South African Health Products
Regulatory Authority
Building A
Loftus Park
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Pretoria

GUIDELINE FOR SAFE DISPOSAL OF UNWANTED / UNDESIRABLE PHARMACEUTICAL PRODUCTS: REGULATORY COMPLIANCE UNIT

This document has been prepared to serve as a guidance document regarding SAHPRA requirements for safe disposal of unwanted / undesirable pharmaceutical products - Regulatory Compliance Unit.

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1. BACKGROUND

1.1 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, Act 101 of 1965, as amended (hereinafter referred to as the Medicines Act). The Authority must ensure health products and medicines registered or authorised by the Authority, during the entire life cycle, comply with the information that has been evaluated and approved by the Authority through section 2B(1)(c) of the Act.

1.2 The Regulatory Compliance Unit is responsible for ensuring that the disposal of unwanted / undesirable Health products including Substandard/falsified products is conducted.

1.3 The Regulatory Compliance Unit is also responsible for adhering to the Hazardous Substances Act (Act No.15 of 1973) and the National Health Act ,2003 (Act No.61 of 2003) during the disposal of unwanted / undesirable products.

2. PURPOSE

2.1 This guideline has been developed to provide guidance to all stakeholders handling health products, medical devices, medicines registered or authorised by the Authority (herein referred to as pharmaceutical products) to ensure safe disposal of unwanted / unwholesome health products and prevent its re-entry into the supply chain.

3. SCOPE

3.1 Sections 23 of the Medicines and Related Substances Act, Act 101 of 1965, provides for the proper handling, treatment, and disposal of unwanted / undesirable health products so as to protect human and animal health and the environment from potential hazards.

3.2 The scope covers products that are seized in terms of section 28(d) of the Medicines Act

3.3 The scope covers health products that does not meet the provisions of Section 15 and 22 of the Medicines Act

3.4 Products that are recalled and or withdrawn due to safety, efficacy, and quality issues.

3.5 The scope does not include scheduled substances disposed as the provisions of Regulation 44 of the general regulations to the Medicines Act.

3.6 The scope does not include expired /unwanted stock from personnel licenced under 22C1(a) of the medicines Act and at pharmacies.

4. DEFINITIONS

4.1 Unwanted / Undesirable means any medicine, medical device or IVDs that does not meet regulatory requirement or when consumed/used can be injurious to health of the consumer: this includes Substandard / Falsified (SF) products.

4.2 Medicines Act: Medicines and Related Substances Act, Act 101 of 1965 as amended.

4.3 Authority: South African Health Products Regulatory Authority (SAHPRA)

4.4 Pharmaceutical products/ Health products: Medicines, Medical Devices and IVDs (including Complementary medicines.)

4.5 Pharmacist: means a person registered as such under the Pharmacy Act, 1974.

4.6 Destruction: Means the safe disposal of any unwanted / undesirable products beyond retrieval by a waste management company.

5. GENEREAL REQUIREMENTS

5.1 No person shall dispose of any unwanted / undesirable product without permission and supervision from the Authority.

5.2 Permission for safe disposal of any unwanted / undesirable product shall be sought from the Authority via application.

5.3 Applicants will notify SAHPRA should there be unwanted /undesirable products; or

5.4 SAHPRA shall through its market surveillance inspectorate prevent, detect and respond to unwanted /undesirable products; and

5.5 Also upon notification of unwanted/undesirable products by other stakeholders e.g. police, port health, SARS customs, whistle blowers, SAHPRA shall ensure that they are removed and from the market and are disposed off.

5.6 Should need arise, SAHPRA will inspect the site for investigation and determination regarding the product affected

5.7 Management of unwanted / undesirable product shall include:

5.7.1 maintaining a register for such unwanted / undesirable product.

5.7.2 quarantining unwanted / undesirable products especially products that fall under specified scheduled medicines as described in the Medicines Act and any other hazardous products.

5.7.3 quarantining unwanted / undesirable products into different categories by dosage forms (e.g., solids, liquids etc).

5.7.4 clearly and properly labelled product (DO NOT USE) to avoid its unintended use.

5.8 The concerned unwanted / undesirable products will be destroyed at the company's own costs.

5.9 The applicant shall arrange with the relevant accredited local Waste Management Company to conduct the destruction in line with the National Environmental Management: Waste Act, 2008. and be responsible for conveyance of the unwanted / undesirable products to the site of destruction and cover all applicable costs.

5.10 Where necessary SAHPRA delegate/s with authorized representative from the company in question and the South African Police Service (SAPS) shall be present as witnesses during the destruction.

6 AUTHORISATION FOR THE SAFE DISPOSAL OF UNWANTED / UNDESIRABLE PHARMACEUTICAL PRODUCTS

6.1 Every Applicant or any person except those licenced under section 22C 1(a) who is in possession of unwanted /undesirable products needs to get authorization from the SAHPRA.

6.2 All applications for destruction of unwanted / undesirable products shall be made to the

SAHPRA office through a letter addressed to:
Regulatory Compliance Unit
South African Health Products Regulatory Authority
Building A, Loftus Park
Arcadia
Pretoria

6.3 The letter shall be accompanied by a filled application form and the list of products in both ***hard*** and ***soft copy (excel format)*** with the following details:

a) Product description
b) Quantities
c) Unit cost
d) Batch numbers
e) Reason (s) for which the products are declared unwanted / undesirable.
f) Any other relevant information authority may require

6.4 The authority shall, upon receipt of the request for disposal, appoint a regulatory compliance officer to verify and authenticate the information submitted in relation to the consignment to be disposed. If after verification, the submitted list is varied by addition of other products, the applicant shall be made to pay an additional fee as required.

6.5 The applicant shall arrange with the Authority on a convenient date on which the destruction can be undertaken.

6.6 The Waste Management Company shall after completion of the disposal exercise issue a certificate of destruction of the products.

7 OFFENCES

7.1 Any person who contravenes or fails to comply with any provision of this guideline or who directly or indirectly aids another person in committing an offence relating to the disposal of unwanted / undesirable pharmaceutical products commits an offence under the Medicines and Related Substances Act, Act 101 of 1965, as stipulated under section 29F.

8 UPDATE HISTORY

Date	Reason for update	Version & Publication
23 September 2021	First publication	Version 1, 23 September 2021

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