



health

Department:
Health
PROVINCE OF KWAZULU-NATAL

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POLICY AND PROCEDURES FOR THE DISPOSAL OF PHARMACEUTICAL WASTE

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Policy Number	KZN PS-POL/SOP-2015-001

POLICY

1. SCOPE OF THE POLICY

This policy should be read in conjunction with:

Legislation:

- a) The Medicines and Related Substances Control Act (Act 101 of 1965), and its supporting Regulations.
- b) Environmental Management Act (Act 107 of 1998)
- c) Standards Act (Act 29 of 1993)
- d) Occupational Health and Safety Act (Act 85 of 1993)
- e) Hazardous Substances Act (Act 15 of 1973)
- f) Pharmacy Act, 1974 (Act 53 of 1974)

Codes, Guidelines and Policies

- a) KZN DOH Policy on Health Care Risk Waste Management
- b) National Waste Management Strategy
- c) Current Contract with Waste Service Provider
- d) SABS Code of Practice - SANS 10248:2004, 2008, 2011 "Management of Healthcare Waste"
- e) Guidelines for the Destruction of Schedule 5 Medicines and Substances – Medicines Control Council
- f) SAPC: Rules Relating to Good Pharmacy Practice (BOARD NOTICE 34 OF 2012)

NOTE: This policy does not cover the disposal of Radioactive Pharmaceutical Waste.

2. DEFINITIONS

For the purpose of this policy, "**Pharmaceutical Waste**" will mean:

- Expired, unused, unusable, spilt and contaminated pharmaceutical products, medicines, cytotoxic preparations, vaccines, sera that are no longer required and need to be disposed of appropriately.
- Items used in the pharmacy for the handling/manipulation of pharmaceuticals e.g. bottles, boxes, ampoules, vials with residue, gloves, masks, connecting tubing.

"**Contractor**" will mean:

The waste management company contracted to the Department in terms of contract ZNT 5027/98: Disposal/Removal of Waste or any contract that replaces said contract.

"**Disposal**" will mean:

The removal of medicines and scheduled substances destined for destruction without the intention of retrieval, in compliance with existing legislation.

"**Destruction**" will mean:

Rendering of medicines and scheduled substances unusable or irretrievable for use or consumption, taking into consideration the environment and harm to health.

3. GENERAL PRINCIPLES

- 3.1 The destruction of pharmaceutical waste is described in regulation 27 of the General Regulations to the Medicines and Related Substances Act (Act 101 of 1965) as amended. Additional minimum standards to Annexure A of the Rules relating to good pharmacy practice in terms of section 35A(b)(ii) of the Pharmacy Act 53 of 1974, as amended, were published in Board Notice 34 of 2012, regarding destruction and disposal of medicines and scheduled substances.

- 3.2 All disposal and subsequent destruction must take place in accordance with provincial policy as well as local municipal regulations regarding the disposal of chemical or medicinal waste. The person responsible for the destruction may be requested to prove that the method of destruction is in accordance with such regulations.
- 3.3 All medicines and scheduled substances (including medicines and scheduled substances returned by patients) must be destroyed in such a manner that does not allow recovery or retrieval.
- 3.4 In respect of schedule 5 and 6, a person authorised by the Director General: Health must provide a certificate of destruction and in the case of an officer of the South African Police Services (SAPC); a case number must be provided. These references must be kept with the relevant record or register for a period of 5 years.
- 3.5 All quantities destroyed must be recorded in the relevant record or register on the date of destruction and signed by the person responsible for the destruction, indicating the reference to the destruction certificate or case number as the case may be.

PURPOSE

The purpose of this document is to ensure that the disposal and destruction of medicines and scheduled substances within pharmacies is undertaken safely and in accordance with the requirements of Regulation 27 of the General Regulations of the Medicines and Related Substances Act, 101 of 1965, relevant waste legislation and with due regard to minimising the risk of such an activity causing harm to the environment or harm to health.

DISPOSAL PROCEDURES

The disposal procedures are separated into Medicines up to and including Schedule 4 and Schedule 5 & 6 medicines.

Medicines and scheduled substances destined for destruction should be separated into six types and labelled accordingly:

- (a) Solid dosage form;
- (b) Creams, ointments and powders;
- (c) Ampoules and liquids (contained in glass);
- (d) Aerosols;
- (e) Cytostatic and cytotoxic medicines
- (f) Scheduled 5 and 6 substances.

1. Medicines up to and including Schedule 4

LEGISLATIVE REQUIREMENTS

If a contractor is not used, a medicine containing Schedule 1, 2, 3, and 4 substances may only be destroyed in the presence of a pharmacist or an authorised person in charge of a place where medicines and scheduled substances are kept. Such pharmacist or authorised person shall certify such destruction.

1.1 Collection of Pharmaceutical Waste

All pharmaceutical waste from wards and clinics must be returned to the Pharmacy. The ward or clinic must compile a list that must reflect:

- a) Name,
- b) Schedule,
- c) Quantity
- d) Strength
- e) Dosage form
- f) Batch number,
- g) And expiry date

Medicines returned by patients/families of patients must be collected by the pharmacy but need not be itemised.

These medicines must be rendered unusable by removal of outer cardboard packaging and from PVC blister packs, and disposed into a communal bin labelled “**miscellaneous medicines returned by patients**”.

1.2 Filling of Green Specibins

- Solid dosage forms must be removed from their packaging and be disposed into the Green Specibins mixed.
- Substances that have the potential to react with others must be disposed in separate containers.
- Medicines packed in PVC blister packs must be removed from the blister packing before disposing them in the Green Specibin. The blister packaging must be discarded with the general waste in black bags.
- Liquid dosage form medicines must be disposed in their bottles into the Green Specibins.
- Waste aerosol dispensers must be stored separately in black plastic bags and marked “Waste aerosol dispensers” in such a way that they can be easily identified from general waste (SANS 10248 - 7.3.4.2.1).
- Cytotoxic substances must be packed separately from other waste. Green Specibins must be used (SANS 10248 – 4.3.3 table 1). These containers must carry a Cytotoxic hazard label (SANS 10248 – 4.4.2) – supplied by the contractor.
- Once filled to the correct level, they must be permanently closed preventing the reopening of the container.

1.3 Labelling of sealed Green Specibins

- A unique reference number must be marked on the Green Specibin with a permanent marker.
- A structured sequence for numbering must be followed to ensure that each Green Specibin is given a different, traceable number.
- This reference number must also appear on the contents list and in a register of Green Specibin numbers that must be kept by the pharmacy.
- A list of items included in each Green Specibin must be completed – using **Annexure A**.

1.4 Storage

- Pharmaceutical waste must be stored separately from the general waste in the pharmacy disposed in appropriately sized tamperproof Green Specibins.
- The Green Specibins are available from the contracted waste disposal company.
- The containers must be carefully packed.

1.5 Board of Survey

Before any expired, unused, unusable medicines are destroyed, a Board of Survey (BOS) **must** be convened. The items recommended for destruction must be safely and securely stored until the collection for destruction takes place.

Note: Medicines returned by patients/families of patients should not be included in the Board of Survey.

1.6 Contacting Contractor to Remove Waste

When a reasonable quantity of sealed Green Specibins has been collected, the Pharmacy Manager must liaise with the Institution’s Waste Management Officer to contact the contractor and arrange for the collection and disposal of the waste. Copies of all Green Specibin contents must be provided to the contractor.

1.7 Removal of Pharmaceutical Waste from the Pharmacy

- The Contractor collecting the Pharmaceutical Waste must produce the waste manifest listing the items to be collected.
- The institution’s Waste Management Officer and the pharmacist will be responsible for checking this list against the waste to be removed and recording the details on the Waste Collection Document

(WCD) for Pharmaceutical and Medicinal Products.

- The Contractor must record the reference number of each Green Specibin on the WCD. This will enable the waste to be tracked from pharmacy of origin to final destruction.
- The Contractor will load the Green Specibins onto the vehicle removing them from the facility.
- The contractor takes responsibility for the waste from collection until final destruction.

1.8 Destruction

- The contractor is responsible for the sealed Green Specibins from the time of collection from the pharmacy until they are destructed.
- The contractor must provide the facility with the destruction certificate signed by those who witnessed the destruction.
- The Destruction Certificate must be referenced against the relevant Green Specibin in the Green Specibin Register.
- The Destruction Certificate must be securely stored with the Board of Survey form for at least 5 years.

2. Schedule 5 and 6 Medicines

LEGISLATIVE REQUIREMENTS

- For medicines and scheduled substances containing a Schedule 5 and 6, the Responsible Pharmacist of the institution/facility where the medicines and scheduled substances are kept, should first obtain approval for destruction from a person duly authorised by the Director General: Health.
- The medicines and scheduled substances may only be destroyed in the presence of an inspector, an officer of the South African Police Services or any other person authorised by the Director General. Such person or officer, as the case may be, shall issue a certificate confirming the destruction of the medicine and in the case of an officer; the case number must be entered in the register.

2.1 Collection of Pharmaceutical Waste

All Schedule 5 and 6 pharmaceutical waste from wards and feeder clinics must be returned to the Pharmacy at the main hospital

The following details should be recorded:

- (a) Name, quantity, strength, batch numbers (if applicable) and dosage form of the medicines and scheduled substances;
- (b) Date of expiry of the medicines and scheduled substances;
- (c) The name, position and signature of the person and the witness disposing of the medicines and scheduled substances;
- (d) The reason for disposing the medicines and scheduled substances e.g. expiry, damage, obsolete

Medicines returned by patients/families of patients must be collected by the pharmacy but need not be itemised. These medicines must be rendered unusable by removal of outer cardboard packaging and from PVC blister packs, and disposed into the Green Specibin labelled “**miscellaneous medicines returned by patients**”.

2.2 Obtaining Approval for Destruction

- The Responsible Pharmacist/Pharmacy Manager must request permission for destruction in writing from the Directorate: Inspectorate and Law Enforcement, National Department of Health:

Contact: Rirhandzu Doris Hlungwani

Tel: 012 395 8661

Fax: 086 632 9200

Email: hlungd@health.gov.za

- The request should be made on the institution/facility letterhead stating the following details:

- (a) Name, quantity, strength, batch numbers (if applicable) and dosage form of the medicines and scheduled substances
- (b) The date of expiry of the medicines and scheduled substances

2.3 Filling of Green Specibins

- Separate Green Specibins must be used for the disposal medicines and scheduled substances containing a Schedule 5 and 6.
- Solid dosage forms must be removed from their packaging and be disposed into the Green Specibins mixed.
- Medicines packed in PVC blister packs must be removed from the blister packing before disposing them in the Green Specibin. The blister packaging must be discarded with the general waste in black bags.
- Liquid dosage form medicines must be disposed in their bottles into the Green Specibins.
- Once filled to the correct level, they must be permanently closed preventing the reopening of the container.

2.4 Labelling of sealed Green Specibins

- A unique reference number must be marked on the Green Specibin with a permanent marker.
- A structured sequence for numbering must be followed to ensure that each Green Specibin is given a different, traceable number.
- This reference number must also appear on the contents list and in a register of Green Specibin numbers that must be kept by the pharmacy.
- The Green Specibins must be marked that they contain medicines and scheduled substances containing a Schedule 5 and 6.
- A list of items included in each Green Specibin must be completed – using **Annexure A**.

2.5 Storage

- The Green Specibins containing medicines and scheduled substances containing a Schedule 5 and 6 must be stored locked away

2.6 Board of Survey

Before any expired, unused, unusable medicines are destroyed, a Board of Survey (BOS) **must** be convened. The Green Specibin containing the medicines and scheduled substances recommended for destruction must be kept locked away until collection for destruction.

2.7 Contacting Contractor to Remove Waste

- The Pharmacy Manager must ensure that all the required documents are obtained before the contacting the contractor.
- The Green Specibins containing medicines and scheduled substances 5 and 6 should be disposed of at the same time as the medicine containing schedule 1, 2, 3, and 4 to contain the contractor's collection trips.
- The Pharmacy Manager must liaise with the Institution's Waste Management Officer to contact the contractor and arrange for the collection and disposal of the waste.
- Copies of all Green Specibin contents must be provided to the contractor.

2.8 Removal of Pharmaceutical Waste from the Pharmacy

- If a contractor is not used, at least one pharmacist and one member of the pharmacy support personnel must witness the removal and the destruction of the correct quantities of the medicines and scheduled substances authorised for destruction, regardless of the where the destruction will take place.

- In the case of where a contractor is used, at least one pharmacist and one member of the pharmacy support personnel must witness the removal of the medicines and scheduled substances authorised for destruction.
- The Contractor collecting the Pharmaceutical Waste must produce the waste manifest listing the items to be collected.
- The institution's Waste Management Officer and the pharmacist will be responsible for checking this list against the waste to be removed and recording the details on the Waste Collection Document (WCD) for Pharmaceutical and Medicinal Products.
- The Contractor must record the reference number of each Green Specibin on the WCD. This will enable the waste to be tracked from pharmacy of origin to final destruction.
- The Contractor will load the Green Specibins onto the vehicle removing them from the facility.
- The contractor takes responsibility for the waste from collection until final destruction.

2.8 Destruction

- The destruction must be properly documented:
 - (a) All quantities destroyed must be recorded and in the case of specified Schedule 5 (where applicable) and schedule 6 medicines and scheduled substances, the quantities of medicines and scheduled substances to be destroyed must be indicated in the relevant register and signed by the witnesses required in the procedure.
 - (b) Destruction Certificates (where applicable) and the letter of authorisation by the person duly authorised by the Director General: Health must be referenced in, or attached to the relevant specified schedule 5 and schedule 6 register and retained for the same period of time as the register itself (5 years)
- The contractor must issue a Certificate of Destruction, which must include at least the following:
 - (a) Name of the person/contractor/company who has issued the Certificate of Destruction;
 - (b) The details of the pharmacist responsible for the destruction;
 - (c) The date of destruction of the medicines and scheduled substances;
 - (d) A list of the medicines and scheduled substances destructed

4. SCHEDULE 5 and 6 REGISTERS for SPECIFIED SCHEDULE 5 and for SCHEDULE 6 SUBSTANCES

3.1 The quantities, and Green Specibin number, of any medicines or substances to be destroyed must be annotated in the relevant register on the date of collection for destruction.

3.2 The entries in the register must be signed by the two pharmacists who undertook the removal from stock, the rendering incapable of recovery and packaging for final destruction.

3.3 The Board of Survey report, case number (where applicable) and destruction certificate from the Contractor must be referenced in the relevant register. They must also be securely stored and retained for a period of 5 years.

5. REPORTING REQUIREMENTS

4.1 The certificate of destruction, once received from the contractor, must be retained in the institution's records for a minimum of 5 years. A copy must be sent to the District Pharmacy Manager, along with the total value of medicines that have been destroyed. It is also necessary to forward a copy of the certificate to the Medicines Control Council.

4.2 Once the stock (all schedules) has been collected for destruction and written off the relevant registers, a loss report **must** be completed and sent to Financial Management at Head Office – see intranet for form and procedure. A copy of the Board of Survey and certificate of destruction should accompany the loss report form.

6. MONITORING OF STOCK

5.1 It is the responsibility of the Pharmacy Manager to ensure that the quantities of medicines that need to be destroyed are kept to a minimum. Stocks of medicines, irrespective of where they are kept in an institution or

clinic, must be regularly checked to ensure that short-dated and slow moving stock is regularly rotated and if necessary redistributed for use.

5.2 It may be inevitable that some stock will have to be destroyed from time to time. Pharmacy Managers must ensure that Boards of Survey are conducted on a regular basis so that the stock that may have to be destroyed at any one time is kept to manageable quantities.

Pharmaceutical Waste for Destruction – up to and including Schedule 6 medicines



ANNEXURE A

HOSPITAL:		SPECIBIN SIZE:	
PHARMACIST:		BIN REFERENCE NUMBER:	
BOARD OF SURVEY date		Disposal date	

	Name of Medicine	Schedule	Quantity	Packaging (tablets, ampoules, boxes, bottles, etc)	Expiry date	Contractor's signature	Pharmacist Signature
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							
16							
17							
18							
19							
20							

Name; Qualifications and Signature of Pharmacy Manager or Authorised person _____ Date _____