BOARD NOTICE 194 OF 2010

THE SOUTH AFRICAN PHARMACY COUNCIL

RULES RELATING TO GOOD PHARMACY PRACTICE

The South African Pharmacy Council herewith publishes additional minimum standards to be 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.

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 be added to Annexure A of the *Rules relating to good pharmacy practice* in accordance with section 35A(b)(ii) of the Act -

2.1 Minimum standards regarding destruction and disposal of medicines.

TA MASANGO
REGISTRAR

MINIMUM STANDARDS REGARDING DESTRUCTION AND DISPOSAL OF MEDICINES

1. INTRODUCTION

The destruction of Scheduled medicines and 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 may be disposed of into municipal sewerage systems and that the destruction or disposal of medicine or scheduled substances must be conducted in such a manner as to ensure that they are not retrievable.

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

2. PURPOSE

The purpose of this standard is to ensure that the destruction of medicines 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 Regulations and with due regard to minimizing the risk of such an activity causing pollution 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 applicant (person requesting destruction) may be requested to prove that the method of destruction is in accordance with such regulations.

3.2 All medicines or scheduled substances (including medicines returned by patients) must be destroyed in such a manner that does not allow recovery or retrieval.

3.3 The inspector must, on behalf of the Medicines Regulatory Authority (MRA), provide a certificate of destruction and in the case of an officer of the SAPS; a case number must be provided. These references must be kept with the register for a period of 5 years.[1]

3.4 All quantities destroyed must be recorded in the relevant record on the date of destruction and signed by the applicant, indicating the reference to the destruction certificate or case number as the case may be.

[1] Applicable to the destruction of schedule 5, 6,7 and 8

3.5 The destruction must be properly documented:-

(a) All quantities destroyed must be recorded and in the case of specified schedule 5 and schedule 6 medicines the quantities of medicines to be destroyed must be indicated in the relevant registers and signed by the witnesses required in the procedure;

(b) Destruction certificates (where applicable) and the letter of authorisation by the Medicine Regulatory Authority(MRA) 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 or scheduled substance;

(b) Date of expiry;

(c) The name, position and signature of the person destroying the medicines or scheduled substance and the witness;

(d) The reason for the destruction; and

(e) Date of destruction.

(f) The weight of the medicines or scheduled substances for medicines or scheduled substances returned by patients.

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 or scheduled substances are kept. Such pharmacist or authorised person shall certify such destruction;

4.2 For medicines containing a Schedule 5 and 6, 7 or 8, the Responsible Pharmacist of the institution/facility where the medicines are kept, should first obtain approval for destruction from the MRA. 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 or scheduled substance;

(b) Date of expiry;

4.3 The medicines 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 authorized by the Director General. Such inspector or 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 the Rule 4.1 and 4.2 the Medicines Control Council may authorize 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

A medicine or 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** employed by the applicant must witness the **removal and destruction** of the correct quantities of the medicines or 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 applicant, the contractor must issue a certificate of destruction. **Two** pharmacists employed by the applicant must witness the **removal from the stock** of the correct quantities of the medicines or 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.

6. DISPOSAL OF MEDICINES

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

(a) Solid dosage form medicines;
(b) Ampoules;
(c) Liquids, creams and ointments;
(d) Aerosols;
(e) Radioactive drugs
(f) Cytostatic and cytotoxic medicines.

TA MASANGO
REGISTRAR/CEO

Printed by and obtainable from the Government Printer, Bosman Street, Private Bag X85, Pretoria, 0001
Publications: Tel: (012) 334-4508, 334-4509, 334-4510
Advertisements: Tel: (012) 334-4673, 334-4674, 334-4504
Subscriptions: Tel: (012) 334-4735, 334-4736, 334-4737
Cape Town Branch: Tel: (021) 465-7531
Gedruk deur en verkrygbaar by die Staatsdrukker, Bosmanstraat, Privaatsak X85, Pretoria, 0001
Publikasies: Tel: (012) 334-4508, 334-4509, 334-4510
Advertensies: Tel: (012) 334-4673, 334-4674, 334-4504
Subskripsies: Tel: (012) 334-4735, 334-4736, 334-4737
Kaapstad-tak: Tel: (021) 465-7531