administrative office or changing room, a toilet equipped with a water supply, handwashing sink, and proper drainage, and, where applicable, a compounding room and a drug information center.
10. Ensure the presence of adequate lighting and ventilation and organized interior
11. Check that the dispensary is clearly identifiable with appropriate signage. Confirm that the placement of the medicines counter limits access to unauthorized individuals. The dispensing counter should have a smooth, impervious, and washable surface, and there should be sufficient space to accommodate the expected volume of activities.
12. Check that the layout allows the pharmacist to maintain patient confidentiality and provide adequate supervision over the sale and supply of medicinal products within the dispensary, at the medicines counter, and in the patient counselling area.
13. Ensure that the facility is accessible to persons with disabilities by verifying the presence of wide doorways and appropriately designed counters. Check that a ramp with a proper slope, handrails, and a non-slip surface is available. The entrance should be barrier-free access for persons with disabilities.
14. Check the waiting area is labeled and has chairs for customers
15. Check that the pharmacy shall have a designated patient consultation room with signage stating “counselling room,” designed to provide adequate privacy for the customer. Ensure the presence of visual and auditory privacy equipped with chairs and desks/tables, charts/posters and counseling records

6.2.1.2. Equipment and Materials

1. Ensure the community pharmacy is equipped with the essential tools and materials required to provide quality pharmaceutical services. Check the availability and working condition of:
    - Medicine shelves and cabinets
    - Functional refrigerator for cold chain items (2-8°C) with thermometer and twice-daily temperature records/logs
    - Calibrated thermometer for storage and dispensing rooms
    - Hygrometer for humidity monitoring
    - Lockable metal cabinet for narcotics and psychotropic substances
    - Fire extinguisher (functional, tagged, and checked within the last year), first aid kit (complete and accessible), tablet counter, computer, weighing scale, scientific calculator, tablet cutter, etc.
2. Check the presence of appropriate dispensing equipment such as tablet counters, dispensing containers (tablet vials, bottles, ointment jars, plastic bags/cardboard cartons), disposable plastic cups etc.
3. Check the presence of extemporaneous preparation equipment (if applicable) such as graduated cylinders, ointment slab, electronic balances, stainless steel beakers, mortars and pestle labels, spatulas, workbench and stirrers, etc.
4. Check equipment calibration and maintenance documentation.
5. Verify cleanliness and hygienic condition of all counters, shelves, and tools.
6. Ensure the community pharmacy holds required reference materials (such as Martindale, Standard treatment guidelines (STGs), National essential medicines List (NEML), etc.).
7. Hazardous and high-risk items (e.g., narcotics, chemo drugs) kept in secure and restricted areas.

6.2.2. Personnel, training, and Documentation

6.2.2.1. Staffing, and Professional Qualifications

1. Confirm that the pharmacy is led by a registered and licensed pharmacist (technical manager) with at least three years of relevant experience. Verify that at least one licensed pharmacist or druggist is available to provide assistance. Check the same for drug stores as per the requirements for drug stores
2. Check that current certificate of competence issued is available at the community pharmacy and is displayed such that it is visible from the public pharmacy area

3. Ensure a qualified delegate is assigned during the technical manager's absence (if applicable).
4. Verify the availability of valid professional licenses and educational credentials of the staff.
5. Observe and check that staff wear white coat and display visible badges with their names, title, and profession.
6. Check staffs are free from conditions (e.g., addiction, mental illness) impairing professional performance

6.2.2.2. Documentations and Record Keeping

1. 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 standards and legal documents.
2. Check medical check-up reports for all staff (done annually) are available
3. Confirm the presence of job descriptions that are dated and signed
4. Check the presence of updated standard operating procedures (SOPs) for all processes carried out in the community pharmacy, such as dispensing, storage of medicines, procurement and inventory, storage and record keeping for controlled drugs, disposal of medicines, etc.
5. Review documentation of staff orientation and training exist covering legal and regulatory awareness, good dispensing/compounding practices, hygiene, safety, and infection control and reporting adverse events and handling controlled substances
6. Check that the prescription register/daily dispensing reports for the previous two years are available for review at the community pharmacy

6.2.3. Storage and Handling

6.2.3.1. General

1. Ensure that medicines are stored and handled to preserve quality, prevent misuse, and reduce wastage or public health risks, and check storage rooms are dry, well-ventilated, and sun/heat protected.
2. Check medicines are stored on shelves or pallets, 20 cm above the floor, 25 cm from walls, 1 m between shelves and arranged systematically following pharmacological category, alphabetical order, or dosage form.
3. Confirm use of FEFO or FIFO stock rotation method and inspect for physical segregation of expired, damaged, or returned products.

4. Check products are stored according to manufacturer and national specifications (e.g., temperature, humidity)
5. Check how the medicines are arranged and identified such as the presence of clear shelf labeling with product name and strength, expiry dates visible

6.2.3.2. Cold Chain Management

1. Ensure a dedicated refrigerator is exclusively used for storing cold-chain medicines and that the temperature is consistently maintained between 2–8°C.
2. Check that the temperature log is recorded twice daily and the refrigerator is functioning properly. Request to see the temperature logbook and inspect the refrigerator display to ensure proper temperature maintenance.
3. Check the refrigerator is clean, organized, has no food stored and is adequately sized for medicine stock. Check that all medicines are stored in the refrigerator in good condition and the fridge has an adequate capacity to permit the orderly storage of medicines
4. Check that the refrigerator is serviced (preferably annually).
5. Check that the maximum/minimum refrigerator temperature is monitored, recorded and reviewed on a daily basis and the pharmacy-maintained temperature logs are used to clearly identify out-of-range temperatures and document actions taken in response to an out-of-range temperature.
6. Check the emergency preparedness processes in place to address any temperature excursions or breaks in the cold chain (e.g., due to equipment failure, power outages, etc.).
7. Check the presence of backup power sources (e.g., generator, solar) during power outage

6.2.3.3. Controlled substances storage and handling

1. Ensure narcotic drugs and psychotropic substances are stored in a locked metal cabinet and assess security measures for controlled substances
2. Verify narcotics drugs and psychotropics substances are dispensed by technical manager or delegate.
3. Check and review detailed dispensing records for controlled substances (prescriber info, date, batch number, etc.).
4. Check the presence of complete records for all controlled substances and verify the quantities of narcotics drugs and psychotropic substances recorded in the register match with actual stock quantities.

5. Check that expired/returned controlled drugs stored in a designated part and appropriately labelled

6.2.3.4. Safety and Hygiene

1. Check for appropriate storage, labeling and separation of hazardous or flammable materials
2. Verify sanitation procedures are followed including sanitation schedule and cleaning records.
3. Ensure no food/drinks are stored in dispensing or refrigeration areas.
4. Verify availability and usability of a fire extinguisher and first aid kit and check that staffs are aware of emergency procedures and safety protocols.

6.2.3.5. Waste Management

1. Confirm expired/damaged/returned products are segregated, labeled, and stored separately.
2. Ensure waste is disposed of within 6 months and review documentation of disposal procedures in line with national directives.
3. Verify staff use appropriate personal protective equipment and are trained in waste handling

6.2.4. Dispensing Practice

6.2.4.1. Inspectors shall ensure that dispensing activities are conducted based on a valid prescription that contains patient's name, age, and sex; the prescriber's full name, qualification, license number, and signature; the medicine's name, dosage form, strength, dose, frequency, route of administration, and total quantity; and the date of issue with the institution's official stamp.

6.2.4.2. Verify that pharmacies dispense prescription-only medicines against the prescription, in full courses and doses, and in accordance with the Good Dispensing manual of EFDA.

6.2.4.3. Inspectors should verify that prescriptions in the pharmacy or drug shops are dispensed if prescribed within 30 days (15 days for narcotics and psychotropic substances).

6.2.4.4. Inspectors should verify that pharmacies use standardized transcription papers for unavailable medicines and that pharmacists exercise their right to refuse dispensing if prescriptions are unsafe or incomplete.

6.2.4.5. Inspectors should check whether pharmacy professionals properly receive and validate prescriptions by verifying patient identity, checking prescriber details, and ensuring the prescription is current and legible.

6.2.4.6. Inspectors should verify if special color-coded special prescription papers are appropriately utilized by pharmacies or drug shops for narcotics and psychotropic substances (where appropriate).

6.2.4.7. Inspectors should check for the availability of dispensing and measuring tools to dispense tablets, capsules and liquid dosage forms to prevent contamination (counting trays and graduated cylinders)

6.2.4.8. Inspectors shall confirm that all dispensed medicines are appropriately labeled with essential information, including patient name, drug details, dosage instructions, and expiry date.

6.2.4.9. Inspectors should verify pharmacies and drug shops provide clear and individualized counseling to patients, ensuring they understand how to take their medicines correctly.

6.2.4.10. Inspectors should observe whether pharmacists explain dosage, potential side effects, storage conditions, and contraindications.

6.2.4.11. Inspectors should check if pharmacies and drug shops provide counseling in a private area to maintain privacy and confidentiality for sensitive issues.

6.2.4.12. Inspectors should check documents for counseling sessions in pharmacies and drug shops, particularly for high-risk medicines, and whether they gather patient feedback to confirm understanding.

6.2.4.13. Inspectors shall verify that pharmacies and drug shops actively promote rational medicine use through proper prescription screening, antimicrobial stewardship, and regulatory adherence.

6.2.4.14. Inspectors should verify that drug shops comply with their authorized scope of practice, ensuring they do not dispense injectables or prescription-only medicines unless explicitly permitted. Inspectors should assess whether prescriptions are screened for irrational combinations, duplications, or contraindications; whether clients are properly denied antibiotics without valid prescriptions with appropriate explanations; and whether drug shops adhere to their approved medicine lists.

6.2.4.15. Inspectors should evaluate the quality and comprehensiveness of client counseling provided by pharmacy staff. Counseling shall cover essential information including the medicine's purpose, proper dosage, treatment duration, potential side effects, storage requirements, and necessary precautions.

6.2.4.16. Inspectors should assess whether staff employ interactive communication techniques, such as asking open-ended questions to confirm patient understanding, and whether visual aids like posters and dosing calendars are available in counseling areas.

6.2.5. Narcotic and psychotropic substances handling

6.2.5.1. Inspectors should ensure that narcotic and psychotropic medicines are dispensed only by the pharmacy's (drug shop's) technical manager or a designated delegate.

6.2.5.2. Inspectors shall verify that special prescriptions for these substances are valid for only 15 days and that no more than one narcotic or psychotropic drug is dispensed per prescription.

6.2.5.3. Inspectors should check and verify that records for narcotics and psychotropics include the dispensing pharmacist's name and signature, date and time of dispensing, drug name and quantity, and prescription serial number.

6.2.5.4. Inspectors should also verify that narcotic and psychotropic substances are not dispensed directly to patients under 18 years.

6.2.6. Drug Information and Referral Services

6.2.6.1. Inspectors should verify the availability of up-to-date reference materials, such as STGs and NEML.

6.2.6.2. Inspectors should verify drug information centers are well-maintained, free from promotional content, and equipped with educational materials.

6.2.6.3. Inspectors should check the availability and utilization of documented referral slips

6.2.7. AMR Prevention and containment

6.2.7.1. Inspectors should evaluate the availability and use of visual aids such as EFDA-endorsed posters, pictorial leaflets, and reminder stickers for AMR prevention and containment, visibly displayed and actively incorporated into counseling sessions to reinforce key messages about responsible antibiotic use.

6.2.7.2. Inspectors should verify that pharmacies and drug shops display color-coded AWaRe charts (green for Access, orange for Watch, red for Reserve antibiotics) in both dispensing and client education areas

6.2.7.3. Inspectors should verify that pharmacies maintain designated AMR focal persons, conduct regular staff training updates, and keep accurate logs of antibiotic dispensing, counseling, and refusal incidents.

6.2.8. Public Health Promotion Services

6.2.8.1. Inspectors should verify capacitated pharmacies conduct blood pressure monitoring, blood glucose checks, and body mass index assessments using calibrated equipment and sterile techniques.

6.2.8.2. Inspectors should check and evaluate documentation of screening activities and referral outcomes

6.2.8.3. Inspectors should evaluate non-compliance in chronic disease screening including performing unauthorized diagnostic tests, failing to refer high-risk clients, or inadequate infection control during screenings.

6.2.8.4. Inspectors should assess whether pharmacies provide evidence-based counseling on oral contraceptives, emergency pills, and condoms, including proper demonstration of condom use when needed.

6.2.8.5. Inspectors should ensure family planning and reproductive health counseling areas fulfill visual and auditory confidentiality, especially for adolescent clients.

6.2.8.6. Inspectors will verify the display of current national immunization schedules and availability of EFDA-approved educational materials addressing common vaccine concerns.

6.2.8.7. Inspectors should check the availability of services for emergency response including first aid provisions, sterile supplies (bandages, gloves) and proper sharps disposal systems.

6.2.8.8. Inspectors should verify emergency kit contents, staff knowledge of referral pathways, and documentation of outbreak response activities.

6.2.8.9. Inspectors should verify that pharmacies maintain accessible counseling spaces, offer pictorial dosage charts, and employ teach-back methods to confirm understanding by elderly, pregnant women, displaced persons, individuals with disabilities, and socioeconomically disadvantaged clients

6.2.9. Clinical Pharmacy Services

6.2.9.1. Inspectors should thoroughly evaluate medication therapy review logs to verify comprehensive medication reconciliations are being performed, particularly for clients with chronic conditions.

6.2.9.2. Inspection teams should examine medication action plans to confirm individualized adherence strategies are being developed and documented.

6.2.9.3. Inspectors should meticulously assess compliance with national symptom response standards, avoiding inappropriate symptom management.

6.2.9.4. Inspectors should verify appropriateness of clinical monitoring services in community pharmacies including equipment verification, staff competency assessments, documentation review and privacy.

6.2.10. Compounding

6.2.10.1. Inspectors shall first verify all compounded preparations strictly adhere to approved formulas and protocols.

6.2.10.2. Inspectors should verify the availability of compounding procedures in every pharmacy containing all standard operating procedures during the inspection.

6.2.10.3. Inspectors should verify the appropriateness of the compounding area designed and maintained to ensure product quality and personnel safety.

6.2.10.4. Inspectors should evaluate whether the compounding space is adequately separated from dispensing activities, with proper ventilation and environmental controls in place.

6.2.10.5. The inspection should assess and evaluate the condition and maintenance of compounding equipment, including verification of calibration records and proper functioning of essential tools such as balances, hot plates, and mortars/pestles.

6.2.10.6. Inspectors should evaluate the appropriateness of storage conditions for active pharmaceutical ingredients and excipients, including temperature monitoring documentation and proper segregation of hazardous substances

6.2.10.7. Inspectors should review compounding personnel records to verify completion of approved compounding training programs and ongoing continuing education.

6.2.10.8. Inspectors should examine batch records for compounded products, reviewing documentation of ingredient quantities, compounding procedures, and quality control checks.

6.2.10.9. Inspectors should review sample labels and observe counseling sessions to verify that patients receive adequate instructions about proper use, storage, and stability of their compounded medications.

6.2.10.10. Inspectors should verify the availability and organization of key documents including compounding formulas, ingredient certificates of analysis, equipment maintenance logs, and quality control test results.

6.2.11. Complaint and Incident Handling

6.2.11.1. Inspectors should verify that the pharmacy and drug store have a documented procedure for receiving, evaluating, investigating and managing complaints, including those related to damaged products, personnel behavior, and medication errors.

6.2.11.2. Inspectors should check if complaints are appropriately validated, responsibility is acknowledged, and corrective actions such as replacement, apology, or client reassurance are taken.

6.2.11.3. Inspectors should confirm that serious complaints involving medication errors or potential harm are referred to relevant authorities and that appropriate consultations (e.g., with physicians or pharmacovigilance units) are conducted.

6.2.11.4. Inspectors should verify the availability and proper use of a Complaint Logbook or equivalent register, documenting essential information such as date, complainant details, nature of complaint, actions taken, and follow-up.

6.2.11.5. Inspectors should assess the availability of incident reports submitted to facility managers, particularly for complaints involving dispensing errors or adverse patient outcomes.

6.2.11.6. Inspectors should verify that all records related to complaint handling and incident management are well-organized, up-to-date, and readily retrievable for review.

6.2.12. Documentation and record keeping

6.2.12.1. Inspectors should verify that the pharmacy has SOP covering recording of procurement, stock management, expired, damaged products, and disposal.

6.2.12.2. Inspectors should check that all products procured, current stock status, recalls, expired or damaged items, and disposed products are promptly and accurately recorded on stock control tools such as bin cards, stock cards, or electronic systems.

6.2.12.3. Inspectors should confirm that receiving, requesting, and dispensing documents are properly filled out by authorized pharmacy personnel.

6.2.12.4. Inspectors should verify that pharmacies maintain standardized records for patients enrolled in chronic illness medication programs, updating patient medication profiles during every refill visit using approved tracking formats.

6.2.12.5. Inspectors should verify that ADRs and medication errors are recorded and reported per EFDA’s pharmacovigilance procedures and reporting formats prepared for this purpose.

6.2.12.6. Inspectors should ensure that the community pharmacy properly files and labels key documentation for easy retrieval, including invoices, receipts, daily sales records, stock control cards, dispensed prescriptions ordered by date, narcotic and psychotropic prescription logs, valid competency certificates of professionals, relevant laws and guidelines, and official medicine lists.

6.2.12.7. Inspectors should verify compliance with record retention requirements, confirming that narcotic and psychotropic substance prescriptions and registration logs are kept for at least five years, while other medicine records are retained for a minimum of two years.

6.2.12.8. Inspectors should check whether the pharmacy reports any discrepancies in stored, dispensed, or stock quantities of narcotic and psychotropic drugs to the appropriate regulatory authority as required.

6.2.12.9. Iinspectors should verify that consumers receive a receipt for each dispensed medicine that includes medicine name and dose, quantity, unit and total price, date of dispensing, dispenser's signature, and pharmacy address.

7. Inspection Report Writing, Administrative Measures and Documentation

7.1. Inspection Reporting writing

Upon conclusion of the inspection, the inspection team shall prepare a formal inspection report that captures the complete outcomes of the inspection process. The report serves as the primary regulatory document for communicating findings, informing compliance decisions, initiating CAPA, and determining whether enforcement measures are warranted. As such, it must be prepared with the highest standards of accuracy, neutrality, and completeness. Emotional language, speculation, and subjective judgment must be avoided entirely.

The inspection report shall be prepared in accordance with the Standard Operating Procedure on Inspection Report Writing and Archiving, using the standardized national inspection report template as attached in the procedures. The report shall be drafted in clear, professional language, using consistent regulatory terminology. Technical language may be used when necessary but must be accompanied by brief definitions to ensure interpretability by non-technical stakeholders.

The inspection report shall include, at minimum, the following components: a title page containing the facility name, inspection date, license number, and location; an introductory section describing the

facility’s ownership, type, and scope of activities, as well as the inspection's objectives and context; a methodology summary outlining the techniques employed (e.g., observation, document review, interviews, sample collection); categorized findings, grouped as Critical, Major, or Minor non-compliances, each referenced to specific laws, regulations, or standards; a conclusion and recommendation section; inspector credentials including names and signatures; and a review and approval section capturing names, titles, and official stamps of the approving regulatory authority.

All reported findings must be supported by verifiable inspection evidence. This may include reviewed documentation, photographic records (where permitted), interview notes, sample results, and field logs. Each piece of evidence must directly correspond to the observation described. Observations shall be classified based on their risk level: Critical non-compliances are serious deviations from the set requirements that pose immediate and serious risks to public health; Major non-compliances are significant deviations from the requirement that have the potential to affect product integrity or operational reliability. This may not immediately impact product quality or safety but could lead to critical impact if not corrected; Minor non-compliances present low risk or does not pose an immediate risk to products or patient safety but represents a departure from the requirements and still require corrective attention. The classification helps to determine follow-up actions by both the inspected entity and the regulatory authority.

The draft inspection report must undergo internal review by a second inspector or designated supervisory officer to ensure accuracy, consistency, and legal defensibility. The finalized report shall be submitted to the inspected facility. This ensures timely communication of findings and triggers the CAPA response process.

The inspected facility is required to submit a CAPA plan in response to the report. The CAPA response must include a detailed root cause analysis, specific corrective and preventive actions, designated responsible personnel, realistic implementation timelines, and success indicators. Inspection teams shall assess each CAPA submission based on adequacy, effectiveness, and feasibility. Where the CAPA response is incomplete or unsatisfactory, a request for revision shall be issued.

Follow-up inspections shall be scheduled for facilities with unresolved critical observations, persistent major non-compliances, or inadequate CAPA implementation. Scheduling of follow-up visits shall take

into account the facility's compliance history, type of regulated products handled, and the overall risk rating. In cases where CAPA is not submitted within the agreed timeframe, where non-compliances persist, or where the risk to public health remains high, EFDA may initiate enforcement actions. These may include issuance of formal warnings, suspension or revocation of licenses, and, where warranted, legal prosecution under applicable national laws.

Facilities retain the right to formally appeal inspection findings or proposed regulatory actions through official appeal procedure. Requests for reconsideration must be submitted in writing within the timeframe stipulated in laws and guidelines. Appeals shall be reviewed by an independent committee designated by the Authority or regional regulatory bodies, and enforcement actions may be suspended pending resolution of the appeal, unless immediate public health risk necessitates urgent action.

All inspection reports, CAPA documents, responses, and follow-up correspondence must be processed through electronic system or properly documented manual procedure to ensure traceability, transparency, and timely workflow management. Reports shall be archived in both electronic and physical formats for a minimum of five (5) years. Reports related to legal proceedings or significant enforcement actions shall be retained for longer periods in line with national legal requirements.

Inspection reports and associated documents are classified as confidential regulatory records. Any disclosure to external entities shall comply with internal information-sharing policy and national laws. Inspectors and all regulatory personnel must ensure that confidentiality is maintained at all stages of report handling, storage, and dissemination.

The inspection report and follow-up process must be implemented consistently and transparently, reinforcing EFDA's or RRB's role in safeguarding public health and promoting regulatory compliance. High-quality reporting, timely CAPA follow-up, and effective enforcement are essential to upholding trust in the regulatory system and ensuring that all facilities meet the standards of Good Distribution, Storage, and Dispensing Practices.

7.2. Non-compliance and Measures

When importers, wholesalers, or community pharmacy fail to comply with regulatory requirements, the regulatory authority may take one or more of the following measures:

7.2.1. Warning and Corrective Actions

7.2.1.1. A warning letter may be issued to importers, wholesalers, or community pharmacies in response to identified non-compliances. The letter shall include a request for corrective actions and a written response within a specified period, typically fifteen (15) working days from the date of receipt. However, such period may vary based the nature and urgency of issues related to non-compliances

7.2.1.2. The authority and/or the respective regional regulatory body will evaluate the response to the issued warning letter. If the response is inadequate, or if no response is received, the Authority will begin follow-up action as necessary to achieve correction.

7.2.1.3. The inspector should ensure the root cause of the non-conformance is appropriately investigated, and effective corrective actions are taken to correct the problem and prevent recurrence.

7.2.1.4. Inspectors may verify the implementation of corrections through a follow-up inspection. Such inspections should be conducted promptly after the agreed completion date of the corrective actions, if necessary.

7.2.2. Suspension of license

7.2.2.1. The operations of importers, wholesalers and community pharmacy may be temporarily suspended until full compliance is demonstrated.

7.2.2.2. The Authority and/or respective regional regulatory body may suspend the Certificate of Competence for importers, wholesalers, and community pharmacies based on the inspector’s inspection or investigation report in compliance with the administrative measure taking and grievance handling directive. The suspension is issued when Authority and/or respective regional regulatory body is convinced that the non-conformance poses a danger to health

7.2.2.3. The Authority and/or respective regional regulatory body may issue suspension letter to the importers, wholesalers and community pharmacies if they failed to correct the issues on prior warnings or notices of non-compliance within the given timeframe.

7.2.2.4. The Authority may suspend the Certificate of Competence where a complaint is received from the public or through EFDA post market activities, and where the under listed issues are reported, investigated and found to be credible.

7.2.2.5. The period of suspension should be aligned with the administrative measure taking and grievance handling directive of the Authority and other applicable international or regional legislation.

7.2.3. Revocation of License

7.2.3.1. For repeated or serious non-compliances that threaten public health, regulatory authorities may revoke the establishment's license of importers, wholesalers and community pharmacies.

7.2.3.2. After prior warnings, notices of non-compliance, or suspension letters have been issued and the importers, wholesalers and community have failed to correct the issues within the given timeframe.

7.2.4. Administrative Sanctions

7.2.4.1. Importers, wholesalers, and community pharmacies may be subjected to monetary penalties in accordance with national regulations equivalent to non-compliance.

7.2.4.2. The inspector has the right for product seizure for confirmed substandard and falsified products

7.2.4.3. The inspector has the right to issue quarantine orders until the investigation or testing results are confirmed.

7.2.5. Legal Actions

7.2.5.1. In cases involving criminal negligence, document falsification, or the distribution of substandard products, the regulatory authority may initiate legal prosecution in accordance with applicable laws.

7.2.5.2. In emergency situations, regulatory authorities may publicly disclose the names of non-compliant entities in order to safeguard public health and safety.

7.2.6. Product Recall

A product recall is a process undertaken by the manufacturer, importer, or wholesaler to remove or withdraw a particular product from all levels of the distribution chain. This process is initiated when critical quality defects or serious adverse drug reactions are reported, which may pose health risks to consumers. The decision for recall shall be made when there is or may cause potential risk to the users by reason of faulty production or on medical grounds (e.g., safety concerns, adverse effects). Recall can be:

- **Voluntarily** undertaken by the manufacturers and distributors.

- **Mandatory** as directed by the EFDA.

No recall shall take place without first informing the Authority. Recalls that involve specific batch will not involve any other batch/batches that currently available in the market.

7.2.6.1. Recall Classification

Recall classification indicates the relative degree of health hazard and classified into three.

a) Class I: a situation in which there is a reasonable probability that the use of, or exposure to, a defective product will cause serious adverse health consequences or death
b) Class II: a situation in which the use of, or exposure to, a defective product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote.
c) Class III: a situation in which the use of, or exposure to, a defective product is not likely to cause any adverse health consequences.

7.2.6.2. Recall Procedures:

Inspectors must ensure that organizations handling medical products have robust and compliant recall procedures. Inspectors should verify the following critical points during inspections:

a) **Written Recall Procedure**
   - Verify that a written recall procedure exists.
   - Confirm that it complies with applicable national or regional regulatory requirements.
   - Ensure the procedure enables effective and prompt recall of medical products.
b) **Annual Effectiveness Check**
   - Check that the recall procedure is evaluated for effectiveness at least once per year.
   - Confirm that the procedure has been updated as necessary following the review.
c) **Notification to Manufacturer or Market Authorization Holder**
   - Verify that in the event of a recall, the manufacturer, and/or marketing authorization holder or local agent is promptly informed.
d) **Regulatory Authority Notification**
   - Ensure that the organization notifies the regulatory body about any recall activities.
e) **Handling of Recalled Products**

- Confirm that all recalled products are securely stored, segregated from other stock, clearly labeled as “Recalled”, and transported and stored under suitable conditions, with original storage requirements maintained where possible.

f) **Accessibility and Content of Records**

- Verify that all recall-related records, especially distribution records, are readily accessible, and contain sufficient detail, including importers names and addresses, contact details, batch numbers, quantities,

g) **Recall Tracking and Reporting**

- Verify that the progress of the recall is documented throughout the process, and a final report is generated, including a reconciliation between delivered and recovered quantities.

h) **Disposal od recalled products**

- Ensure that the destruction of recalled products complies with national disposal regulations and guidelines.
- Verify that disposal measures protect the environment, and public health.

7.2.6.3. Mock recall:

Ensure that a mock recall is conducted for at least one batch of a widely distributed product to test the effectiveness of recall procedures. Effectiveness may also be evaluated through the assessment of an actual recall.

7.2.6.4. Level of recall

The level of recall depends on the nature of problem, extent of the product’s distribution and degree of hazard involved. Level of recall is classified into three:

- Level A: To all consumers (end users).
- Level B: To all points of sales (e.g. Hospitals, Pharmacies, Clinics, Specialty Centres).
- Level C: To all distributors (importers, wholesalers).

7.2.6.5. Public Notification

Not all product recalls are publicly announced (e.g., through press releases). However, if a recalled product has been widely distributed or poses a serious health risk, the EFDA may issue a public notification if deemed necessary to protect consumers.

7.3. Documentations and data protection

Inspectors shall ensure that all inspection records—including reports, checklists, observations, and supporting evidence such as photographs and electronic data—are complete, accurate, and maintained in accordance with internal procedures. These records shall be attributable, legible, contemporaneous (recorded at the time of inspection), original, and securely stored to preserve their integrity and reliability.

All inspection records shall be retained for a minimum of five years to ensure availability for regulatory audits or legal proceedings. Electronic records shall be backed up regularly to confirm data integrity. Physical records shall be stored in locked, access-controlled cabinets to prevent unauthorized access or loss. Digital records shall be secured using encryption, and access logs to detect and prevent tampering.

Non-public information obtained during inspections—such as trade secrets or patient data—shall be treated as confidential and disclosed only to authorized personnel or when requested by law. Any breaches of confidentiality shall be reported immediately to the responsible EFDA or RRBs officials. Inspectors shall use approved devices and secure communication channels when transmitting inspection data. When handling personal or proprietary data or patient related data, inspectors shall comply with the Ethiopian Data Protection Proclamation and internal policies. Any suspected falsification, omissions, or systemic data integrity issues shall be escalated to the EFDA or RRBs top managements.

Reference

1. WHO Technical Report Series No. 1025, 2020. Annex 7 - Good storage and distribution practices for medical products
2. WHO Technical Report Series No. 996, Annex 4 – Guideline on Good Data and Record Management Practices trs1033-annex4-guideline-on-data-integrity.pdf
3. WHO Technical Report Series No. 961, Annex 9: *Good Storage Practices for Pharmaceuticals.*
4. Federal Democratic Republic of Ethiopia. Food and Medicines Administration Proclamation No. 1112/2019. Addis Ababa, Ethiopia; 2019
5. Institute of Ethiopian Standards (IES). Pharmacy Requirements (CES 363:2024). Addis Ababa, Ethiopia: IES; 2024.
6. Ethiopian Food and Drug Authority (EFDA). Community Pharmacy Implementation Guideline. Addis Ababa, Ethiopia: EFDA; 2024.
7. International Pharmaceutical Federation (FIP), World Health Organization (WHO). Good Pharmacy Practice: Joint FIP/WHO Guidelines on GPP – Standards for Quality of Pharmacy Services. Geneva, Switzerland: WHO; 2011.