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# National Agency for Food & Drug Administration & Control (NAFDAC)

## Investigation & Enforcement (I & E) Directorate

# GUIDELINES FOR HANDLING AND DISPOSAL OF UNWHOLESOME MEDICINES AND NAFDAC REGULATED PRODUCTS (FOOD, MEDICINES, MEDICAL DEVICES, COSMETICS ETC.) IN NIGERIA

1. **General**

1.1. These Guidelines are for the general public and in particular, companies that intend to dispose of unwholesome NAFDAC regulated products.

1.2. It is necessary to emphasize that, no regulated product shall be manufactured, imported, exported, advertised, sold, distributed or used in Nigeria unless it has been registered in accordance with the provisions of NAFDAC Act CAP N1 (LFN) 2004, other related Legislations and the accompanying Guidelines.

1.3. Medicines and other regulated products shall be considered as unwholesome when they are:-

1.3.1. expired

1.3.2. improperly sealed

1.3.3. damaged, and improperly stored

1.3.4. improperly labeled

1.3.5. counterfeit, substandard and adulterated

1.3.6. prohibited

1.3.7. unauthorized

2. **Handling Of Unwholesome Medicines and Other NAFDAC Regulated Products at Facility Level**

2.1. In order to properly manage unwholesome medicines and NAFDAC regulated products at a facility level, the following requirements shall be adhered to:

2.1.1. Maintain an inventory book (Annex I) for unwholesome medicines and other NAFDAC regulated products.

2.1.2. Sort them into different categories by dosage form such as:-

2.1.2.1. Solids, semi-solids and powders: capsules, powders for injection, tablets, granules, creams, gels, suppositories etc.

2.1.2.2. Liquids: Solutions, suspension, syrups, mixtures, lotions, aerosol, inhalers etc.

2.1.2.3. Raw Materials: Solids, semi-solids and powder; chemical compositions etc.

2.1.3. Keep separately medicines which fall under controlled drugs, antineoplastic, antibiotics and any other hazardous medicines or materials.

2.1.4. Store in containers according to their dosage forms to facilitate verification exercise, sorting and selection of disposal method.

2.1.5. Demarcate an area for storing expired/unwholesome medicines and NAFDAC regulated products which shall be labeled conspicuously with words; Expired Products, Not for Sale, or in red ink.

2.1.6. Maintain safe custody of unwholesome NAFDAC regulated products in registered premises or facility until they are disposed of to avoid pilferage.

2.1.7. The decision of when to initiate disposal of unwholesome medicines and NAFDAC regulated products shall be made jointly by Superintendent pharmacist, owners, officer-in-charge of facility and inspectors (including inspectors at ports of entry) to avoid accumulation of such products.

2.1.8. Application for disposal of unwholesome medicines from Government institutions shall be accompanied by an approval from the head of the institution.

3. **Application for Disposal of Unwholesome Medicines and Other NAFDAC Regulated Products**

3.1. A written application for the destruction of unwholesome medicine or NAFDAC regulated products should be made on the company's letter head paper and addressed to the Director-General, National Agency for Food and Drug Administration and Control (NAFDAC), ATTENTION: Director, Investigation and Enforcement (I & E)

3.2. The letter should be submitted at the Liaison Office of the Director (I&E), NAFDAC, Apapa. The following information should be indicated in the letter:

3.2.1. The name of product and the quantity

3.2.2. Type of destruction [General destruction organized by the Agency; or Private destruction at the instance of the company].

3.3. The request shall be accompanied with an inventory of the products to be disposed of and should clearly state:

3.3.1. Product name

3.3.2. Manufacturer's name and address

3.3.3. Manufacturing date and Expiry date

3.3.4. Batch number

3.3.5. Product category (food, drug, cosmetics etc.)

3.3.6. pharmacological class (if medicine)

3.3.7. Country of source (if imported),

3.3.8. Quantity

3.3.9. Market value

3.3.10. Reason for destruction (Annex I)

4. **Sorting and verification exercise**

4.1. The premises will be visited by NAFDAC Officer(s) to verify and authenticate the information submitted, supervise sorting exercise of unwholesome medicines and other NAFDAC regulated products before determination of disposal method.

4.2. Sorting shall be done in an open or in a well-ventilated area/building as close as possible to the stock pile in an orderly manner.

4.3. Verification process shall involve the following stages.

4.4. Identification of the product.

4.5. Separation of medicines which fall under controlled drugs, antibiotics and any other hazardous materials/products.

4.6. Staff involved in sorting exercise shall be provided with protective gears such as gloves, boots, overalls and dust masks and shall be briefed on the sorting exercise, health and safety risks associated with handling the materials.

5. **Payment**

5.1. Upon approval of the application, the company is contacted to obtain a payment advice.

6. **Scheduling of Destruction Exercise**

6.1. Upon presentation of evidence of payment to the Agency, a date is scheduled for the destruction exercise.

7. **Destruction**

7.1. Destruction of unwholesome medicines and other NAFDAC regulated products shall involve the following procedures:

7.1.1. A regulatory officer and/or policemen shall supervise the transport of consignment from the storage premises to the disposal site for destruction exercise. The cost/logistics of the transportation shall be the responsibility of the owner of the product.

7.1.2. Unwholesome medicines and cosmetic products shall be transported in a closed motor vehicle to avoid pilferage.

7.1.3. The destruction exercise shall be supervised by a team of Regulatory Officers, Environmental Officer, company representative(s) and/or policemen.

7.1.4. Supervisors shall wear protective gears such as overalls, gloves, masks, caps and boots during the exercise.

7.1.5. Upon completion of the exercise, a Destruction Witness Form shall be duly filled in and signed by the supervisors and owner/owner's representative.

7.1.6. The Destruction Witness Form shall be attached to the report of destruction and submitted to the office of the Director (I&E) by the Regulatory Officer that supervised the exercise.

8. **Certificate of Destruction**

8.1. A written application for Certificate of Destruction should be made to the Director (I&E) and the detailed inventory of the product(s) destroyed is attached.

8.2. The Certificate of Destruction is issued to an authorized representative of the company.

9. **Note**

9.1. The Agency is responsible for the planning and cost of logistics for General Destruction.

9.2. Planning and cost of logistics for Private Destruction shall be borne by the owner of the product and supervised by the Agency.

All correspondences should be addressed to:-

Director-General (NAFDAC),

**Attn:** The Director
Investigation and Enforcement Directorate
National Agency for Food and Drug Administration and Control (NAFDAC),
10/15, Mobil Road, Apapa, Lagos.
NAFDAC website: www.nafdac.gov.ng
E-mail: enforcement@nafdac.gov.ng
Telephone no.:

**All submissions should be made at the Office of the Director, I&E, NAFDAC Office Apapa, Lagos or the nearest NAFDAC Office (for those outside Lagos).**