



**Ethiopian  
Pharmaceutical  
Supply Service**

**Proud to  
Serve**

**Ethiopian Pharmaceutical Supply  
Service Unusable Pharmaceuticals  
Waste Disposal Directive No 1117/2025**

**December, 2025**

**Addis Ababa/Ethiopia**

According to Article 10(26) of Proclamation No. 1354/2017, the mandate was given to set the tariff charged for the disposal service provided to other institutions by the directive;

To set an appropriate tariff for the service provided in order to cover its disposal service cost;

In the supply chain, although the Service carry out its tasks to strength the supply and reduce expiration for institutions at each level, it is impossible to completely eliminate expiration. Therefore, it is appropriate to properly dispose expired and damaged pharmaceuticals whose shelf-life has passed;

Due to various reasons pharmaceuticals that have passed their shelf-life, the need to establish a system for disposing of these unusable pharmaceuticals, without causing harm to the environment;

To establish an appropriate system for the management, handling, packing, receiving and tracking of unusable medicines designated for disposal at the disposal center.

The Service issued this directive based on the mandate given under Article 28(2) of Proclamation No.1354/2024 Ethiopian Pharmaceuticals Supply Service and Fund Establishment Proclamation.

## Part One

### General Provisions

#### 1. Short title

This directive may be cited as the “**Unusable Pharmaceuticals Waste Disposal Directive No. 1117/2025**”

#### 2. Defination

- 1/ "**Unusable Pharmaceuticals**" means pharmaceuticals that are unusable due to quality defects, breakage, damage, due to expiry of its expiration date or other defect
- 2/ "**Recyclable wastes**" refer to materials such as pallets, rubber, metal, aluminum bottles, and packaging cartons that can be recycled by reprocessing of their used packaging.
- 3/ "**Unusable waste product**" means packaging materials such as cartons, plastics, paper, and others associated with medicines that have expired and toxic nature and are no longer usable. They cause harm to humans, animals, and the environment.
- 4/ "**Disposal Center**" means the service's disposal centers that have their own temporary storage warehouses with incinerators built in different cities of the country and have organized manpower to dispose of unusable pharmaceuticals and other related supplies in an appropriate way without causing harm to the environment;
- 5/ "**Disposal Certificate**" means a certification document issued by the regulatory authority that contains a detailed description of the Supplies that had been disposed of due to their expiration, quality defects, damage or other reasons;
- 6/ "**Packaging Material**" means a plastic bag, cardboard, plaster, string, etc., used for proper handling or packaging of Supplies that are to be disposed of or burned due to expiration, damage, quality defect or other reasons.
- 7/ "**Shelf Life**" means the period of time given by the manufacturer, which determines the period during which the pharmaceutical can be used and when it cannot be used.
- 8/ "**Regional Health Regulator**" means a regional government body empowered to administer the Food and Medicine Administration Decree and the laws issued to enforce the decree at the regional level in accordance with the Food and Medicine Administration proclamation Decree No. 1112/2019.

- 9/ "**Private Health Institution**" means any organization established by the private sector that provides healthcare services to the public.
- 10/ "**Government Health Institution**" refers to a health service-providing institution that is owned and managed by the federal or regional governments.
- 11/ "**Higher Official**" means the Director-General and Deputy Director-General who oversee the Institution.
- 12/ "**Non-governmental Health Organizations**" means institutions established with the financial support of various charities providing health services to the community.
- 13/ "**Regulatory Authority**" means including appropriate Food and Medicine Authority and the Environmental Protection Authority.
- 14/ "**Temporary Storage Warehouse**" is a warehouse where unused pharmaceutical and other ingredients are stored for no more than two months until they are removed.
- 15/ "**Service**" means Ethiopian Pharmaceutical Supply Service.
- 16/ "**Branch**" means hubs located in different regions that are managed under the Ethiopian Pharmaceutical Supply Service which provide services to health facilities.
- 17/ Words and phrases defined in the Proclamation shall have the same meaning in this Directive.

### **3. Scope of Application**

This directive shall be applicable at the Ethiopia Pharmaceutical Supply service head office and branches, the disposal centers, and facilities that require services as needed.

## **Part Two**

### **Sorting, Packaging, and Transportation of Unused Pharmaceuticals**

#### **4. Sorting Process**

- 1/ Primary sorting shall be done from a facility where Unusable pharmaceuticals are available.
- 2/ It is important to keep Unusable pharmaceuticals that are expired, damaged, or have quality problems separately in accordance with their type and shelf life.
- 3/ Workers participating in the sorting process must use the necessary protective clothing and equipment.

- 4/ The sorting space needs to be sufficiently large and well-ventilated to facilitate sorting.
- 5/ Psychotropic and narcotic medications that require special handling should be kept separately after being properly identified.
- 6/ Chemicals that are volatile and highly flammable, as well as cancer medications, must be carefully separated.
- 7/ Depending on their unique properties, antimicrobial medications that are liquid, solid, or powder should be kept separately.
- 8/ After sorting the list of supplies to be disposed of by name, size, packaging type, batch number, expiration date, manufacturer, and country of manufacture, the price of the supplies and the facility where they were generated should be clearly stated. The sorting process also includes separating recyclables from non-reusables and selecting the proper disposal method for non-reusables.
- 9/ According to Ethiopian food and drug authority's directive, pharmaceuticals and other related supplies that can and cannot be disposed of at disposal center should be kept separate.

## **5. Packaging**

- 1/ Pharmaceuticals and other related supplies that are no longer usable must be packaged separately according to their characteristics (liquid, solid, powder, combustible, etc.).
- 2/ When pharmaceuticals and other Supplies that need to be disposed of are packaged together, the type of Supplies contained in the container, as well as their quantity and characteristics, must be indicated on the outside of the package.
- 3/ Anti-cancer medicines and other hazardous medicines shall be distinguished with purple color, radiopharmaceuticals with brown color, while other substances shall be marked with blue color during packaging.

## **6. Transportation**

- 1/ Institutions that need disposal services for unusable pharmaceuticals must transport them to the disposal facility and hand over them to disposal centers. Branches of the service that wish to dispose of unusable pharmaceuticals and other related supplies must transport and deliver them to disposal centers. However, this process shall be carried out based on a formal disposal service agreement between the institutions and the service provider. The branches of the

service responsible for transportation and delivery to disposal centers may operate under the coordination of the Directorate for the Management of unusable pharmaceutical waste disposal, as needed.

2/ Unusable pharmaceuticals should be transported carefully in a covered vehicle or tarpaulin during transportation to disposal centers.

3/ Disposable pharmaceuticals shall be packaged and delivered to the incinerator.

### **Part Three**

#### **Receiving, Storing, Disposal of non-usable Pharmaceutical and other related supplies, recycling of packaging materials and Certification**

##### **7. Receiving**

1/ Any customer or Ethiopian pharmaceutical supply service's branches seeking disposal services must present a permit and request letter from the local regulatory authority, stating the type, quantity, manufacturer, serial number, expiration date, price, and other additional information about the material to be disposed of.

2/ The disposal center must make sure that the materials to be disposed of are unusable and that it is able to do so; if the materials are beyond the scope of the disposal system, they should be returned to their original location.

3/ The legal issuing receipt must be attached to a confirmation letter from the service requesting organization stating that it is being requested to be disposed of.

4/ Referring to the legal issue document, the handover system must be carried out; the receiving document should be issued and given to the delivery party after it has been confirmed that the delivery documents' list matches with the actual supplies in terms of both type and the quantity.

5/ The disposal center should receive the Supplies to be disposed of according to the name, type, measure, quantity, serial number, expiration date, reason for disposal, manufacturer's name, country of manufacture and price list.

##### **8. Storing**

1/ The supplies to be disposed of must be transferred from the delivery location to temporary storage after the completion of the handover;

- 2/ The name of the organization asking to dispose of the package must be labeled on them when they are kept in a warehouse.
- 3/ Supplies that are flammable and easily ignited must be kept in a separate location.
- 4/ Unauthorized persons are not permitted to enter temporary storage warehouses.

**9. Disposal of non-usable Pharmaceuticals**

- 1/ The disposal center must develop the plan and perform the disposal under the supervision of the Food and Drug Authority or the regional health regulatory body.
- 2/ It must be ensured that pharmaceuticals brought to the disposal facility are disposed of by the disposal centers.
- 3/ It must be ensured that the details on the outer packaging of the materials brought to the disposal center are the same as those on the inside.
- 4/ It is necessary to verify that payment has been made or that credit has been applied if the supplies to be disposed of are from sources other than the service's main office and branches.
- 5/ Customers looking for disposal services must have a detailed service agreement with the disposal center.
- 6/ After the disposal of unused materials, any residual product or ash remaining must be disposed of properly.

**10. Recycling of Packaging Materials**

The management of recyclable waste products will be determined by the top management of the service.

**11. Certification**

- 1/ The disposal center shall receive a certificate of approval from the regulatory authority after disposal of unusable pharmaceutical and Supplies wastes.
- 2/ The service-seeking institution shall be given a certificate of approval from the disposal center.
- 3/ The certificate given by the regulatory authority must be properly documented.

## Part Four

### Service Prices and Cash Collecting/Billing

#### **12. Pricing Principles of Disposing Unusable Pharmaceuticals**

- 1/ The service fee charged to the disposal center for the disposal of materials shall be determined by this directive, taking into account the cost of disposing of unusable pharmaceuticals, supplies and the cost of fixed equipment within 10 years;
- 2/ The direct Costs per kilogram of waste disposal:
  - a) Depreciation cost of waste disposal machines
  - b) Salaries and benefits of workers
  - c) Electricity and water costs
  - d) Fuel consumption costs
  - e) Maintenance and replacement costs
  - f) Insurance costs
  - g) Recyclable waste and ash management costs
  - h) loading and unloading costs
  - i) Costs for risk allowance
  - j) Costs for personal protective equipment
  - k) Costs for packaging and sorting
  - l) Costs for temporary storage
- 3/ Since the amount of direct costs should reflect the current market conditions, it will be adjusted based on a price adjustment study conducted annually or as necessary within a period of less than one year, and approved by the service's executive committee.
- 4/ The indirect costs per kilogram of waste disposal:
  - a) Labour per diem allowance costs
  - b) Phone and internet costs
  - c) Office service and administrative costs
  - d) Public relations service costs
  - e) Costs of banking services
- 5/ The indirect cost amount specified in Sub-Article (4) of this Article shall be 15% of the direct cost.
- 6/ The tariff charged for the disposal service of pharmaceuticals shall be 15% by covering direct and indirect expenses as specified Sub-Article (2) and (4) of this Article.

## **Part Five**

### **Monitoring and Evaluation System**

#### **13. Key Performance Indicators**

- 1/ Regarding the management of the disposal system for unused medicines and related inputs, it is necessary to establish key performance indicators to ensure that the ongoing activities are continuously improved and modern practices are expanded, and to measure performance and implement corrective actions.
- 2/ A system for monitoring and evaluating the performance of the disposal activities for unused medicines and related inputs must be established based on the service's planning, monitoring, and evaluation framework.

## **Part Six**

### **Miscellaneous Provisions**

#### **14. Repealed and Non-Executable Directives**

Any directive or practice that contradicts this directive shall not apply to the matters covered by this directive.

#### **15. Amendment of the Directive**

This directive will be amended as necessary and Section Five of the directive will be implemented by studying the current market conditions and making price predictions.

#### **16. Execution of the Directive**

This directive shall come into effect from the date it is registered by the Ministry of Justice and uploaded on the official website of the Service.

**December, 2025**

**Abdulkadir Galgalo (Dr.)**

**Director General of Ethiopian Pharmaceutical Supply Service**