MEDICINES CONTROL AGENCY

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GUIDELINE FOR SAFE DISPOSAL OF MEDICINES AND RELATED PRODUCTS

Document number and version:	MCA-GL-304, Version 2
Date of implementation:	01 July 2020

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1. INTRODUCTION

1.1 LEGAL BASIS

1.1.1. The regulation of medicines and related products in The Gambia is governed by the provisions and requirements of the Medicines and Related Products Act, 2014 ("Act"), by which the Medicines Control Agency (MCA) was established as the regulatory body for medicines and related products.

1.1.2. The Medicines and Related Products Regulations, 2019 ("Regulations") details the legal requirements.

1.1.3. The Agency cooperates with the National Environmental Agency (NEA) concerning disposal of products.

1.1.4. The Agency charges non-refundable fees for disposal of medicines and related products as specified in the MCA Fee Schedule due at the time of application.

1.2 INTERPRETATION AND ABBREVIATIONS

Interpretations and abbreviations contained in the MCA Glossary can be found on the MCA Website: **www.mca.gm**

1.3 PURPOSE

1.3.1. This guideline provides advice on the safe disposal of unusable medicines and related products, as applicable and describes methods for safe disposal, which involve minimal risks to public health and the environment.

1.3.2. Safe disposal of medicines and related products forms part of their quality and rational use.

1.4 SCOPE

1.4.1. The guideline applies to medicines and related products as defined in the Act and the Regulations.

1.4.2. This document applies to the central medical stores and regional medical stores management as well as manufacturer/importers, wholesalers, retailers and health facilities (public, private and NGO).

1.4.3. It does not cover the disposal of other wastes generated by health facilities including for example, infectious waste, photographic chemicals, solvents, wastes with a high content of heavy metals (e.g. mercury and cadmium), laboratory wastes, or radioactive waste. Specialized advice for these categories of waste is available from World Health Organization (WHO).

1.4.4. In the following text, the term 'medicine' will only be used, but the guideline applies to related products accordingly.

2. PREREQUISITES FOR DISPOSAL

A series of steps need to be taken when disposing of unwanted medicines, and these are briefly summarised below.

2.1 DECISION:

2.1.1. The authorised person of the respective health facility decides when action needs to be initiated.

2.1.2. In the public sector the authorised person of the respective health facility should consult with the Directorate of National Pharmaceutical Services.

2.1.3. Medicines that always have to be considered as medicines waste include:

- all expired medicines;
- all unsealed syrups or eye drops (expired or unexpired);
- all cold chain (expired or unexpired) medicines that should have been stored in a cold chain but were not (for example: insulin, polypeptide hormones, gamma globulins and vaccines);
- all loose tablets and capsules;
- all unsealed tubes of creams, ointments, etc. (expired or unexpired);
- all punched or torn sachets of powders, granules, etc.

2.2 PLANNING:

2.2.1. Planning in terms of funding, necessary expertise, human resources, time, space, equipment, material and available disposal options will be required. This is essential before practical steps can be taken to start disposal.

2.2.2. To obtain a rough estimate of the volume of products to be disposed of, it is recommended that measurements are made using a tape measure, and conversion from volume of material to weight is made using a density figure of 0.2 metric tons/cubic metre.

2.2.3. The costs of safe disposal in the public sector are covered by the Ministry of Health (MoH); in the private sector/NGOs the costs are to be covered by their management.

2.3 APPROVAL:

2.3.1. Approval of disposal of medicines must be applied for in writing to the MCA indicating the products by name and description, their quantities and the planned method of disposal.

2.3.2. MCA will provide an approval letter for confirmation and to agree on a suitable date for disposal in due time.

2.4 FORMING TEAMS FOR DISPOSAL:

2.4.1. In the public sector disposal should be conducted by teams identified by the authorised person of the relevant health facility. The size of each team and the ratio of experts to workers will be determined by the volume and composition of the stockpiles and working conditions at the sites.

2.4.2. In the private sector/NGO a pharmacist or appropriate pharmaceutical personnel should conduct the disposal of medicines.

2.5 PREPARATION:

2.5.1. Unusable medicines should be removed from the shelves, packed in boxes, sealed and labelled 'Expired Products' or 'Unusable Products' and stored at a separate location within the facilities.

2.5.2. Appropriate storage and transportation requirements apply also to unusable medicines (see MCA *Guideline for Storage and Distribution of Medicines and Related Products*)

2.6 HEALTH AND SAFETY OF WORK TEAMS:

2.6.1. All workers should wear appropriate protective equipment including overalls and boots at all times, and gloves, masks and caps when appropriate.

2.6.2. Masks should be worn when tablets or capsules are being crushed as part of the disposal technique and when there is a risk of powders being liberated.

2.6.3. Particular care is required when handling antineoplastics (cytotoxic-anti-cancer medicines).

2.7 DISPOSAL:

2.7.1. Medicines are ideally disposed of by high temperature (e.g. above 1,200ºC) incineration. Other disposal methods can be used when incineration is not feasible.

2.7.2. The disposal procedure must be witnessed by an authorised representative of the MCA.

2.7.3. Secondary packaging should be disposed of as non-medicine, non-chemical materials.

2.8 SECURITY:

2.8.1. Controlled substances (e.g. narcotics and psychotropics) require tight security and control (see MCA *Guideline for Storage and Distribution of Medicines and Related Products*).

2.8.2. Scavenging of material from landfills is a frequent problem, and disposed medicines may be recovered and sold by the scavengers. Measures are therefore necessary to prevent diversion during preparation for disposal, and pilfering of medicines from landfills.

3. CONSEQUENCES OF IMPROPER DISPOSAL OR NON-DISPOSAL

3.1. In general, disposal of expired or otherwise unusable medicines do not represent a serious threat to public health or to the environment.

3.2. Improper disposal may be hazardous if it leads to contamination of water supplies or local sources used by nearby communities or wildlife.

3.3. Pilfering from a stockpile of waste medicines or during preparation may result in expired or otherwise unusable products being diverted to the market for resale and misuse. Most medicines past their expiry date

become less efficacious and a few may develop a different adverse drug reaction profile.

3.4. There are some categories of expired or otherwise unusable medicines or defective disposal practices that carry a public health risk. The main health risks are summarized below.

- Contamination of drinking water must be avoided. Landfills must be sited and constructed in a way that minimises the possibility of leachate entering an aquifer, surface water or drinking water system.
- Non-biodegradable antibiotics, antineoplastics and disinfectants should not be disposed of into the sewage system as they may kill bacteria necessary for the treatment of sewage. Antineoplastics should not be flushed into watercourses as they may damage aquatic life or contaminate drinking water. Similarly, disinfectants should not be discharged into a sewerage system or watercourse.
- Burning medicines at low temperatures or in open containers can result in release of toxic pollutants into the air and should be avoided.
- Inefficient and insecure disposal of expired or otherwise unusable medicines may cause scavengers to have access to these products and be diverted for resale to the general public.
- In the absence of suitable disposal sites and qualified personnel to supervise disposal, unwanted medicines should be securely stored in dry conditions. If stored in their original packing there is a risk of diversion and to avoid this they are best stored in sealed containers until safe disposal is feasible.

4. DISPOSAL METHODS

Large stockpiles do not usually accumulate, and waste medicines are best disposed of on a routine basis, small quantities at a time. The disposal methods are briefly described here.

4.1 RETURN TO DONOR OR MANUFACTURER

4.1.1. Wherever practical the possibility of returning unusable medicines for safe disposal by the manufacturer should be explored; particularly medicines which present disposal problems, such as antineoplastics. For unwanted, unrequested donations, especially those that arrive past or unreasonably near their expiry date it may be possible to return them to the donor for disposal.

4.1.2. Expired or spoiled medicines are categorised as wastes to be controlled and may be considered as hazardous waste. As such, if transferred across frontiers, they become subject to the *Basel Convention on the Transfrontier Shipment of Hazardous Wastes*. This involves prescribed procedures to obtain permission to cross international borders along the transit route prior to actual transport, which can take several months to complete.

4.1.3. For the exportation of unusable medicines an export permit by the Agency is required.

4.1.4. The Goods Receipt Note (GRN) by donor or manufacturer after the products have been returned should be provided to the Agency within 7 days of arrival.

4.2 HIGH TEMPERATURE INCINERATION

4.2.1. High temperature technology have furnaces that operate at temperatures well in excess of 1,200ºC, have long combustion retention times and disperse exhaust gases via tall chimneys to high altitudes.

4.2.2. It may be necessary to remove packaging and/or to grind the medicines to avoid clogging and blockage of the fuel feed mechanisms.

4.3 ENGINEERED LANDFILL

4.3.1. To landfill means to place waste directly into a land disposal site. Landfill is the oldest and the most widely practiced method of disposing of solid waste.

4.3.2. An appropriate (engineered) landfill consists of an evacuated pit isolated from watercourses and above the water table.

4.3.3. An engineered landfill has some features to protect from loss of chemicals into the aquifer. Properly constructed and operated landfill sites offer a relatively safe disposal route.

5. INAPPROPRIATE DISPOSAL METHODS

Note: Disposal by inappropriate methods can be hazardous and may lead to prosecution.

5.1 OPEN LANDFILL

5.1.1. Untreated waste discharged into an uncontrolled, non-engineered open dump does not protect the local environment and should not be used. Discarding of untreated waste medicines into such a site is not recommended.

5.1.2. Discarding medicines in open, uncontrolled dumps with insufficient isolation from the aquifer or other watercourses can lead to pollution, with the risk of drinking water contamination in the worst cases.

5.2 BURNING IN OPEN CONTAINERS

5.2.1. Medicines should not be destroyed by burning at low temperature in open containers, as toxic pollutants may be released into the air.

6. FINAL PROVISIONS

6.1. This guideline is the second version published by the MCA and will become effective on 01 July 2020.

6.2. The guideline will be reviewed before 5 years after becoming effective.

7. REFERENCES

- Medicines and Related Products Act, 2014
- Medicines and Related Products Regulations, 2019

- MCA Fee Schedule
- The Gambia National Medicines Policy, 2007
- MCA Guideline for Storage and Distribution of Medicines and Related Products (MCA-GL-301)
- WHO Good Distribution Practices for Pharmaceutical Products, Annex 5, WHO Technical Report Series 957, 2010
- WHO Guide to Good Storage Practices for Pharmaceuticals Annex 9, WHO Technical Report Series, No. 908, 2003
- Secretariat of the Basel Convention No. 97/012. Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal, 1998 and Decisions Adopted by the First (1992), Second (1994) and Third (1995) Meetings of the Conferences of the Parties (September 1997).

8. DOCUMENT HISTORY

Version #	Implementation Date	Reasons for Change:
1	13 December 2017	New document
2	01 July 2020	Editorial changes.