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GUIDELINE FOR DESTRUCTION OF MEDICINES AND SCHEDULED SUBSTANCES

This document provides guidance regarding safe disposal and destruction of medicines and scheduled substances by health facilities in accordance with Regulation 44 of the General Regulations of the Medicines and Related Substances Act, 101 of 1965, and relevant waste legislation. To ensure the correct handling of the disposal and destruction of medicines and scheduled substances.

The General Regulations of the Medicines and Related Substances Act (Act 101 of 1965) gazetted on 25 August 2017, replaced regulation 27 (destruction of medicines) with regulation 44 (destruction of medicines or scheduled substances). The Authority reserves the right to request any additional information to establish the safe destruction of any Scheduled medicines and/ or substances in South Africa.

Document History

Final Version	Reason for Amendment	Effective Date
1	Guidelines 5.05 and 5.06 for the destruction of schedule 5 and 6 medicines and scheduled substances, respectively, were combined into guideline 5.16	February 2008
2	Update to new template and change of document number 5.16 to SAHPGL-INSP-RC-03	September 2021
3	Updated due to changes in Regulation 27 to Regulation 44	October 2025

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APPROVED

Glossary

Abbreviation	Meaning
CEO	Chief Executive Officer
SAHPRA	South African Health Products Regulatory Authority

Term	Meaning
Applicant	means a company or person who applies for permission to dispose of and destroy scheduled medicines and substances.
Authority	means the South African Health Products Regulatory Authority (SAHPRA).
Disposal	means the removal of medicines and scheduled substances from a pharmacy, medicine room, or health establishment for purposes of destruction by a waste treatment facility duly authorized in terms of the National Environmental Waste Management Act, 59 of 2008.
Destruction	means rendering the medicines and scheduled substances unusable or irretrievable for use or consumption, taking into consideration the environment and harm to the health of the population.
Waste treatment facility	means a site licensed in terms of the National Environmental Waste Management Act 59 of 2008 that may be used to accumulate waste for storage, recovery, treatment, reprocessing, recycling, or sorting of that waste.

1. INTRODUCTION

The South African Health Products Regulatory Authority (SAHPRA) (hereinafter referred to as the Authority) is a statutory body, established to provide for the monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, scheduled substances, clinical trials and medical devices, IVDs and related matters in the public interest according to section 2A of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), as amended (Medicines Act). The Authority must ensure health products and medicines in the market comply with the Medicines Act provisions during the entire life cycle. This ensures that the public has access to medicines that are safe, efficacious, and of quality.

Health products anywhere within the supply chain may require removal from the market by the authority due to non-compliance with prescribed conditions and must be disposed of and destroyed. The various reasons for disposal/ destruction of medicines or scheduled substances may include, but are not limited to, expired, substandard, falsified, imported unlawfully, or declared undesirable. SAHPRA may recall products from the market, and those must be destroyed. Medicines and scheduled substances disposal and destruction must be in accordance with Regulation 44 of the General Regulations of the Medicines Act, read with the Good Pharmacy Practice Rules of the South African Pharmacy Council.

1.1 Purpose

This document provides guidance regarding safe disposal and destruction of medicines and scheduled substances by health facilities in accordance with Regulation 44 of the General Regulations of the Medicines and Related Substances Act, 101 of 1965, relevant waste legislation. To ensure the correct handling of the disposal and destruction of medicines and scheduled substances.

1.2 Scope

This guideline applies to all facilities that keep medicines and scheduled substances, like Pharmacies, medicine manufacturers, wholesalers, distributors, and any other authorised professionals authorized to dispense medicines in terms of Section 22C(1)a of the Medicines Act. The guidelines also apply to any other person or facility having access to or in possession of medicines or scheduled substances that need to be disposed of and destroyed.

2. LEGAL PROVISION

Regulation 44 of the General Regulations to the Medicines and Related Substances Act, 1965 (Act 101 of 1965) prescribes for destruction of medicines or scheduled substances as follows:

44. (1) A medicine or scheduled substance shall only be destroyed by a waste treatment facility

authorised to destroy medicines or pharmaceutical waste in terms of the National Environmental Management: Waste Act, 2008 (Act No. 59 of 2008).

(2) No medicines or scheduled substances other than those as determined by the Authority shall be disposed of into municipal sewerage systems.

(3) The destruction or disposal of medicines or scheduled substances must be conducted in such a manner to ensure that the medicines or scheduled substances cannot be salvaged and the medicine or scheduled substance has been denatured.

(4) A Schedule 0 medicine or Schedule 1, 2, 3 or 4 substance or medicine must be destroyed at a site in terms of subregulation (1) and such destruction must be certified as determined by the Authority.

3. GENERAL REQUIREMENTS

3.1 General disposal and destruction principles

- 3.1.1 To ensure that dangers associated with the incorrect disposal/ destruction of medicines and scheduled substances are prevented.
- 3.1.2 To alert the health professional that medicines and scheduled substances waste must comply with the Good Pharmacy Practice rules of the South African Pharmacy Council.
- 3.1.3 Anyone who notices non-compliance should report that to the SAHPRA¹ for investigation and appropriate action.

3.2 Destruction of schedule 5, 6, 7 and 8 Medicines or scheduled substances authorised by SAHPRA

Regulation 44(5) (6)(7) states:

- (5) A Schedule 5 or 6 substance or medicine shall be destroyed in terms of subregulation (1) in the presence of- (a) an inspector; (b) a pharmacist; or (c) any other person authorised by the Chief Executive Officer.*
- (6) A Schedule 7 or 8 substance or medicine shall be destroyed in terms of subregulation (1) in the presence of- (a) an inspector; (b) two pharmacists; or (c) any other person authorised by the Chief Executive Officer.*

¹ <https://www.sahpra.org.za/complaints-relating-to-medicine-and-medical-devices/>

(7) The waste treatment facility shall issue a certificate and maintain a record of the destruction contemplated in subregulations (5) and (6), which shall contain the following information:

- (a) the name of the medicine or scheduled substance, if known; or the schedule of the medicine or scheduled substance concerned;*
- (b) the quantity destroyed;*
- (c) the date of destruction of the medicine or scheduled substance;*
- (d) the name and designation of the person in whose presence such destruction took place; and*
- (e) any other information as determined by the Authority.*

South Africa, as a UN Member State, reports on control of narcotic drugs and psychotropic substances in the country to the United Nations Commission on Narcotic Drugs (The CND). This reporting is to the International Narcotics Control Board (INCB), a committee of CND. The reporting function to INCB is implemented by SAHPRA based on the Medicines Act, and it includes information regarding imports, exports, manufacture, consumption, use, and disposal of narcotics and psychotropic substances. SAHPRA historically and currently receives, and processes applications requiring permission to dispose of or destroy the medicines and scheduled substances listed in Schedule 5,6,7 and and 8 categories as follows:

3.2.1 Pharmacies/ pharmaceutical establishments/ clinics send the request for permission regarding disposal and destruction of the above-mentioned to the Regulatory Compliance via the email destructions@sahpra.org.za. The applicants must complete the SAHPRA Destruction Form (GLF-RC-INSP-03A) available on the SAHPRA website which require inclusion of the information:

- name of each medicine or substance to be destroyed,
- exact quantities and batch numbers of the medicines or substances to be destroyed,
- dosage form and pack size of the medicine/ substance,
- expiry dates for the medicines/ substances,
- name of the waste destruction company,

- the reason for the destruction,
- name/s of the Responsible Pharmacist or the Pharmacist responsible for waste management at the facility,
- name of the authorised dispenser or holder of section 22C (1) (a) licenses or any other authorised person responsible for scheduled medicines or scheduled substances,
- name of the Pharmacist/s to witness the destruction, and
- signed cover letter from the facility applying for destruction.

Upon receipt of correct and complete application, it will be processed and finalised within 10 working days with the outcome communicated to the applicant.

4. REFERENCES

The following related documents are referenced:

- 4.1 Medicines and related substances Act (Act 101 of 1965) as amended. https://www.sahpra.org.za/wp-content/uploads/2019/09/Medicines-and-Related-Substances-Act_101-of-1965_Act_GG-40869_2017-05-26.pdf
- 4.2 The general regulations to Medicines Act. <https://www.sahpra.org.za/wp-content/uploads/2022/07/General-Regulations-Medicines-and-Related-Substances-Act-25-Aug-2017-Gazetted.pdf>
- 4.3 Environmental Management Act: Waste Management Act, <https://www.sahpra.org.za/wp-content/uploads/2022/07/Environmental-Management-Act-107-1998.pdf>

5. VALIDITY

This guideline is valid for a period of 5 years from the effective date of revision and replaces any previous revision. It will be reviewed on this timeframe or as and when required.