ETHIOPIAN FOOD AND DRUG AUTHORITY

GUIDELINE FOR MEDICINE AND MEDICINE RAW MATERIAL PORT CLEARANCE

Document Number	EFDA/GDL/077	Version No.	001
Date of Approval	15.08.2025	Date of Issue	29.08.2025

Document History

Version No.	Reason for Amendment	Effective date
001	Newly issued document	29.08.2025

WONDU KETELE

Branch Coordination Lead Executive Officer

August 2025

Addis Ababa, Ethiopia

Foreword

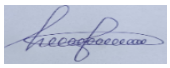
Ensuring the safety efficacy, and quality of medicines and medical products is a fundamental responsibility of the Ethiopian Food and Drug Authority (EFDA). Ethiopia, like many developing countries, relies significantly on imported pharmaceuticals to meet the healthcare needs of its population. In this context, robust regulatory oversight at points of entry is essential to protect public health and maintain confidence in the pharmaceutical supply chain.

This guideline provides a comprehensive framework for the importation and clearance of pharmaceutical products, detailing the roles and responsibilities of importers, clearing agents, regulatory authorities, and other stakeholders. It standardizes processes for documentation, physical inspection, laboratory testing, and regulatory approval, while ensuring alignment with national laws, EFDA directives, and internationally recognized best practices, including those recommended by the World Health Organization (WHO).

The guideline addresses key aspects such as labelling, storage, handling, controlled substances, and the importation of medicines for personal use or registration purposes. By establishing clear procedures, it aims to prevent the entry of substandard, falsified, or unregistered medicines and to facilitate the timely availability of safe and effective pharmaceuticals for the Ethiopian population.

EFDA remains committed to continuous improvement of regulatory practices. This guideline will be periodically reviewed and updated to reflect emerging public health priorities, evolving international standards, and lessons learned from regulatory experience.

I extend my appreciation to all stakeholders involved in the development and implementation of this guideline. Your commitment and cooperation are essential to safeguarding public health and ensuring that quality-assured medicines reach those who need them most.



Heran Gerba

Director General
Ethiopian Food and Drug Authority

Acknowledgments

The Ethiopian Food and Drug Authority (EFDA) gratefully acknowledge the contributions of all individuals and institutions involved in the development of this guideline on pharmaceutical importation and port clearance. This document represents a collaborative effort to strengthen regulatory oversight and ensure that all imported medicines and medical products comply with national standards, EFDA directives, and internationally recognized best practices, including those recommended by the World Health Organization (WHO).

The Ethiopian Food and Drug Authority remain committed to continuous improvement, regulatory excellence, and safeguarding public health. The collective efforts reflected in this guideline strengthen Ethiopia's regulatory capacity, facilitate the safe and timely availability of medicines, and reinforce the Authority's mission to protect and promote the health of the nation.

Special recognition is extended to the Technical Working Group (TWG) for their exceptional dedication, technical expertise, and rigorous review of regulatory processes. The TWG played a pivotal role in consolidating inputs, validating procedures, and ensuring the guideline reflects both national regulatory requirements and international standards. Their contributions have been instrumental in enhancing the clarity, consistency, and effectiveness of the guidance provided.

Contents

Acronyms and Abbreviations

EFDA – Ethiopian Food and Drug Authority

WHO – World Health Organization

POE – Port of Entry

ESW – Electronic Single Window

GDP – Good Distribution Practices

GSP – Good Storage Practices

GMP – Good Manufacturing Practices

COA – Certificate of Analysis

COO – Certificate of Origin

AWB – Air Waybill

BL – Bill of Lading

NGO – Non-Governmental Organization

OTC – Over-the-Counter (medicine)

POM – Prescription-Only Medicine

NPS – New Psychoactive Substances

UNODC – United Nations Office on Drugs and Crime

ICH – International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

ESLSE – Ethiopian Shipping and Logistics Services Enterprise

1. INTRODUCTION

1.1 BACKGROUND

Ethiopia, similar to numerous developing nations, heavily depends on the importation of medicines and medical products. Although local pharmaceutical manufacturers are expanding their capabilities, it is essential for public health that all imported pharmaceuticals adhere to recognized standards of quality, safety, and efficacy

The Ethiopian Food and Drug Authority (EFDA), established under the Food and Medicine Administration Proclamation No. 1112/2019**,** is legally mandated to regulate and control the importation, distribution, and use of medicines and medical products. This mandate includes ensuring that pharmaceutical consignments entering the country comply with national laws, international obligations, and the Authority's directives**.**

In line with WHO guidelines on regulatory systems strengthening, port clearance serves as a frontline regulatory control to prevent the entry of substandard, falsified, expired, or otherwise unsafe medical products. According to WHO, effective clearance systems should combine risk-based screening, documentation review, physical inspection, and inter-agency collaboration at borders and points of entry. These measures help to reduce public health risks, facilitate legitimate trade, and ensure timely access to essential medicines.

Accordingly, this guideline establishes a clear framework for importers, clearing agents, and regulatory stakeholders on the processes and requirements for pharmaceutical port clearance in Ethiopia**.** Clearance activities—comprising document verification, physical inspection, laboratory testing where applicable, and regulatory approval—are conducted to ensure compliance with both EFDA standards and WHO-recommended best practices.

The EFDA will consistently review and revise this guideline at regular intervals to align with changing regulatory practices, emerging global health challenges, international trade obligations, and national health priorities.

1.2 PURPOSE

The purpose of this guideline is to give effect to the mandate of the Ethiopian Food and Drug Authority (EFDA), as established under Food and Medicine Administration Proclamation No. 1112/2019, to protect and promote public health through the regulation of imported pharmaceutical products. Specifically, it seeks to ensure that only safe, effective, and quality-assured pharmaceutical products are permitted entry into the Ethiopian market; to prevent the circulation of substandard, falsified, counterfeit, or unregistered pharmaceuticals; and to standardize port clearance processes through transparent and risk-based procedures. In addition, the guideline provides binding direction to importers, customs authorities, clearing agents, and other relevant stakeholders, thereby reinforcing legal and regulatory compliance while facilitating the efficient management and clearance of pharmaceutical consignments at points of entry.

1.3 SCOPE

This guideline applies to all importers of pharmaceutical products, including manufacturers, and distributors duly licensed by the Ethiopian Food and Drug Authority (EFDA). It also covers government agencies, such as the Ministry of Health and Regional Health Bureaus that import medicines for national health programs or as donations, as well as, non-governmental organizations (NGOs), humanitarian agencies, and development partners engaged in the importation of pharmaceuticals for health interventions in Ethiopia. The scope of this guideline encompasses all categories of pharmaceutical products, including human medicines, vaccines, biological, herbal and traditional medicines intended for distribution and use within the country. Geographically, it applies to all designated ports of entry, including Bole International Airport (Addis Ababa), Modjo Dry Port, Kality Dry Port, and any other entry points officially recognized by EFDA in coordination with the Ethiopian Customs Commission. In accordance with EFDA's mandate under Proclamation No. 1112/2019, and in line with WHO Good Regulatory Practices and WHO guidance on preventing the entry of substandard and falsified medical products, compliance with this guideline is mandatory for all stakeholders involved in the clearance, inspection, and management of pharmaceutical consignments entering Ethiopia.

1.4 DEFINITIONS

Authority (EFDA): The Ethiopian Food and Drug Authority, mandated to regulate the quality, safety, and efficacy of medicines and medical products.

Importer: Any entity licensed by EFDA to bring pharmaceutical products into Ethiopia.

Pharmaceutical Product: Any medicine, vaccine, biological, herbal, or traditional preparation intended for human use.

Port of Entry (POE): An EFDA-designated airport, dry port, or border point authorized for pharmaceutical importation.

Clearance: The EFDA process of document verification, inspection, and approval before release of consignments.

Cold Chain Products: Temperature-sensitive pharmaceuticals requiring continuous controlled storage and transport.

Consignment: A shipment of pharmaceutical products covered by the same invoice or shipping document.

Controlled Substances: Narcotics, psychotropic's, and precursors regulated under EFDA directives and international conventions.

Electronic Single Window (ESW): The national electronic platform for submission and processing of import clearance documents.

Shelf-life: The approved duration a product remains within quality standards under specified storage conditions.

Falsified Medicine: A medicine that deliberately or fraudulently misrepresents its identity, composition, or source.

Counterfeit Medicine: A medicine that infringes trademark or intellectual property rights by imitating a legitimate product.

Good Distribution Practices (GDP): Standards ensuring that medicines are consistently stored, transported, and handled under suitable conditions throughout the supply chain.

Good Storage Practices (GSP): Standards ensuring that medicines are stored under appropriate conditions to maintain their quality, safety, and efficacy

2. GENERAL REQUIREMENTS FOR IMPORTEDMEDICINE

2.1 IMPORTATION

In line with EFDA's mandate and the Medicines and Medical Devices Directives, the importation of pharmaceutical products is subject to the following requirements:

1. **Registration and Authorization:** All pharmaceutical products for commercial importation must be registered with EFDA or granted special import authorization prior to clearance. Consignments requiring pre-approval must be accompanied by valid pre-authorization permits issued by EFDA.
2. **Importer Licensing(Licence):** Only importers holding a valid EFDA import license are authorized to import pharmaceutical products.
3. **Designated Ports of Entry:** Pharmaceuticals shall be imported exclusively through designated POEs approved by EFDA in coordination with the Ethiopian Customs Commission. Importation via post, hand carry, or other non-designated channels is strictly prohibited without prior EFDA authorization.
4. **Documentation Submission:** Required clearance documentation must be submitted through the Ethiopian Electronic Single Window (ESW).Documents must be complete, clear, legible, and free of alterations or inconsistencies.
5. **Inspection of Consignments:** All imported pharmaceutical consignments are subject to risk-based physical inspection at the designated POE prior to release.
6. **Minimum Remaining Shelf-Life Requirements:** All medicines must meet the following minimum remaining shelf-life at the time of arrival: 30 months remaining if the assigned expiry date is between 48 and 60 months**.**24 months remaining if the assigned expiry date is between 37 and 48 months**.**15 months remaining if the assigned expiry date is between 25 and 36 months**.**12 months remaining if the assigned expiry date is 24 months or less.

Importers must ensure compliance with these requirements prior to shipment; consignments failing to meet the shelf-life criteria may be rejected by EFDA.

The Authority may, at its discretion, authorize the importation of medicines regardless of their remaining shelf-life when circumstances justify such action. This may occur in cases of urgent public health need, taking into account the necessity, urgency, and expected duration of consumption of the imported quantity. Importers seeking such exceptions must provide sufficient justification to EFDA for review and approval prior to shipment.

7. **For non-commercial Imports:** Government, humanitarian, or donor imports for non-commercial purposes, such as donations or emergency supplies, require prior EFDA approval.

Rejection of Non-compliant Consignments:

Any consignment failing to meet the above requirements, including documentation, registration, or inspection criteria, will be rejected. EFDA will notify the applicant in writing via the ESW system within three (3) working days, providing the reasons for rejection.

EFDA Medicine Import Process – Guidance Flowchart

Step 1: Pre-Import Preparation

- Verify product registration with EFDA or obtain special import authorization.
- Confirm that the importing entity holds a valid EFDA import license.
- For government, humanitarian, or donor imports, obtain prior EFDA approval.

Step 2: Arrival at Designated Port of Entry

- Import exclusively through EFDA-approved POEs (Bole International Airport, Modjo Dry Port, Kality Dry Port, or other recognized POEs).

Step 3: Documentation Submission

- Prepare all required documents (invoice, packing list, import license, pre-approval permits, certificates of analysis, etc.).
- Submit via Ethiopian Electronic Single Window (ESW**)** Ensure documents are complete, clear, legible, and unaltered

Step 4: Inspection of Consignments

- EFDA conducts risk-based physical inspection of consignments.
- Verify product quality, labelling, and compliance with shelf-life requirements.

Step 5: Minimum Remaining Shelf-Life Check

- Medicines and medical devices must meet these requirements:
  - 30 months remaining for products with 49–60 months total shelf-life.
  - 24 months remaining for 37–48 months total shelf-life.
  - 15 months remaining for 25–36 months total shelf-life.
  - 12 months remaining for 24 months or less total shelf-life.
- Exception**:** EFDA may allow import regardless of remaining shelf-life in urgent public health situations, based on necessity, urgency, and expected consumption.

Step 6: Clearance Decision

- Compliant Consignment**:** Released for distribution and use.
- Non-compliant Consignment**:** Rejected; EFDA issues written notification via ESW with reasons for rejection.

Step 7: Post-Clearance Compliance

- Importers must ensure continued compliance during storage, distribution, and use.
- EFDA may conduct ongoing monitoring and post-market surveillance to ensure quality, safety, and efficacy.

2.2. LABELING REQUIREMENTS FOR IMPORTED MEDICINES

All medicines imported into Ethiopia must comply with EFDA labelling requirements in accordance with Proclamation No. 1112/2019**,** the EFDA Medicine Registration and Import Directiv**e**, and applicable international standards for pharmaceutical products. Labels ensure product safety, proper use, and traceability, and must be clear, legible, and indelible.

2.2.1 Mandatory Information on Labels

The immediate container, secondary packaging, and outer carton of all imported medicines must display the following information:

1. Brand (trade) name of the product.
2. Generic (International Non-proprietary Name – INN) of the active ingredient(s).
3. Strength of the drug.
4. Dosage form (e.g., tablet, capsule, suspension, injection).
5. Quantity of active ingredients in the formulation.
6. Batch/lot number.
7. Date of manufacture
8. Shelf-life (expiry date)
9. Storage and handling conditions, as recommended by the manufacturer.
10. Full name and address of the manufacturer, including country of origin.
11. For vaccines and biological products: storage temperature and cold-chain requirements must be clearly indicated.
12. Package inserts or patient information leaflets must be provided in English and/or Amharic**.**

2.2.2 Special Labelling Considerations

- Labels must be permanent and indelible, resistant to removal or alteration.
- Imported medicines must match the labelling and artwork approved by EFDA during registration or pre-authorization.
- Any medicine that is misbranded, falsified, or inadequately labelled may be detained or rejected at the port of entry.

2.2.3 Pharmaceutical Raw Materials and Packaging

Competency and Authorization:
Any individual importing pharmaceutical raw materials or samples of packaging materials must possess a valid competency certificate issued by the Ethiopian Food and Drug Authority (EFDA). Importation is permitted only after obtaining EFDA approval through a formal request letter, signed by the company's authorized representative, duly stamped, and clearly indicating that the materials are **"for sample purposes only."**

Quantity and Purpose Restrictions:

Importation of pharmaceutical raw materials or packaging samples shall be allowed solely when the quantities or volumes are consistent with sampling purposes and do not suggest commercial intent. EFDA reserves the right to prohibit importation if there is reasonable suspicion that the quantity or volume is intended for commercial distribution rather than for sampling purposes.

All raw materials and packaging materials must be labelled in English or Amharic, using clear, legible, and permanent ink. Labels must include, at a minimum:

1. Name of the material.
2. Quantity or size.
3. Identification code or batch/lot number.
4. Expiry date.
5. Name and full address of the manufacturer.
6. Handling instructions and precautionary notes.

Special Requirement for Radiopharmaceuticals:

- Radiopharmaceuticals must be packaged in specially designed materials appropriate for safe handling, transport, and storage, in accordance with EFDA regulations and international standards.

2.2.4 Alignment with International Standards

Labelling of imported medicines should follow WHO guidelines and best practices, ensuring that:

- Information is accurate, complete, and easily understood.
- Storage, handling, and administration instructions are clearly indicated.
- All labelling supports safe use and traceability of the product in the supply chain.

Compliance with these labelling requirements is mandatory and forms part of EFDA's regulatory oversight of imported medicines to protect public health, prevent falsified or substandard products, and ensure the correct and safe use of medicines in Ethiopia.

3. DESIGNATED PORTS OF ENTRY (POE)

Pharmaceutical consignments may be imported into Ethiopia only through Ports of Entry (POEs) officially designated by the Ethiopian Food and Drug Authority (EFDA), in coordination with the Ethiopian Customs Commission. The currently designated POEs are as follows:

1. **Bole International Airport (Addis Ababa):** Primary entry point for air cargo shipments of pharmaceuticals.
2. **Modjo Dry Port and Logistics Facility:** Main inland port for containerized shipments arriving via Djibouti Port.
3. **Kality Dry Port and Logistics Facility:** Main inland port for containerized shipments arriving via Djibouti Port.
4. **Other officially recognized border or customs entry points** as designated by EFDA in consultation with the Ethiopian Customs Commission.

Pharmaceutical consignments arriving through non-designated entry points will be considered unauthorized and will not be cleared by EFDA. Importers assume full responsibility for any losses or consequences resulting from such unauthorized imports.

4. DOCUMENTS REQUIRED FOR PHARMACEUTICAL CONSIGNMENTS

All pharmaceutical consignments imported into Ethiopia must be accompanied by the following documentation, in accordance with the Ethiopian Food and Drug Authority (EFDA) Proclamation No. 1112/2019, relevant EFDA directives, and WHO standards for regulatory control of medicines:

1. **Commercial Invoice:** Must include complete details of the shipment, including product description, quantity, unit price, and total value.
2. **Packing List:** Itemized list specifying batch numbers, dosage forms, quantities, and packaging details.
3. **Bill of Lading (BL) or Airway Bill (AWB):** Issued by the shipping company or airline, confirming transport of the consignment.
4. **Importer's Declaration:** A signed statement (or electronic confirmation via the EFDA Single Window system) affirming that the invoice and packing list are authentic and consistent with the originals submitted to customs.

5. **Batch Certificate / Certificate of Analysis (COA):** Mandatory for intravenous fluids, vaccines, biological products, and other products as specified by EFDA.
6. **Special pre Import Certificate:** Required for nationally or internationally controlled substances, issued by EFDA.
7. **Export Certificate:** Issued by the exporting country for internationally controlled substances.
8. **Pre-import certificate:** Required for medicines that necessitate EFDA pre-approval prior to importation.
9. **Certificate of origin (COO)** is a mandatory document for all imported medical products, providing official confirmation of the country where the products were manufactured. EFDA requires the COO as part of the regulatory documentation to ensure traceability, authenticity, and compliance with national and international quality standards.
10. **Sample Import Authorization:** For pharmaceutical products imported solely for registration, evaluation, or testing purposes.
11. **NDMA Test Report:** Required for medicines such as ranitidine and other products identified by EFDA where nitrosamine contamination testing is necessary.
12. **Other Supporting Documents** – Any additional documents deemed necessary by EFDA on a case-by-case basis to facilitate regulatory review and import clearance.

Note: The specific documentation required may vary depending on the type of pharmaceutical product and the applicable EFDA directives. Failure to provide complete and accurate documentation may result in consignment rejection, clearance delays, or other regulatory actions.

4.1. REQUIREMENTS FOR DOCUMENTATION

4.1.1. Commercial Invoice must state:

All commercial invoices for pharmaceutical consignments imported into Ethiopia must include the following information, in compliance with EFDA medicine directives and guidelines:

- Invoice Number and Date – Unique identification and issuance date of the invoice.
- Supplier Information – Full name and address of the exporting company or supplier.
- Generic Name (INN) – International Non-proprietary Name of the medicine.
- Trade/Brand Name – Commercial name of the product.
- Manufacturer Details – Name of the manufacturer, manufacturing site, and country of origin.

- Strength and Dosage Form – Concentration and pharmaceutical form (e.g., tablet, injection, syrup).
- Multiple Active Ingredients – For combination products, specify the name and strength of each active ingredient.
- Quantity per Batch – Total quantity to be imported for each batch.
- Batch Number(s) – Specific batch or lot numbers corresponding to the consignment.
- Pricing Information – Unit price and total price, in USD or other EFDA-accepted currency.
- Manufacturing and Expiry Dates – Clearly indicated production and expiration dates.
- Special Storage Conditions (if applicable)– Any temperature, humidity, or other storage requirements, where applicable.

Note: Accuracy and completeness of the commercial invoice are critical for EFDA clearance. Incomplete or inconsistent information may result in inspection delays or rejection of the consignment

4.1.2 Packing List must state:

For each pharmaceutical consignment, the following information must be clearly documented and provided to EFDA for regulatory review and clearance:

- List of Medicines– Complete description of all products included in the consignment
- Quantity or Size – Number of units, packs, or volume for each product.
- Batch Number – Where applicable, the batch or lot number for traceability.
- Expiry Date – Where applicable, the expiration date for each product or batch.
- Shipping Box/Carton Number – Identification number of the shipping container or carton holding the products.

Note: Accurate and complete documentation of these details is essential for EFDA inspection and import clearance. Incomplete or inconsistent information may result in delays or rejection of the consignment.

4.1.3Certificate of origin must state:

The Certificate of Origin (COO) shall contain the following essential information, presented clearly, accurately, and in a legible manner, in accordance with EFDA regulatory requirements.

- **Exporter Information**: Full name, address, and contact details of the manufacturer or exporter, Registration/license number in the country of origin, if applicable.
- **Consignee/Importer Information**: Full name, address, and contact details of the importer in Ethiopia.
- **Product Description**: Generic and brand name of each medical product, Dosage form, strength, and pharmaceutical form (e.g., tablet, injection, IV fluid), Batch or lot numbers, Quantity (units, packs, or vials).
- **Country of Origin**: Explicit statement of the country where the product was manufactured, for products assembled or packaged in a different country, specifies the manufacturing country and the country of packaging.
- **Certifying Authority**: Name, designation, and signature of the authorized official issuing the COO, Official stamp or seal of the issuing chamber of commerce, competent authority, or other recognized body in the country of origin.
- **Invoice or Consignment Reference**: Reference to the commercial invoice, airway bill, or bill of lading linked to the consignment.
- **Date of Issue**: COO must be issued on or before the shipment date.
- **Declaration Statement:** A formal statement certifying that the products listed are wholly produced or manufactured in the country of origin and meet all applicable standards.

Pharmaceutical consignments imported into Ethiopia without a valid or complete Certificate of Origin (COO) may be considered unauthorized and will not be cleared by the Ethiopian Food and Drug Authority (EFDA). Importers are fully responsible for any resulting losses, delays, or regulatory actions arising from incomplete, inaccurate, or non-compliant COO documentation..

5. PORT REGULATION OF CONTROLLED (NPS) SUBSTANCES

- Port-of-entry officers must ensure that the importation of narcotic medicines, psychotropic substances, and precursor chemicals is conducted in full compliance with EFDA proclamations, relevant medicine directives, and international standards. Prior to the arrival of the shipment, officers should confirm that the importer has submitted all required documentation as stipulated under Article 17(1) of the EFDA Medicine Directive. This includes the import permit, certificates of analysis, and any additional supporting regulatory documents. Officers must also verify that the Special Entry Permit issued by the EFDA has

been obtained and that the shipment manifest and invoice are prepared distinctly for the controlled substances.

- Upon arrival, the shipment must be inspected to ensure that it has been transported exclusively by air and is placed in a separate, secure enclosure, with no other products shipped alongside. Officers should verify the integrity of the packaging and seal, cross-check the contents against the invoice, manifest, and entry permit, and record serial numbers, batch numbers, and other identifying details for traceability. Where required, samples may be collected for laboratory analysis to confirm the identity, purity, and compliance of the substances, ensuring proper labeling, chain-of-custody documentation, and secure transport to the laboratory.
- Clearance of the shipment should only be granted after all documentation has been reviewed, physical inspection confirms compliance, and laboratory results (if applicable) indicate conformity with regulatory requirements. Officers must document the release, noting the date and time, responsible personnel, and references to the Special Entry Permit and applicable EFDA directives. Detailed records of all inspections, verifications, and transactions must be maintained securely for audit and regulatory review. Any discrepancies, suspected diversion, or regulatory violations must be promptly reported to EFDA.
- All procedures must be carried out in strict adherence to the Narcotic Medicines, Psychotropic Substances, and Precursor Chemicals Control Directive, and in alignment with WHO recommendations on secure handling, transportation, and traceability of controlled substances. Personnel involved in handling these substances must be trained, aware of their legal responsibilities, and vigilant in ensuring the safe and compliant importation of controlled medicines and chemicals.

6. IMPORTATION OF MEDICINES FOR PERSONAL USE

Pharmaceutical products may be imported for personal use only under strict regulatory control by the Ethiopian Food and Drug Authority (EFDA), in accordance with EFDA Proclamation No. 1112/2019 and relevant EFDA medicine directives. The requirements are as follows:

1. **Over-the-Counter (OTC) Medicines**
   - May be imported for personal use without a prescription.

- Official request submitted by an individual to the Ethiopian Food and Drug Authority (EFDA) for the clearance and release of pharmaceutical products intended solely for personal use.
- A copy of the patient's National ID or passport is mandatory
- Quantity is limited to a maximum 90-day supply.
- Importation exceeding this limit requires prior EFDA authorization.

2. **Prescription-Only Medicines (POM)**
   - Official request submitted by an individual to the Ethiopian Food and Drug Authority (EFDA) for the clearance and release of pharmaceutical products intended solely for personal use.
   - A copy of the patient's National ID or passport is mandatory
   - Must be accompanied by a valid prescription issued by a licensed medical practitioner.
   - Prescription must be submitted with a copy of the patient's National ID or passport.
   - Maximum quantity allowed is a 90-day supply.
   - For treatments exceeding 90 days, EFDA may authorize importation up to a 6-month supply, subject to submission of full medical documentation.
3. **Controlled Substances (Narcotics, Psychotropic's, and Precursors)**
   - Require a valid prescription issued within the last three months.
   - Official request submitted by an individual to the Ethiopian Food and Drug Authority (EFDA) for the clearance and release of pharmaceutical products intended solely for personal use.
   - A copy of the patient's National ID or passport is mandatory.
   - If the prescription is issued by an Ethiopian health facility, it must be written on the **official EFDA Controlled Drug Prescription Format**.
   - For prescriptions issued abroad: the prescription must include the prescriber's full name, signature, professional registration number (if available), and details of the drug (name, dosage, quantity, duration).
   - The total prescribed quantity must be **clearly written in words andnumbers** to prevent alterations.

Note: Repeated misuse of personal-use provisions—such as importing OTC or POM medicines in excess, or for resale—will result in regulatory penalties and restrictions in accordance with EFDA directives.

7. IMPORT OF MEDICINE SAMPLES FOR REGISTRATION

Importers intending to bring medicine samples into the country for the purpose of product registration must obtain prior authorization from the EFDA. Only quantities necessary for laboratory testing, dossier evaluation or clinical assessment are permitted for importation. All invoices for such samples must be accompanied by EFDA's official sample import authorization letter. Under no circumstances shall the imported registration samples be sold, distributed, or otherwise used for commercial purposes.

8. INSPECTION OF IMPORTED CONSIGNMENTS AT PORTS OF ENTRY

All pharmaceutical consignments entering Ethiopia are subject to **risk-based inspection** at designated Ports of Entry (POEs) in line with EFDA directives, inspection guidelines, and international standards. These inspections shall be conducted exclusively by authorized EFDA port inspectors using the official **Medicine Physical Inspection Checklist** and other approved regulatory tools.

The primary objective of visual inspection is to confirm that each consignment meets national and international regulatory requirements. Specifically, inspectors must verify that:

- The shipment aligns with the documentation provided to EFDA, which includes import permits and accompanying records.
- Packaging, labelling, and storage conditions are compliant with EFDA standards and WHO Good Distribution Practices (GDP).
- The consignment does not contain falsified, counterfeit, unregistered, or expired medical products. The packaging, labelling, and storage conditions adhere to EFDA standards and comply with WHO Good Distribution Practices (GDP
- Cold chain products, such as vaccines, insulin, or other temperature-sensitive medicines, have been transported under the required conditions, with temperature monitoring records available for verification.

Consignments of controlled substances—including narcotics, psychotropics, and precursor chemicals—shall undergo 100% physical inspection to ensure full compliance with regulatory controls.

Importers shall ensure that all consignments are presented in an orderly and accessible manner to facilitate inspection at the port of entry. All required documentation shall be submitted through the Electronic Single Window (ESW) system immediately upon the consignment's arrival and prior to customs clearance, in order to avoid delays.

Any consignment found to be non-compliant during inspection shall be subject to detention, rejection, or disposal in accordance with EFDA regulations and international best practices. EFDA port inspectors must document all inspection outcomes, maintain records for audit purposes, and immediately report any suspected falsification, diversion, or regulatory violations.

Visual inspection of pharmaceutical consignments at the port of entry shall be conducted in accordance with standard operating procedures (SOPs) developed and approved by EFDA inspectors. All inspection activities must strictly follow these SOPs and comply with applicable EFDA directives, national guidelines, and international best practices.

8.1 Opening and Verification

- Inspectors shall confirm the integrity of container seals and verify that the airway bill or bill of loading corresponds with the shipment manifest.

- Inspectors shall verify the identity of the consignment against the information submitted through the Electronic Single Window (ESW) system, including International Non-proprietary Name (INN) or brand name, strength, dosage form, pack size, marketing authorization or import permit number, quantity, batch/lot number, and expiry date.

8.2 Physical/Visual Checks (use Medicine Physical Inspection Checklist)

- Packaging and Presentation

  - Inspectors shall verify that outer cartons and inner packs are intact, with no evidence of water damage, crushing, or tampering.
  - Lot numbers and expiry dates must be clearly legible.
  - Packaging must display tamper-evident features where applicable.

- Labelling Compliance

- Labels shall comply with EFDA regulatory requirements, including use of English or Amharic as applicable.
- Required label elements include: International Non-proprietary Name (INN), brand name (if applicable), strength, dosage form, storage conditions, manufacturer's name and address, importer's details, lot/expiry dates, marketing authorization (MA) number (where applicable), and barcodes/unique identifiers.

•Product Integrity

- Inspectors shall check for any indication of falsification or counterfeiting, such as poor-quality printing, colour inconsistencies, spelling errors, or irregular security features.

•Cold Chain Products (Where Applicable)

- Inspectors shall confirm that cold chain products (e.g., vaccines, insulin, biological) have been transported under continuous temperature control.
- This includes verifying packaging type, validity of coolant, and reviewing temperature logger data.
- Records of any temperature excursions must be available with justifications and corrective actions documented.

•Controlled Substances (Narcotics, Psychtropic's, Precursors)

- All consignments containing controlled substances are subject to 100% physical inspection.
- Inspection shall include confirmation of permit validity, segregation of products, verification of invoicing prepared separately, and confirmation of quantities by dosage strength.
- Security of enclosures must also be verified.

• Precursors

- Special entry permits must be presented for precursor chemicals.
- Inspectors shall verify accompanying Safety Data Sheets (SDS), handling requirements, storage segregation, and diversion-risk control measures.

9. SAMPLING OF PHARMACEUTICAL CONSIGNMENTS

Sampling of consignments at the port of entry shall be conducted by EFDA inspectors in accordance with the Authority's directives, official sampling plans, and international standards. Sampling shall be triggered under conditions such as high-risk consignments, suspected quality defects, consignments from new or unverified suppliers, receipt of complaint signals, concerns regarding Good Manufacturing Practice (GMP) compliance, or evidence of temperature excursions during transport.

When sampling is required, inspectors shall:

- Draw official samples strictly following the EFDA sampling plan and standard operating procedures.
- Maintain a complete chain-of-custody record to ensure accountability and traceability.
- Secure samples using EFDA-approved tamper-evident seals.
- Dispatch the sealed samples promptly to the designated EFDA Quality Control Laboratory for testing and regulatory decision-making.

Compliance and Enforcement:

- Consignments from which samples indicate non-compliance, substandard quality, falsification, or deviations from regulatory requirements shall be subject to **detention, rejection, recall, or destruction** in accordance with EFDA regulations.
- EFDA shall issue official notices to importers regarding the outcome of sampling and any required corrective or enforcement actions.
- All actions and decisions must be documented and retained for regulatory audit and traceability

10. NON-CONFORMITY TRIGGERS

EFDA inspectors shall escalate consignments for further action when any of the following non-conformities are identified:

- Evidence of falsified or counterfeit products.
- Products that is unregistered, where registration is required.
- Expired medicines or products with remaining shelf-life below EFDA-defined thresholds.

- Missing, invalid, or incomplete import permits or authorizations.
- Significant labelling non-compliance, including missing or incorrect mandatory information.
- Temperature excursions for cold chain products without proper stability justification.
- Damaged packaging that may compromise product safety or integrity.
- Quantity discrepancies between the consignment and submitted documentation.

Any consignment exhibiting one or more of these non-conformities shall be subjected to appropriate regulatory action, including detention, rejection, recall, or destruction, in accordance with EFDA regulations and international best practices.

11. REGULATORY DECISION REGARDING CONSIGNMENT RELEASE

11.1 Release of consignments after inspection

A pharmaceutical consignment shall be authorized for release at the Port of Entry only when all regulatory requirements are fulfilled. Release shall be granted if:

- The consignment fully satisfies all documentary, quality, and physical verification requirements in accordance with EFDA directives and international standards.
- No violations of EFDA proclamations, regulations, or import directives are identified during inspection.
- The products are compliant with their approved registration details or are covered by a valid EFDA pre-authorization (for products exempted from prior registration).

Upon approval of release, EFDA port inspectors shall**:**

- Grant electronic clearance through the Electronic Single Window (ESW) system, enabling the Ethiopian Customs Commission to finalize customs release.

Importer's Responsibility:
Importers must ensure that Ethiopian Customs is notified in advance of the requirement for EFDA regulatory clearance, in order to facilitate timely processing and avoid unnecessary delays or demurrage.

11.2 Withholding and detention of products

All consignments are subject to EFDA's authority at ports of entry. Products may be withheld temporarily or permanently under the following conditions:

11.2.1. Permanent Withholding of Products

A pharmaceutical product shall be subject to **permanent detention and disposal** if, upon inspection, it is determined to meet any of the following criteria:

- The product **is** counterfeit, falsified, misbranded, or adulterated.
- The product is not registered in Ethiopia and lacks a validEFDA pre-authorization**.**
- The product is the subject of an international or national safety alert.
- The product is expired or has remaining shelf-life below the minimum threshold established in EFDA directives.
- The product is banned in Ethiopia or in its country of origin.
- The product is imported without a valid EFDA import certificate, including controlled substances.
- The product is imported through unauthorized ports not designated by EFDA for entry.
- The product is inappropriately labelled, missing essential information, or labelled exclusively in a foreign language without English or Amharic translations as required by EFDA regulations.
- The product is a donation or sample imported without EFDA authorization.

Products meeting any of the above criteria shall be handled in accordance with EFDA's regulatory procedures for secure detention and supervised destruction, ensuring public health protection and compliance with national and international standards.

11.2.2 Temporary Withholding of Products

A pharmaceutical consignment may be temporarily withheld at the port of entry under the following circumstances:

- Verification of import documentation, laboratory test results, or further regulatory investigation is required.
- Concerns regarding the safety, efficacy, or quality of the product are under review.

A formal regulatory decision on a temporarily withheld consignment shall be made within an acceptable timeframe, taking into account the reasons for the temporary hold from the date of withholding. Following this review, the consignment shall either:

- Be released if found compliant with EFDA regulations and directives; or
- Be permanently detained and disposed of in accordance with EFDA regulatory procedures.

11.3 Disposal of withheld products

The Ethiopian Food and Drug Authority (EFDA) is responsible for ensuring the safe and compliant disposal of pharmaceutical products that have been rejected or permanently detained. Disposal activities shall be carried out in collaboration with relevant stakeholders, including:

- The Ethiopian Customs Commission;
- The Ethiopian Shipping and Logistics Services Enterprise (ESLSE)**;**
- Ethiopian Airlines Cargo; and
- Authorized environmental and hazardous waste management operators.

Importers whose consignments are disposed of in accordance with EFDA regulatory procedures may be subject to administrative sanctions or legal action, consistent with Proclamation No. 1112/2019 and other applicable EFDA regulations.

All disposal operations shall adhere to EFDA guidelines, international best practices, and environmental safety standards to ensure protection of public health and the environment.

12. IMPORTANT NOTES TO IMPORTERS

- **Priority Clearance:** Pharmaceutical consignments shall be granted the highest clearance priority at the port of entry, reflecting their critical importance to public health.
- **Timely Submission of Documents:** Importers shall submit all required documentation to EFDA through the **Electronic Single Window (ESW) system** in a timely manner to prevent clearance delays.
- **Consignment Presentation:** Products must be arranged and presented to allow **efficient and unhindered inspection** by EFDA port inspectors.

- **Compliance with Storage and Handling Requirements:** All manufacturer-provided storage and handling instructions shall be strictly adhered to throughout transport, handling, and inspection.
- **Responsibility for Delays and Costs:** Importers are fully responsible for any **demurrage charges, delays, or penalties** resulting from incomplete, inaccurate, or non-compliant documentation.
- **Regulatory Consequences for Non-Compliance:** Failure to comply with EFDA requirements may result in:

    - Rejection of consignments,
    - Suspension of the import license, or
    - Legal action in accordance with **Proclamation No. 1112/2019** and other applicable EFDA regulations

REFERANCES

1. Proclamation No.1112/2019 Food and Medicine Administration
2. Regulation No. 531/2023 Definition of Organization, Powers and Duties of the Ethiopian Food and Drug Authority Council of Ministers Regulation
3. Medicine-and-Medical-Device-Import-Export-and-Wholesale-Control-Directive-872-2022
4. Ethiopian food and drug authority Guideline for Registration of Medicine ,EFDA/GDL/017 Version No: 005
5. Guideline for Good Storage Practices, Good Distribution Practice and Pharmaceutical Product Recall
6. EFDA Standard Operating Procedure for Medicine Inspection at Ports of Entry
7. WHO Good Distribution Practices (GDP) for Pharmaceutical Products.
8. WHO Technical Report Series on Quality Assurance of Medicines.
9. International Council for Harmonisation (ICH) Guidelines on Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP).
10. United Nations Office on Drugs and Crime (UNODC) guidelines for handling controlled substances