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BOARD NOTICES

BOARD NOTICE 104 OF 2011

THE SOUTH AFRICAN PHARMACY COUNCIL

RULES RELATING TO GOOD PHARMACY PRACTICE: WITHDRAWAL OF BOARD NOTICE

The South African Pharmacy Council hereby withdraws Board Notice 194 of 2010, Government Gazette 33898, published on 20 December 2010 relating to the minimum standards added to Annexure A of the *Rules relating to good pharmacy practice* which was published on the 17 December 2004 Government Gazette No: 27112 of Board Notice 129 of 2004 in terms of section 35A(b)(ii) of the Pharmacy Act 53 of 1974, as amended:

Minimum standards regarding destruction and disposal of medicines

TA MASANGO
REGISTRAR

BOARD NOTICE 105 OF 2011

THE SOUTH AFRICAN PHARMACY COUNCIL

RULES RELATING TO GOOD PHARMACY PRACTICE

The South African Pharmacy Council intends to publish additional minimum standards to Annexure A of the *Rules relating to good pharmacy practice* which was published on the 17 December 2004 Government Gazette No: 27112 of Board Notice 129 of 2004 in terms of section 35A(b)(ii) of the Pharmacy Act 53 of 1974, as amended.

Interested persons are invited to submit, within 30 days of publication of this notice, substantiated comments on or representations regarding the Minimum standards regarding destruction and disposal of medicines and scheduled substances to the Registrar, The South African Pharmacy Council, Private Bag X40040, Arcadia, 0007, or Fax 086 5063010 or email: debbie.hoffmann@sapc.za.org (for the attention of the Senior Manager: Legal Services.

SCHEDULE

Rules relating to what constitutes good pharmacy practice

1. In these rules "the Act" shall mean the Pharmacy Act, 53 of 1974, as amended, and any expression to which a meaning has been assigned in the Act shall bear such meaning.

2. The following minimum standard as published herewith shall constitute an additional standard to Annexure A of the *Rules relating to good pharmacy practice* in accordance with section 35A(b)(ii) of the Act –

   a. Minimum standards regarding destruction and disposal of medicines and scheduled substances.

TA MASANGO
REGISTRAR/CEO

MINIMUM STANDARDS REGARDING DESTRUCTION AND DISPOSAL OF MEDICINES AND SCHEDULED SUBSTANCES

1. INTRODUCTION

The destruction of medicines and scheduled substances may only take place in accordance with the Medicines and Related Substances Act (Act 101 of 1965) and other applicable legislation.

Regulation 27 of the General Regulations published under the Medicines and Related Substances Act (Act 101 of 1965) states that no medicines and scheduled substances may be disposed of into municipal sewerage systems and that the destruction or disposal of medicine and scheduled substances must be conducted in such a manner as to ensure that they are not retrievable.

In addition, pharmacists should not dispose of medicines and scheduled substances in refuse that may be destined for landfill or municipal refuse sites.

2. PURPOSE

The purpose of this standard 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.

3. GENERAL CONSIDERATIONS

Some of the elements in this standard are not statutory requirements but are good practice which pharmacists would be expected to follow whenever practicable.

3.1 All destruction must take place in accordance with 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.

3.2 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.

3.3 In respect of schedules 5, 6, 7 and 8, 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 (SAPS); a case number must be provided. These references must be kept with the relevant record or register for a period of 5 years.

3.4 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.

3.5 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).

3.6 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) in the event of the information detailed in Rule 3.6 (a) and (b) not being available, the weight of the medicines and scheduled substances;

(d) the name, position and signature of the person and the witness destroying the medicines and scheduled substances;

(e) the reason for the destruction; and

(f) the date of destruction.

4. LEGISLATIVE REQUIREMENTS

4.1 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.

4.2 For medicines and scheduled substances containing a Schedule 5 and 6, 7 or 8, 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 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;

4.3 The medicines and scheduled substances in Rule 4.2 may only be destroyed in the presence of an inspector, an officer of the South African Police Service 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.

4.4 Notwithstanding Rule 4.2, 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.

5. MINIMUM REQUIREMENTS FOR THE DESTRUCTION OF MEDICINES AND SCHEDULED SUBSTANCES

A medicine and scheduled substance may be destroyed as follows:

5.1 Destruction by a contractor who specialises in waste disposal regarding the disposal of chemical or medicinal waste;

5.2 If a contractor is not used, **two pharmacists** must witness the **removal and destruction** of the correct quantities of the medicines and scheduled substances authorised for destruction, regardless of the where the destruction will take place;

5.3 In the case of a contractor, where destruction does not take place at the premises of the person responsible for the destruction, the contractor must issue a certificate of destruction. **Two** pharmacists must witness the **removal from the stock** of the correct quantities of the medicines and scheduled substances authorised for destruction. The contractor must have a pharmacist in his/her employment to ensure that the goods are destroyed or disposed in such a manner that precludes their recovery;

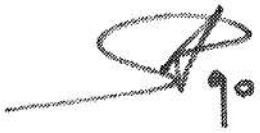
5.4 Particulars to appear on the Certificate of Destruction shall include at least:

(a) name of the person/contractor/company who has issued the Certificate of Destruction;
(b) the details of the person responsible for the destruction;
(c) the date of destruction of the medicines and scheduled substances;
(d) a list of the medicines and scheduled substances to be destroyed.

6. MINIMUM REQUIREMENT FOR THE DISPOSAL OF MEDICINES AND SCHEDULED SUBSTANCES

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) Radioactive drugs;
(f) Cytostatic and cytotoxic medicines and scheduled substances.



TA MASANGO
REGISTRAR/CEO

BOARD NOTICE 106 OF 2011

THE SOUTH AFRICAN PHARMACY COUNCIL

RULES RELATING TO GOOD PHARMACY PRACTICE

The South African Pharmacy Council intends to publish amendments to minimum standards to Annexure A of *Rules relating to good pharmacy practice* which was published on the 17 December 2004 Government Gazette No: 27112 of Board Notice 129 of 2004 in terms of section 35A(b)(ii) of the Pharmacy Act 53 of 1974, as amended.

SCHEDULE

Rules relating to what constitutes good pharmacy practice

1. In these rules "the Act" shall mean the Pharmacy Act 53 of 1974, as amended, and any expression to which a meaning has been assigned in the Act shall bear such meaning.

2. The following sections of Annexure A of the *Rules relating to Good Pharmacy Practice* are to be amended–

   (a) Section 1.2.2
   (b) Section 2.29
   (c) Section 1.2.11.5

3. The following section of Annexure A of the *Rules relating to Good Pharmacy Practice* is to be added –

   (a) Section 1.2.14

Interested persons are invited to submit, within 60 days of publication of this notice, substantiated comments on or representations regarding the Minimum standards for pharmacy premises, facilities and equipment to the Registrar, The South African Pharmacy Council, Private Bag X40040, Arcadia, 0007, or Fax 086 5063010 or email: debbie.hoffmann@sapc.za.org.(for the attention of the Senior Manager: Legal Services and Professional Conduct).

TA MASANGO
REGISTRAR/CEO

MINIMUM STANDARDS FOR PHARMACY PREMISES, FACILITIES AND EQUIPMENT

Section 1.2.2: Another business or practice in a pharmacy premises or a pharmacy in another business, is amended as follows:

Paragraph (b) which read as follows:

(b) The pharmacy premises must be clearly demarcated and identified from the premises of any other business or practice.

is deleted and replaced with subsections 1.2.2.1 and 1.2.2.2 below:

1.2.2.1 A PHARMACY IN ANOTHER BUSINESS

(a) The pharmacy premises must be clearly demarcated and identified from the premises of any other business or practice;
(b) The demarcation must be permanent, solid and closed-off at all times, which demarcation may be inter alia, brick and mortar, aluminium, steel, glass, dry wall or wood partition;
(c) The demarcation must be from floor to the ceiling and must enclose all areas of the pharmacy, which includes but is not limited to the waiting area, the clinic, the semi-private area, the private area and/or clinic;
(d) The pharmacy must have a single point of entry and a single point of exit in compliance with the Occupational Health and Safety Act, 85 of 1993 (OHSA).

1.2.2.2 ANOTHER BUSINESS OR PRACTICE IN A PHARMACY

The following criteria will be applied by Council in considering applications for another business or practice in a pharmacy. The opening and operation of another business in a pharmacy must be such that:

(a) the other business has obtained approval from their statutory council or registration authority (if applicable) and submit same with the application;
(b) the other business does not pose any conflicting interest either ethically or professionally to the practice of pharmacy:
  (i) added security risk to the keeping and supply of medicines;
  (ii) added risk to the patients;
  (iii) compromises the quality, efficacy and safety of the medicine;
(c) the premises of the other business must be clearly demarcated and identified from the pharmacy premises:
  (i) the demarcation must be permanent, solid, closed-off at all times, that is, brick and mortar, aluminium, steel, glass, dry wall or wood partition;
  (ii) the demarcation must be from floor to the ceiling height and must enclose all areas attached to the pharmacy, viz; the waiting area, the clinic, the semi-private area and/or the private area.

Section 1.2.11.5: Reference Sources, is amended as follows:

Paragraph (a) which read as follows:

(a) one of the last three (3) editions of Martindale.

is deleted and replaced with paragraph (a) below:

(a) one of the last five (5) editions of Martindale.

The following new section is added:

1.2.14 PHARMACY TRANSACTIONS

*For a pharmacy that is within another business, the following transactions shall take place **within the pharmacy only**:*

(a) the prescription shall be handed (sic) in or submitted to the pharmacy;
(b) the dispensing process (phase 1,2, and 3);
(c) the recording of medicines and scheduled substances, which includes the recording of schedule 1 and 2 medicines in terms of Regulation 11 of the General Regulations to the Medicines and Related Substance Act, 101 of 1965;
(d) the payment for all medicine and scheduled substances.

Section 2.29: Products which may not be sold in a pharmacy, is amended as follows:

Paragraph (e) which read as follows:

(e) lotto tickets.

is deleted and replaced with paragraph (e) below:

(e) gambling services and/or products.

TA MASANGO
REGISTRAR/CEO