health
Department of Health
NORTHERN CAPE

Policy on Disposal of Medicine and Scheduled Substances (Pharmaceutical Waste)

Version control

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PolicyAim

1. The aim of this policy is to ensure that the disposal[1] and destruction[2] 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 the health of the public.

Policy Scope

2. This policy is applicable to all pharmacists and pharmacy assistants as well as all other Health Care Professionals providing a pharmaceutical related service to patients within the Northern Cape Department of Health.

Policy Statement

3. It is the policy of the Northern Cape Department of Health that the handling(s) of expired, damaged, contaminated and obsolete pharmaceuticals are adhered to in accordance with the following principles:

3.1. General

3.1.1. A suitable and adequate means of waste disposal must be available and in use as specified in the Good Pharmacy Practise. All destruction must take place in accordance with local municipal regulations regarding the disposal of chemical or medicinal waste.

3.1.2. The person responsible for the destruction may be requested to prove that the method of destruction is in accordance with such regulations.

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[1] Disposal in terms of these Rules shall mean the removal of medicines and scheduled substances destined for destruction without the intention of retrieval in compliance with existing legislation

[2] Destruction in terms of these Rules mean rendering the medicines and scheduled substances unusable or irretrievable for use or consumption, taking into consideration the environment and harm to health

3.1.3. 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 of these items.

3.1.4. In respect of schedules 5 and 6 medication, a person authorised by the Head of Department for Health must provide a certificate of destruction and in the case of an officer of the South African Police Services (SAPS); a case number must be provided. These references must be kept with the relevant record or register for a period of 5 years at the institution or facility which have requested the destruction.

3.2. **Identifying and Removal of Medicines to be Destroyed**

3.2.1. All products that are received should be checked for the following:

3.2.1.1. Expiry dates;

3.2.1.2. Integrity of the containers;

3.2.1.3. Quality of the product; and

3.2.1.4. Absence of contamination.

3.2.2. Any product not meeting the above requirements must be returned to the supplier or set aside for destruction.

3.2.3. Should any of the products already be on the shelves of Health Care Facilities / Institutions and be found to have expired, become contaminated or damaged; these items must be removed from stock immediately to prevent the risk of these products being issued to patients.Printed packing materials (cartons, containers) must be defaced to prevent further usage there-of.

3.2.4. All identified products must be placed in an appropriate container in a designated area. The container must be clearly marked: **FOR DESTRUCTION – DO NOT USE**.

3.2.5. Adjustments need to be made to stock quantities to record the removal of these products and reason for removal.

3.2.6. Arrangements must be made with an approved Waste Management company for the destruction of these medicines.

3.3. **Legislative Requirements for the Destruction of Medicine and Schedule Substances**

3.3.1. If a contractor is not utilised, then medicine classified as 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.

3.3.2. For medicines and scheduled substances classified as Schedule 5 and 6 substances, 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 Head of Department for Health. This request should be made on the institution/facility letterhead stating the following details:

3.3.2.1. Name, quantity, strength, batch numbers (if applicable) and dosage form of the medicines and scheduled substances.

3.3.2.2. The expiry date of the medicines and scheduled substances.

3.3.3. The scheduled 5 and 6 substances may only be destroyed in the presence of a council inspector[1], a police officer of the South African Police Service or any other person authorised by the Head of Department for Health. Such person or officer, as the case may be, shall issue a certificate confirming the destruction of the medicine and in the case of a police officer the case number must be entered in the register.

3.3.4. Notwithstanding, the Medicines Control Council may authorise in writing the destruction of specified schedule 5 and 6 substances by a manufacturer of such substances in the absence of an inspector.

[1]Person appointed by the South African Pharmacy Council to inspect Pharmacies.

3.4. **Destruction of Medicines**

3.4.1. 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.

3.4.2. The destruction must be properly documented;

3.4.2.1. All quantities of the medicine and scheduled substances which will be destroyed must be recorded and in the case of specified schedule 5 (where applicable) and schedule 6 medicines, the quantities of these scheduled substances which will be destroyed must be recorded in the relevant register and signed by the witnesses required in the procedure.

3.4.2.2. Destruction certificates (where applicable) and the letter of authorisation by the person duly authorised by the Head of Department for 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 that being 5 years.

3.4.3. The following details should be recorded;

3.4.3.1. Name, quantity, strength, batch numbers (if applicable) and dosage form of the medicines and scheduled substances;

3.4.3.2. Expiry date of the medicines and scheduled substances;

3.4.3.3. The name, position / rank and signature of the person and the witness destroying the medicines and scheduled substances;

3.4.3.4. The reason for the destruction; and

3.4.3.5. The date of destruction.

3.5. **Minimum Requirements for the Destruction of Medicines and Scheduled Substances**

3.5.1. Medicine and scheduled substance must be destroyed as follows:

3.5.1.1. Destruction must be by a contractor who specialises in waste disposal regarding the disposal of chemical or medicinal waste;

3.5.1.2. If a contractor is not utilised, 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;

3.5.1.3. 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;

3.5.1.4. The contractor must appoint, as required from time to time, a pharmacist in charge to ensure that the medicines and scheduled substances are destroyed or disposed in such a manner that precludes their recovery;

3.5.1.5. The contractor must issue a Certificate of Destruction, which must include at least the following:

3.5.1.5.1. Name of the person/contractor/company who has issued the Certificate of Destruction;

3.5.1.5.2. The details of the pharmacist responsible for the destruction; and

3.5.1.5.3. The date of destruction of the medicines and scheduled substances;

3.5.1.5.4. A list of the medicines and scheduled substances to be destroyed.

3.6. **Minimum Requirements for the Disposal of Medicines and Scheduled Substances**

3.6.1. All damaged, contaminated or expired stock must be stored in a specified area that is enclosed, lockable and separate from usable stock.

3.6.2. After recording all stock destined for disposal, it should be separated and placed into the green waste containers according to types and labelled accordingly.

3.6.2.1. Solid dosage form medicines;

3.6.2.2. Ampoules;

3.6.2.3. Liquids, creams and ointments;

3.6.2.4. Aerosols;

3.6.2.5. Radioactive drugs;

3.6.2.6. Cytostatic and cytotoxic medicines; and

3.6.2.7. Others

3.6.3. In order for all medicines to be rendered unrecoverable, medicines need to be removed from any packaging. Tablets need to be removed from blister packing and crushed, liquids poured out and ampoules crushed.

3.7. **Safety Measures**

3.7.1. Storage area for unusable stock should be enclosed, lockable and separate from usable stock.

3.7.2. No medicines should be disposed of into municipal sewage system.

3.7.3. Precautions should be taken to protect the operator, the product and the environment from potential exposure.

3.7.4. Unusable stock should be clearly labelled.

Roles and Responsibilities

4. The **Head of Department shall**:

4.1. Appoint a person who has the power to approve the destruction of medicine.

5. The **Pharmacists / Pharmacist's Assistants shall**:

5.1. Adhere to all necessary legislation and guidelines stipulated in the Good Pharmacy Practice Manual while during the storage and destruction of pharmaceutical waste.

Review and Distribution

6. The Director for Pharmaceuticals is the responsible manager for this policy and for ensuring it is reviewed and updated.

7. This Policy will be reviewed after 3 years but not later than 5 years from the publishing date. If necessary an updated version will be issued, if not a formal cover letter will be issued to supplement the cover of this Policy (identifying a revised publication date).

8. The **Director for Policy & Planning** will distribute updated versions to:

- Member of the Executive Council for Health
- Head of Department of Health
- All Chief Directors, Directors and Deputy Directors (who will in turn distribute to their staff as appropriate.)

Acknowledgements and Sources

9. Pharmacy Act (Act no 53 of 1974)

10. Medicine and Related Substances Control Act (101 of 1965) as amended

11. National Drug Policy

12. Good Pharmacy Practice