Medicines Waste Management and Disposal Directive

Food, Medicine and Healthcare Administration and Control Authority of Ethiopia

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Introduction

WHEREAS, it is found necessary to protect the public health and the environment from health risks emerging out of unsafe management and disposal of medicines waste.

WHEREAS, it is found necessary to avert problems related with diversions of unfit for use medicines and the management and disposal of medicines waste shall comply with the required standards.

WHEREAS, it is found necessary to create favorable conditions to encourage private investors to participate in the proper medicines waste management and disposal system.

WHEREAS, in order to make the unorganized and poor quality administrative and regulatory system of medicines waste management and disposal, it is found necessary to standardize the disposal practice.

NOW, THEREFORE, in order to rectify the existing situation on medicines waste management and disposal practice, it is found necessary to formulate this medicines waste management and disposal directive in accordance with Article 55 (3) of the Food, Medicine and Healthcare Administration and Control Proclamation No.661/2009.

Part One: General

1. Short Title

This directive may be cited as "Medicines Waste Management and Disposal Directive No. 2/2011".

2. Definitions

Without prejudice to the definitions in Proclamation No. 661/2009, in this directive, unless the context otherwise requires:

1. **"Antibiotics" means** medicines used to treat infections caused by bacteria and other microorganisms.
2. **"Antineoplastics or cytotoxic/anti-cancer medicine" means** a medicine that inhibits and combats the development of cancer.
3. **"Appropriate organ" means,** as the case may be, the Food, Medicine, Healthcare Administration and Control Authority or a regional government organ authorized to implement food, medicine and controllable health related institution administration and control activities at a region level or other organ authorized by law.
4. **"Biodegradable" means** a type of waste, typically originating from plant or animal sources, which may be degraded by other living organisms.
5. **"Central disposal site" means** a site established and operated by appropriate organ which provides medicines waste management and disposal service.
6. **"Disposal Firm" means** any waste management company licensed to dispose medicines waste. It can be a medicines importer, wholesaler, distributor, manufacturer or any private or public business authorized to dispose medicines wastes for fee.
7. **"Disposal Referral System" means** a system to pass on medicines wastes to a licensed disposal firm, medicines supplier, manufacturer or central disposal site for disposal service for fee.

8. **"Environmental Impact Assessment"** means the methodology of identifying and evaluating in advance any effect, be it positive or negative, which results from the implementation of a proposed project or public instrument. It shall contain, as a minimum, a description of:
    a. The nature of the project, including the technology and processes to be used,
    b. The content and amount of pollutant that will be released during implementation as well as during operation,
    c. Source and amount of energy required for operation,
    d. Information on likely trans-regional impacts,
    e. Characteristics and duration of all the estimated direct or indirect, positive or negative impacts,
    f. Measures proposed to eliminate, minimize, or mitigate negative impacts,
    g. Contingency plan in case of accident, and
    h. Procedures of self auditing and monitoring during implementation and operation.
9. **"Hazardous Substance" means** a waste that poses substantial or potential threats to public health or the environment ignitability, reactivity, corrosiveness and toxicity.
10. **"Health Care Facilities" means** hospitals, health centers, health posts, clinics, diagnostic centers and other related facilities which involve in diagnosis and treatment of illnesses.
11. **"High Temperature Incinerator" means** an incinerator that generates at least 1200°C in the secondary chamber, and is fitted with gas cleaning equipment.
12. **"Highly Engineered Sanitary Landfill" means** an engineered landfill with landfill gas extraction, groundwater monitoring and leachate treatment facilities and monitored by trained staff.
13. **"Medical Supply" means** any article that may be used on the inner or outer part of the body for diagnosis or treatment of a disease in man. This includes, suturing materials, syringes, bandages, gauze, cotton and other similar articles and x-ray films.

14. **"Medicines Waste" means** waste which encompass the following:
    a. All properly unsealed bulk products or loose tablets and capsules. If unexpired these shall only be used when the container is still sealed, properly labeled or still within the original unbroken blister packs,
    b. All cold chain damaged, unexpired medicines that should have been stored in a cold chain but were not,
    c. Counterfeit, substandard and adulterated,
    d. Discarded items used in the handling of medicines,
    e. Expired, unused, spilt, and contaminated,
    f. Improperly sealed or labeled or stored,
    g. Expired, damaged, and improperly sealed or labeled or stored laboratory reagents,
    h. Expired, damaged, and improperly sealed or stored medical supplies;
    i. Prohibited or unauthorized medicines,
    j. Expired, damaged, and improperly sealed or labeled or stored raw materials, and
    k. Discarded packing materials.

15. **"Medium Temperature Incinerator" means** a two-chamber incinerator with minimum temperature of 850^0C.
16. **"Open Controlled landfill" means** a landfill where medicines waste is covered with large amount of municipal wastes but it is still left open.
17. **"Open uncontrolled landfill" means** a landfill where medicines waste is not covered with large amount of municipal wastes and it is left open.
18. **"Quality Incompliance" means** non-conformity with the regulatory requirements/standards issued by the Authority.
19. **"Sewer" means** a flushing of medicines wastes to the sewerage system after proper dilution and regulation.
20. **"Supplier" means** importer, wholesaler, or distributor which provides medicines to health institutions, universities, research institutions and others.

21. **"Untreated waste" means** medicines waste which is not immobilized or incinerated.
22. **"Waste Inertization" means** a variant of encapsulation and involves removing the packaging materials including blister packs, paper, cardboard and plastic from the medicines and then crushing and mixing medicines with cement, lime and water.
23. **"Waste Encapsulation" means** a landfill approach to reduce the risk of medicine waste through immobilizing the medicine in a solid block within a plastic or steel drum.

3. Objective

To protect the public and the environment from health risks and hazards of medicines waste by ensuring safe management and disposal practice.

4. Scope of Application

The directive shall be applicable to:

a) The disposal of medicines waste, but not to medical equipments and the management of other health care wastes generated by health institutions;
b) All governmental, non-governmental and private organizations involved in medicines waste handling and disposal.

Part Two: Medicines Waste Management and Disposal Systems

5. General

1. Medicines which are unfit for use shall not be stored for more than six months.
2. Approval and authorizing of disposal of medicines shall be sought from the appropriate organ.
3. Any medicines waste disposal practice, including diluting and flushing of liquid medicines into sewers and burning of packaging materials, shall be attended by an inspector of the appropriate organ.
4. After disposal of medicines waste have been carried out, disposal certificates shall be issued by the appropriate organ (Annex VII & VIII).
5. Disposal sites shall be environment and society friendly and shall be approved by appropriate organ in accordance with Environment Impact Assessment (EIA).
6. Re-use of any medicines waste including re-packing and re-labeling is prohibited.
7. Scavenging of medicines is prohibited and security measures to prevent scavenging shall be in place at disposal sites and temporary storage areas.
8. Any health institution which does not have a disposal facility approved by the appropriate organ shall not carry out medicines waste disposal.
9. Without prejudice to sub-article (8) of this article, any health institution which does not have an approved disposal facility shall use disposal referral system of licensed disposal firms, respective medicines suppliers or central disposal sites.
10. Custom and Revenue Authorities and police officers shall adhere to this directive for proper disposal of confiscated medicines.

6. Handling of Medicines Waste

1. As stipulated by this directive, the disposal of medicines waste shall be carried out according to the sorting procedures and recommended disposal methods by the appropriate organ.
2. All workers who are involved in a disposal process shall wear appropriate personal protective equipment such as overalls, boots, gloves, safety glasses/goggles, masks, and caps.
3. The separation of unfit for use medicines shall be made into those that can be safely used/ returned to the medicines supply system and those that require disposal by different methods.
4. Each medicine waste shall be recorded on the register book (Annex III).
5. Special emphasis shall be given to segregate and store controlled drugs or substances, antineoplastics or cytotoxic/anti–cancer medicines, anti-infective medicines, radiopharmaceuticals and any other hazardous non-medicine products like antiseptics and disinfectants until their separate and safe disposal.
6. Medicine wastes other than mentioned under sub-article (5) shall be categorized and kept by dosage forms:
    a) Solids, semi-solids and powders: tablets, capsules, granules, powders for injection, mixtures, lotions, creams, gels, suppositories etc.,
    b) Liquids: solutions, suspension, syrups, ampoules etc., and
    c) Aérosol canisters : propellant - driven sprays and inhalers.
7. Waste paper and packing materials may be sorted and recycled (if facilities are available), burned or disposed of as normal waste to a landfill.
8. Plastic, metal and glass items may be reused, recycled or disposed of in a landfill. Depending on the type of material and the purpose of reuse, appropriate treatment such as cleaning or disinfecting of reusable materials may be needed.
9. Containers shall be kept according to dosage forms to facilitate verification exercise, sorting and selection of disposal methods.

10. An area or room for keeping containers of medicines waste shall be demarcated and labeled conspicuously with words "Expired medicines–Not for Sale" or "Unfit medicines–Not for sale" in red ink.

7. Healthcare Facilities & Retail Medicine Outlets

1. Without prejudice to sub-article (9) of article 5, health care facilities & retail medicine outlets shall submit applications for disposal of unfit for use medicines to:

- **a.** Central disposal sites,
- **b.** Respective suppliers, or
- **c.** Licensed disposal firms and shall report/copy to the appropriate organ.

2. To request for approval of disposal of medicines waste, except recyclable materials, cartons, leaflets and labels, health institutions shall submit applications to the appropriate organ (Annex IV).

3. All applications for disposal of medicines waste shall be accompanied with lists of products to be disposed clearly stating trade name and/or generic name, strength (where applicable), dosage form, pack type and size, quantity, batch number, expiry date, manufacturer, supplier, country of origin, and product price (Annex VI).

4. Without prejudice to sub-articles (2) & (3) of this article, after a disposal request has been approved by the appropriate organ, the healthcare facilities shall organize a disposal committee comprising the facility pharmacist, facility environmental health personnel, warehouse personnel and finance head as appropriate to the organization.

5. Without prejudice to sub-articles (2) & (3) of this article,

a. The selection of disposal method and the disposal process shall be conducted in the presence of an inspector of the appropriate organ.
b. After the disposal process is completed, the appropriate regulatory organ shall issue disposal certificate to the health institution within one week (Annex VII).
c. Depending on the risk of medicines waste and complexity of the disposal method, health institutions may use disposal referral system. If that is the

case, disposal service applications to licensed disposal firms shall be reported/copied to the appropriate organ by the health institutions (Annex V).

6. Unfit for use medicines of health institutions, except recyclable materials, cartons, & leaflets, shall be returned back to respective suppliers for disposal. The appropriate organ shall be sent a copy of the referral/receipt form by the health institutions (Annex X).
7. Health institutions shall present their disposal certificates whenever requested by concerned organ.

8. Medicine Manufacturers and Suppliers

1. Medicine manufacturers and suppliers shall accept and manage medicines waste disposal requests from respective clients.
2. Medicine manufacturers and suppliers who have their own disposal facilities shall get an approval from FMHACA. In cases where medicines manufacturers and suppliers do not have their own disposal facilities, they shall have contractual agreement with licensed disposal firms.
3. Without prejudice to sub-article (2) of this article, medicine manufacturers and suppliers who provide disposal service for fee at their disposal facilities shall have a separate license.
4. Medicine manufacturers and suppliers shall submit applications to the appropriate organ to get approval for disposing medicines waste at their disposal facilities. (Annex IV).
5. All requests for disposal of medicines waste shall be accompanied with lists of products to be disposed clearly stating trade name and/or generic name, strength (where applicable), dosage form, pack type and size, quantity, batch number, expiry date, manufacturer, supplier, country of origin, and product price (Annex VI).
6. The selection of disposal method and disposal process shall be conducted in the presence of an inspector of FMHACA.

7. After the disposal process is completed, a certificate shall be issued to the manufacturer or supplier by FMHACA within one week (Annex VII).
8. Manufacturers and suppliers shall present their disposal certificates when requested by a concerned organ at any time.

9. Disposal Firms

1. Any person who wants to establish and operate a medicines waste disposal firm shall be licensed by the Authority and the license shall be displayed in a conspicuous place.
2. Medicines waste disposal firm shall have the following professionals:
    a. Pharmacist,
    b. Environmental health professional,
    c. Sanitary Engineer (for landfill only)
    d. Security guards and other administrative staff for the disposal site.
3. A disposal firm shall have secured disposal site depending on the Environmental Impact Assessment (EIA) conducted with the support of the Environmental Protection Authority (EPA) of Ethiopia. In addition, a disposal firm shall have all the facility and practice standards prescribed under these directives.
4. A disposal firm shall have dedicated and secured transportation vehicles in accordance with national regulations and international conventions on transporting of hazardous substances ratified by Ethiopia.
5. Safe custody of medicines waste shall be maintained in separate, secure premises with security fences to avoid pilferage. However, once received, medicines waste shall be disposed within one month.
6. Disposal firms shall have all necessary equipments for the disposal methods they are implementing.
7. Disposal firms shall have security guards 24 hrs a day and 365 days a year.
8. A contractual agreement made between a health institution and a licensed disposal firm shall be reported to appropriate organ.

9. Prior to disposal, any disposal firm shall request and get approval of disposal of medicines waste from the appropriate organ.
10. All disposal requests made by health institutions shall be reported to the appropriate organ by the disposing firm.
11. Without prejudice to sub-article (10) of this article, the report shall include the name and address of the disposal firm, date of request, name and address of the service requester, generic and/or brand name of the wastes, strength, dosage form, package type & size, quantity, batch number, expiry date, reason for disposal, manufacturer/supplier, country of origin, purchase value and other relevant information (Annexes V& VI).
12. A list of medicines waste to be disposed shall be prepared and signed between the applicant and the disposal firm. This form shall have minimum information consisting of generic and/or brand name, strength, dosage form, package type and size, quantity, batch number, expiry date, reason for disposal, manufacturer, supplier (if any), country of origin, purchase value and other relevant data to the appropriate organ (Annex IX).
13. Based on the number of applications for disposal, the disposal firm shall prepare disposal schedule and communicate with the appropriate organ.
14. Disposal method selection and disposal of medicines waste shall be conducted in the presence of an inspector of the appropriate organ.
15. Disposal shall be carried out based on the sorting and disposal methods recommended by the appropriate organ. Sorting may be done either at the health institutions' premise or at the disposal firms' disposal site.
16. The disposal firm shall take necessary measures to prevent diversion and scavenging during sorting, transporting and disposal process.
17. After the disposal process is completed, a certificate shall be issued to the disposal firm by the appropriate organ within one week (Annex VIII). A copy of the certificate shall be given to the respective disposal service requester.
18. Any person shall present disposal certificates whenever requested by concerned organ at any time.

Part Three: Disposal Methods

10. Return of Medicines Waste to Supplier/Manufacturer/Donor

1. As stipulated by Entry - Exit Inspection and Health Quarantine Directive, whenever medicines with quality incompliance are identified at port of entry, the supplier or donation recipient shall be responsible to return them back to their origin for disposal.
2. Without prejudice to sub-article (1) of this article, if the supplier or donation recipient fails to do so, their disposal practice shall comply with this directive.
3. There shall be a mechanism to return medicines waste which present disposal problems to their origin for safe disposal.

11. Controlled Non-Engineered Landfill

1. Due to hazards to the environment and public, dumping medicines waste in uncontrolled non-engineered landfill is prohibited.
2. Controlled non-engineered landfill shall be in compliance with Environmental Impact Assessment (EIA) and shall not affect the aquifer, other watercourses or air.
3. Controlled non-engineered landfill shall be located at least 50 meters away from any ground water source.
4. The controlled non-engineered landfill shall be protected from flooding, water entry and runoff. It shall also be secured from scavenging by having security guards and security fence.
5. Controlled non-engineered landfill operation shall minimize:
    a) The potential risks for polluting water resources and soil,
    b) The generation of landfill gas i.e. methane and carbon dioxide,
    c) Potential human exposure to volatile chemicals,
    d) Smell, vermin and fire,
    e) Destruction of natural/virgin sites, and
    f) Long term cost intensive clean-ups, remediation and monitoring (aftercare, close-up).

6. Disposal by controlled non-engineered landfill method shall not be used for the following hazardous wastes:
    a) hazardous liquid wastes and hazardous materials containing free liquids,
    b) highly volatile and flammable liquid wastes,
    c) wastes containing appreciable quantities of mineral oils,
    d) spontaneously flammable or pyrophoric solids,
    e) strong oxidizing/reducing wastes,
    f) shock sensitive explosives,
    g) compressed gases,
    h) highly reactive wastes,
    i) water soluble non-convertible materials,
    j) persistent organo-halogen compounds,
    k) volatile materials of significant toxicity,
    l) substances that react with water, air or dilute acids and alkalies to produce hazardous gases or hazardous reactions,
    m) concentrated acids, alkalis, and
    n) Empty containers unless they are crushed, shredded or similarly reduced in volume.
7. Medicines waste immobilized by encapsulation/inertization may be disposed using controlled non-engineered landfill method. In cases where immobilization is impossible, medicines waste disposed by controlled non-engineered landfill shall be covered by 15 centimeter thick municipal waste.

12. Highly Engineered Sanitary Landfill

1. Site selection, design and management of operations of highly engineered sanitary landfill shall be in compliance with Environmental Impact Assessment (EIA).
2. Highly engineered sanitary landfill shall be properly constructed in order to protect the environment, the aquifer, other watercourses or air.
3. Highly engineered sanitary landfill shall consist of an evacuated pit isolated from watercourses and above the water table.

4. The basement of highly engineered sanitary landfill shall be closed and sealed with impermeable materials to prevent gas emission to the open air and water leachate to the environment.
5. Highly engineered sanitary landfill shall be constructed with gas extraction facility, groundwater monitoring facility and leachate treatment facility.
6. The gas extraction facility shall be designed either to burn collected gas or convert into energy.
7. Each day's solid waste shall be compacted and covered with soil to maintain sanitary conditions.

13. Landfill by Waste Immobilization: Encapsulation

1. Clean drums made of steel or plastic shall be used for encapsulation. Using drums that have previously been used to store explosives or hazardous materials is prohibited.
2. In encapsulation, drums shall be filled to 75% capacity with solid and semi-solid medicines waste and the remaining space shall be filled with medium such as cement, cement/lime mixture, plastic foam or bituminous sand.
3. The mixture of lime, cement and water added to fill the drums to capacity shall be in the proportions of 15:15:5 (by weight).
4. After their lids have been sealed with seam or spot welding, the drums shall be placed at the base of a landfill and covered with fresh municipal solid waste.

14. Landfill by Waste Immobilization: Inertization

1. A grinder/road roller, a concrete mixer and supplies of cement, lime and water shall be required for inertization.
2. Packaging materials including blister packs, paper, cardboard and plastic shall be removed from the medicines waste.

3. The medicines waste shall be ground and a mix of water, cement and lime with the approximate ratio by weight of medicines waste: 65%, Lime: 15%, Cement: 15%, Water: 5% or more shall be added to form a homogenous paste.
4. Without prejudice to sub-article (3) of this article, the paste shall be transported in the liquid state by concrete mixer truck to a landfill, decanted into the normal municipal waste and dispersed.

15. Sewer

1. Proper dilution to make liquid wastes neutral and PH monitored (between 6 and 9) at purpose built pits shall be done before flushing into the sewer.
2. Diluting and flushing of liquid wastes to sewers shall be conducted under the supervision of an inspector from the appropriate organ (Refer Guideline Ambient Environment standard for Ethiopia).
3. Diluted liquids, syrups, intravenous fluids and maximum of 50 liters/day of diluted disinfectants shall be flushed into sewers.
4. For disposal of liquid anti-infective medicines see article 23 sub-article 3.
5. Disposing by sewer shall be monitored to avoid impact on the environment and public health.
6. Disposal of antineoplastics, undiluted disinfectants and antiseptics into the sewer is prohibited.

16. Burning in Open Containers or Place

1. Paper and cardboard packaging, if they are not to be recycled, may be burnt.
2. Expired cotton and gauze may be disposed by burning.
3. Medicines waste shall not be disposed by burning at low temperature in open containers.
4. Polyvinyl chloride (PVC) plastic containers shall not be disposed by burning.

17. Medium-Temperature Incineration

1. The medium-temperature incinerators shall be of double chamber design or pyrolytic which operate at a medium-temperature combustion process (850-1,000^{0}C) with a combustion retention time of at least two seconds in the second chamber.

2. The incinerators shall be calibrated by an appropriate body and the certificate shall be presented to the appropriate organ upon request.

3. The following medicines waste shall not be incinerated by medium-temperature incineration:

a) Antineoplastics,
b) Pressurized gas containers,
c) Large amounts of reactive chemical waste,
d) Silver salts and photographic or radiographic wastes,
e) Halogenated medicines,
f) Halogenated plastics such as polyvinyl chloride (PVC),
g) Waste with high mercury or cadmium content, such as broken thermometers, used batteries, and lead-lined wooden panels, and
h) Sealed ampoules or ampoules containing heavy metals.

4. The final ash shall not be left to open air. It shall be collected and dumped into landfill which appropriate bodies have participated at selecting.

18. High-Temperature Incineration

1. High-temperature incinerators shall be double chamber design or pyrolytic which operate at a temperature combustion process in excess of 1,200^{0}C with a combustion retention time of at least two seconds in the second chamber.
2. High-temperature incinerators shall be fitted with gas cleaning equipment.
3. The incinerators shall be calibrated by an appropriate body and the certificate shall be presented to the appropriate organ upon request.
4. Health institutions and disposal firms may use industrial plant cement kilns for halogenated products and antineoplastics.

5. Medicines waste shall be introduced into the furnace as a reasonably small proportion of the total fuel feed (i.e. not more than 5%) at any one time.
6. It may be necessary to remove packaging materials and/or to grind the medicines to avoid clogging and blocking the fuel feed mechanisms.
7. High temperature incinerators may be used for disposal of halogenated compounds, antineoplastics, X-ray contrast media and povidone iodine.
8. The final ash shall not be left to open air. It shall be collected and dumped into landfill which appropriate bodies have selected.

Part Four: Sorting, Storing and Transporting of Medicine Wastes

19. Sorting, Storing and Transporting

1. Sorting of medicines waste shall be done before choosing the appropriate disposal method.
2. An inspector of the appropriate organ shall supervise and verify that sorting of medicines waste is done properly and shall determine the optimal disposal method.
3. The health institution or disposal firm shall assign personnel who are trained on sorting criteria, safety and risks associated with handling medicines wastes.
4. During sorting and verification process, staff shall be supplied with personal protective equipment.
5. Sorting shall be done in open air or at a well ventilated covered area as close as possible to the stockpile.
6. The sorting process shall include:
    a) Identifying each item (quantity, type of packaging material and state of the product e.g. expired, damaged, spilled, unsealed or any other),
    b) Determining whether it is useable,
    c) If usable, leaving packaging intact,
    d) If not usable, making a judgment on the optimal method of disposal and sorting accordingly, and
    e) Leaving packages and boxes intact until reaching definitive disposal location.
7. Sorting shall be done to separate the following medicines waste depending on the disposal method needed:
    a) Controlled drugs or substances,
    b) Antineoplastics or cytotoxic/anti–cancer medicines and other toxic medicines,
    c) Radiopharmaceuticals,
    d) Anti-infective medicines,

e) Hazardous non-medicine products like antiseptics and disinfectants, and
f) Other medicines waste by dosage form:
    I. Solids, semisolids and powders (tablets, capsules, granules, powders for injection, mixtures, creams, lotions, gels, suppositories, etc.),
    II. Liquids (solutions, suspensions, syrups and ampoules), and
    III. Aerosol canisters (propellant-driven sprays and inhalers)

8. The containers/receptacles containing sorted medicines waste shall be labeled and kept in a dry, secure and preferably a separate room.

9. Transporting of sorted medicines waste to temporary storage place and disposal sites shall be done in closed motor vehicles to avoid pilferage.

Part Five: Types of Medicines Waste and Their Disposal Methods

20. Solids, Semi-Solids and Powders

1. Solid, semi-solid and powder dosage forms of anti-infectives, controlled medicines, antineoplastics, and disinfectants shall be disposed according to article 23, 24, 25, and 26 respectively.

2. Solid, semi-solid and powder medicines waste shall be disposed by high temperature incineration.

3. Without prejudice to sub-article (2) of this article, in the absence of high temperature incineration, medium temperature incineration and landfill after immobilization shall be used.

4. Medicines categorized as readily biodegradable organic material in a solid or semi-solid form shall be disposed of in a landfill and covered immediately by 15 centimeter thick municipal waste.

5. The disposal of solid, semi-solid and powder medicines shall comply with the following procedures:

a) Solids, semi-solids and powders shall be removed from their outer packaging but shall remain in their inner packaging and placed in clean plastic or steel drums, for treatment according to the encapsulation method.
b) Outer packaging shall be disposed of as non-drug, non-chemical materials by recycling or burning.
c) The separation of materials shall be as follows:
    I. Tablets and capsules in plastic/foil blisters shall be removed from all outer packaging but not from blisters;
    II. Tablets and capsules in bottles shall be removed from outer packaging but not from bottles;
    III. Tablets and effervescent in tubes shall be removed from outer packaging but not from tubes;
    IV. Powders in sachets or bottles shall be removed from outer packaging but not from sachets or bottles.
d) Loose tablets may be mixed with other medicines waste in several different steel drums.

21. Liquid Medicines

1. Liquid medicines waste may be disposed of using the cement encapsulation method, high temperature incineration or in cement kilns.
2. Medicines with no or low toxicity that can be categorized as readily biodegradable organic material such as liquid vitamins and IV fluids may be diluted and flushed into sewer. Harmless solutions of different concentrations of certain salts, amino acids, lipids or glucose shall also be disposed of in sewers.
3. Without prejudice to article (15), small quantities of liquid medicines may be flushed into sewer.
4. It is not acceptable to discharge liquid medicines, diluted or not, into any surface waters.

22. Ampoules

1. Ampoules shall be crushed on a hard impermeable surface or in a metal drum or bucket.
2. Without prejudice to sub-article (1) of this article:
    a. The crushed glass shall be swept up, placed in a container suitable for sharp objects, sealed and disposed of in a landfill,
    b. The liquids released from the ampoules shall be diluted and disposed in accordance with article 21.
3. Ampoules of antineoplastics or anti-infective medicines shall not be crushed and the liquid shall not be discharged to sewers. They shall be disposed using the encapsulation or inertization method.
4. Ampoules shall not be burnt or incinerated.
5. When disposing ampoules, workers shall wear personal protective equipment.

23. Vials

1. Vials shall be crushed and disposed using the encapsulation or inertization method.
2. Vials of antineoplastics and anti-infective medicines shall not be crushed and the liquid shall not be discharged to sewers.
3. Liquids released from vials of medicines other than antineoplastics or anti-infective medicines shall be diluted and disposed in accordance with liquid disposal procedures of this directive.

24. Anti-infective Medicines

1. Anti-infective medicines shall not be discarded in an untreated form.
2. Anti-infective medicines shall be incinerated, but if that is not possible shall be encapsulated or inertized.
3. Liquid anti-infective medicines shall be diluted in water, left for a minimum of two weeks and disposed to the sewer.

25. Controlled Substances

1. Controlled substances shall be closely monitored during disposal.
2. Controlled substances shall be segregated from other medicines waste and shall be kept separately in clearly marked containers with rigid walls,
3. Controlled substances shall not be crushed or removed from their packages until they are disposed.
4. Controlled substances shall be disposed by high temperature incineration or product immobilization (encapsulation or inertization) followed by covering with 15 centimeter thick municipal waste in landfills.
5. Disposal of untreated controlled medicines waste at landfills is prohibited.

26. Antineoplastics or cytotoxics/anti-cancer

1. Antineoplastic medicines waste shall be handled with great care.
2. Antineoplastics shall be segregated from other medicines waste and shall be kept separately in clearly marked containers with rigid walls.
3. Antineoplastics shall not be crushed or removed from their packages until they are disposed.
4. Antineoplastic wastes shall be disposed using two-chambered high temperature incinerators.
5. Without prejudice to sub-article (4) of this article, if disposal by high temperature incineration is not possible, antineoplastics or cytotoxics/anti-cancer medicines waste shall be disposed using landfills after encapsulation or inertization.
6. Disposal of antineoplastics or cytotoxics/anti-cancer wastes using landfills after encapsulation shall comply with the following procedures:
    a) The drums shall be filled to 50% capacity with medicines waste.
    b) A well-stirred mixture of lime, cement and water in the proportions of 15:15:5 (by weight) shall then be added to fill the drums to capacity.

c) The drums shall then be sealed by seam or spot welding and left to set for 7 to 28 days to form a firm, immobile, solid block of securely isolated wastes.
d) The drums shall later be placed at the working face of a landfill which has been lined with impermeable layer of clay or membrane.

7. Discarding antineoplastics or cytotoxics/anti-cancer medicines waste into the sewerage system, disposing by medium temperature incineration and landfill without encapsulation is prohibited.

27. Disinfectants

1. Small quantities of diluted disinfectants shall be disposed to the sewer provided that the operation is supervised by the appropriate regulatory body and the quantities are strictly controlled to set limits of maximum of 50 liters per day with the disposal spread over the whole working day.
2. Large quantities of disinfectants shall not be flushed into the sewer.
3. Disinfectants diluted or not, shall not be disposed into any surface water.

28. Aerosol Canisters

1. Aerosol canisters may be disposed of using landfill after encapsulation.
2. Provided that aerosol canisters and inhalers do not contain poisonous substances, they shall be disposed of in a landfill after dispersion in municipal solid wastes.
3. Disposable aerosol canisters and inhalers shall not be burnt or incinerated at high temperature.

29. Laboratory Reagents

1. Chemical waste shall be maintained in a secure area and access shall be limited to personnel who are properly trained.
2. Solid chemical waste may be collected in plastic bags, fiber boxes, or plastic containers.

3. Solid and liquid chemical waste shall not be mixed.
4. All chemical waste shall be segregated and properly stored to ensure chemical reactions will not occur if containers were to fail.
5. All hazardous chemical waste shall be stored in suitable containers which are compatible with the chemical contents of the waste and shall be sealed at all times unless waste is being added or removed.
6. Liquid containers shall not be filled full. An air gap of 5-10% shall be left in the container to allow for expansion of the liquid.
7. Before collecting waste in used containers, the containers shall be rinsed to avoid any incompatibility with the waste to be collected.
8. Accumulated chemical wastes (mixed liquid) shall be labeled with the date the accumulation started and the list of the chemical mix.
9. Hazardous chemical waste shall not be accumulated for more than one year.
10. Dilute acids or bases (free from heavy metals or halogens) shall be flushed with large amounts of water into the sewer system after being pH adjusted (between 6 and 9) in neutralization tanks.
11. Solutions of non-toxic chemicals that are miscible in water may be flushed into the sewer system.
12. The following chemical wastes shall not be flushed into the sewer system:
    a) Flammable (flashpoint less than 187^0F) or reactive chemicals,
    b) Concentrated acids or bases,
    c) Toxic heavy metals, carcinogenic/mutagenic or teratogenic chemicals that have not been neutralized or deactivated,
    d) Radioactive wastes,
    e) Unknown or unidentified chemicals, Solids, non-water soluble solvents, and viscous substances (oils and greases), and
    f) Expired or concentrated stock solutions of dyes.
13. The following organic chemical waste may be acceptable for sewer disposal in quantities of 25 liters or less:

a) Acetates: Na, K, Ca, and NH4,
b) Alcohols: water soluble, diluted to 10% or less,
c) Amino acids and their salts,
d) Citric acid and salts of Na, K, Mg, Ca, and NH4,
e) Ethylene glycol: diluted to 10% or less,
f) Lactic acid and salts of Na, K, Mg, Ca, and NH4, and
g) Sugars: dextrose, fructose, glucose, sucrose.

14. The following inorganic chemical waste may be acceptable for sewer disposal in quantities of 25 liters or less:
    a) Common acids and bases: neutralized, pH (6-9), no metals present,
    b) Bicarbonates: Na, K,
    c) Bleach,
    d) Bromides: Na, K,
    e) Carbonates: Na, K, Mg, Ca,
    f) Chlorides: Na, K, Mg, Ca,
    g) Iodides: Na, K,
    h) Phosphates: Na, K, Mg, Ca, NH4, and
    i) Sulfates: Na, K, Mg, Ca, NH4.
15. Flammable liquids which are chemically compatible and have low halogen content shall be blended together. The flammable solvent waste may be burned as fuel in cement kiln.
16. Halogenated solvents and toxic liquids shall be disposed by incineration.
17. Aqueous metal solutions shall be treated for metal recovery before disposal.
18. Organic solvents shall not be disposed in landfill.
19. Solid chemical wastes and non-blendable solvents are packed into plastic or fiber drums and shall be incinerated.

30. Medical Supplies

1. Expired syringes shall be buried in sharp pits or disposed using landfill after encapsulation.

2. Plastic syringes after being detached from the needles may be:
    a. Buried on-site or disposed of in a land fill after shredding by hand mill/ electric shredder, or
    b. Buried on-site or disposed of in a land fill without being shredded, or
    c. Recycled if plastic recycling plant exists.
3. Without prejudice to sub-articles (1) & (2), detached needles shall be disposed by incineration or landfill after encapsulation.
4. Expired gauze, cotton, suturing materials, bandages or IV sets may be disposed of as normal waste to landfill.
5. Used syringes, suturing materials, cotton, bandages, gauze, used IV sets, other similar articles and x-ray films are not treated in this directive.

Part Six: Miscellaneous Provisions

31. Inapplicable Laws

No directive or practice or circular letters shall, in so far as it is inconsistent with this directive, be applicable with respect to matters provided by this directive.

32. Effective Date

This directive shall enter into force one year from the date of signature by the Director General of the Authority.

Done at Addis Ababa, this 12th day of August, 2011.

YEHULU DENEKEW, Director General
The Ethiopian Food, Medicine and Health Care Administration and Control Authority

Annex I: Summary of Disposal Methods

Disposal Methods	Types of Medicines	Comments
Return to supplier, manufacturer or donor	All medicines waste, as per article 10 sub-articles (1)-(3) particularly antineoplastics.	
High temperature incineration with temperature in excess of 1200°C.	Solids, semisolids, powders, antineoplastics, controlled substances, halogenated compounds and plastics, X-ray contrast media and povidone iodine.	Expensive, particularly for purpose-built incinerators. Use of Existing industrial plants may be practical.
Medium temperature incineration with two–chamber incinerator with minimum temperature of 850°C. Cement kiln incineration	Solids, semi-solids, powders, controlled substances.	Antineoplastics best incinerated at high temperature.
Immobilization: Waste encapsulation	Solids, semi-solids, powders, liquids, antineoplastics and controlled substances.	
Waste inertization	Solids, semi-solids, powders, antineoplastics and controlled substances.	
Landfill: Highly engineered sanitary landfill	Limited quantities of untreated solids, semi-solids, powders, antineoplastics, controlled substances, PVC plastics and disposal of medicines waste after immobilization.	
Engineered landfill	Solids, semi-solids and powders preferably after immobilization, PVC plastics.	
Open uncontrolled non-engineered landfill	As a last resort, untreated solids, semi- solids and powders must be covered immediately with large amount of municipal waste. Immobilization of solids, semi-solids and powders is preferable.	Not for disposal of untreated controlled substances.
Sewer	Diluted liquids, syrups, intravenous fluids, small quantities of diluted disinfectants (supervised).	Antineoplastics, and undiluted disinfectants and antiseptics are prohibited.
Burning in open containers/area	Packaging materials, paper, leaflets, labels, posters and cardboard.	Prohibited for PVC plastics and medicines waste.

Annex II: Summary of Medicines Waste and Their Disposal Methods

Category	Disposal methods	Comments
Solids **Semi-solids** **Powders**	Landfill Waste encapsulation Waste inertization Medium and high temperature incineration (cement kiln incinerator)	
Liquids	Sewer High temperature incineration (cement kiln incinerator)	Antineoplastics shall not be disposed in sewer.
Ampoules	Crush ampoules and flush diluted fluid to sewer	Antineoplastics shall not be disposed in sewer.
Anti-infective medicines	Waste encapsulation Waste inertization Medium and high temperature incineration (cement kiln incinerator)	Liquid antibiotics may be diluted with water, left to stand for several weeks and discharged to sewer.
Antineoplastics	Return to supplier, manufacturer or donor, Waste encapsulation, Waste inertization, High temperature incineration (cement kiln incinerator)	Antineoplastics shall not be disposed into landfill unless encapsulated, and shall not be disposed by sewer or by medium temperature incineration.
Controlled substances	Waste encapsulation Waste inertization Medium and high temperature incineration (cement kiln incinerator)	Shall not be disposed into landfill unless immobilized.
Aerosol canisters	Landfill, waste encapsulation	Not to be burnt: may explode.
Disinfectants	To sewer: small quantities of diluted disinfectants (max. of 50 liters per day under supervision)	No undiluted disinfectants shall be disposed to sewer.
PVC plastic, Glass	Landfill	Shall not be disposed by burning.
Paper, cardboard	Recycle, burn or landfill	

Annex III: Medicines Waste Register Book

No.	Description of Medicines Wastes (generic & brand name, strength and dosage form)	Unit Type and Size	Quantity	Batch Number	Expiry Date	Reason for Disposal (expired, damaged, spilled, etc)	Manufacturer/ Supplier	Store Location	Purchase Value
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									

Annex IV: Medicines Waste Disposal Application Form

To: Appropriate Organ (when the applicant has its own disposal facility)

Subject: <u>Request for Medicines Waste Disposal</u>

I/We ----------of (address) ----------undertaking the business of (specify) ----------
---------- hereby apply for disposal of medicines waste.

License Number----------issued on----------

Location of Business----------

Name of person in charge ----------

Reason for disposal----------

Weight (in Kg) ----------

Value (in Birr) ----------

Attached herewith is the list of products to be disposed of.

Declaration:

I certify that the information provided in the application form is true and correct. Date of application----------

Signature of Applicant----------Stamp----------

Annex V: Medicines Waste Disposal Application Form

To: Disposal Firm (when the applicant is a health institution looking for disposal service)

Subject: <u>Request for Medicines Waste Disposal</u>

I/We ----------of (address) ----------undertaking the business of (specify) ----------

---------- hereby apply for disposal of medicines waste.

License Number----------issued on----------

Location of Business----------

Name of person in charge ----------

Reason for disposal----------

Weight (in Kg) ----------

Value (in Birr) ----------

Attached herewith is the list of products to be disposed of.

Declaration:

I certify that the information provided in the application form is true and correct.

Date of application---------- Signature of Applicant----------Stamp----------

Cc:

To appropriate organ

Annex VI: List of Medicines Waste to Be Disposed

No.	Description of Medicines Wastes (generic & brand name, strength and dosage form)	Unit type and size	Quantity	Batch Number	Expiry Date	Reason for Disposal (expired, damaged, etc)	Manufacturer/ Supplier	Country of Origin	Purchase value
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									

Annex VII: Certificate of Medicines Waste Disposal for Health Institution

Name of appropriate organ

Date of Disposal:

We undersigned below would like to certify that (name of disposal firm) _____with license number _____ located at_____ has disposed medicines wastes listed below under the direct supervision of (name of inspector) _____and disposal committee of this health institution.

No.	Description of Medicines Wastes (generic & brand name, strength & dosage form)	Unit type and size	Quantity	Batch Number	Expiry Date	Reason for Disposal	Disposal Method	Manufacturer/ Supplier	Country of Origin
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
Name and Signature of Inspector					Name and Signature of appropriate organ				

Copy Distribution: 1st copy to health institution and 2nd copy to appropriate organ

Name and Address of Disposal Firm	**Annex VIII: Certificate of Medicines Waste Disposal for Disposal Firm**	Name and address of appropriate organ Date of Disposal:

We undersigned below would like to certify that (name of disposal firm) _____ with license number_____ located at_____ has disposed medicines wastes listed below for (name of disposal service requester) _____ license number _____located at_____ under the direct supervision of (name of inspector)_____

No.	Description of Medicines Wastes (generic & brand name, strength & dosage form)	Unit type and size	Quantity	Batch Number	Expiry Date	Reason for Disposal	Disposal Method	Manufacturer/Supplied or Purchased from
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								

Name and Signature of Inspector	Name and Signature of appropriate organ

Copy Distribution: 1st copy to disposal firm, 2nd copy to health institution (disposal service requester) and 3rd copy appropriate organ

Annex IX: Referral / Receipt Form for Disposal Firm

Name of Disposal Firm

REFERRAL/RECEIPT FORM

Serial Number:

Date of Receipt:

I/We_____ undersigned below have received/issued medicines wastes listed below from (name of person) _____who is delegate of (health institution)_____ for safe disposal.

No.	Description of Medicines Wastes (generic & brand name, strength & dosage form)	Unit type & size	Quantity	Batch Number	Expiry Date	Reason for Disposal	Manufacturer/ Supplier	Country of Origin	Purchase Value
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									

Name and Signature of Receiver

Name and Signature of Issuer

Copy Distribution: 1st copy to disposal firm, 2nd copy to health institution *and 3rd copy to* appropriate organ

Annex X: Referral/Receipt Form for Supplier or Manufacturer

Name of Supplier or Manufacturer

REFERRAL/RECEIPT FORM

Serial Number:

Date of Receipt:

I/We_____ undersigned below have received/issued medicines wastes listed below from (name of person) _____who is delegate of (health institution)_____ for safe disposal.

No.	Description of Medicines Wastes (generic & brand name, strength & dosage form)	Unit type & size	Quantity	Batch Number	Expiry Date	Reason for Disposal	Manufacturer/ Supplier	Country of Origin	Purchase Value
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									

Name and Signature of Receiver

Name and Signature of Issuer

Copy Distribution: 1st copy to supplier or manufacturer 2nd copy to the health institution *and 3rd copy to* appropriate organ

Annex XI: License for Medicines Waste Disposal Firm

የኢትዮጵያ የምግብ፣የመድኃኒትና ጤና ክብካቤ አስተዳደርና ቁጥጥር ባለሥልጣን
FOOD MEDECINE AND HEALTH CARE ADMINISTRATION AND CONTROL AUTHORITY OF ETHIOPIA
ጥቅም ላይ የማይውሉ መድኃኒቶችን አስወጋጅ ድርጅት የብቃት ማረጋገጫ ምስክር ወረቀት
License for Medicines Waste Disposal Firm

□□ር□ቱ ስም _____ **ለማስወገድ የምጠቀምበት ዘዴ**_____
Name of the Organization _____ Type of Disposal Method being utilized ____

Address of the organization:
አድራሻ፣
□ልል _____**ክ/ከተማ** _____ **ዞን** _____ **□ረ□** _____
Region_____ Sub-city_____ Zone_____Woreda_____
ከተማ _____**ቀበሌ** _____**የቤት ቁ.**_____**ስል□ ቁ□ር** _____
City _____ Kebele _____ House No. _____Tel _____

□□ርጅቱ ባለንብረት ስም _____
Owner's Full Name _____
የድርጅቱ የቴክኒክ □ላ□ ስም _____
Technical Leader's Name _____
መ·□ _____**□ም□□ባ ቁ□ር** _____
Qualification _____Registration No._____

ድርጅቱ ተፈላጊውን ሙያዊ፣ ድርጅታዊና ሌሎች መሥፈርቶችን ማሟላቱን በተደረገው ኢንስፔክሽን ተረጋግጦ ይህ የብቃት ማረጋገጫ ምስክር ወረቀት በኢትዮጵያ የምግብ፣ መ□ኃኒትና ጤና ክብካቤ አስተዳደርና ቁጥር አዋጅ ቁጥር 661/2002 መሠረት በማድረግ ተሰጥቷል፡፡
This license is issued to the Medicines Waste Disposal Firm in accordance with Food, Medicine and Healthcare Administration and Control Authority Proclamation No 661/2002 after assuring the fulfillment of the required personnel, premises and other requirements through inspection.

_____ _____
የባለሥልጣንፊርማ **□ተሰጠበትቀን**
Signature of an Authorized Officer Date of Issue

□□ሷል Renewed 200 ____ E.C. 200 ____ G.C **የደረሰኝ ቁጥር** _____ R/No _____ **□ርማ** _____ Signature _____	□□ሷል Renewed 200 ____ E.C. 200 ____ G.C **የደረሰኝ ቁጥር** _____ R/No _____ **□ርማ** _____ Signature _____	□□ሷል Renewed 200 ____ E.C. 200 ____ G.C **የደረሰኝ ቁጥር** _____ R/No _____ **□ርማ** _____ Signature _____

□□ስ 251-1-521392 ✉ 5681 ☎ 524122/23