BOARD NOTICE 99 OF 2018

THE SOUTH AFRICAN PHARMACY COUNCIL

RULES RELATING TO GOOD PHARMACY PRACTICE

The South African Pharmacy Council intends to publish amendments and 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 in Board Notice 129 of 2004, in terms of section 35A(b)(ii) of the Pharmacy Act 53 of 1974.

Interested parties are invited to submit, within **60 days** of publication of this notice, substantiated comments on or representation regarding the amendments to the existing minimum standards and/or the additional minimum standards. Comments must be addressed to the Registrar, the South African Pharmacy Council, Private Bag 40040, Arcadia, or fax (012)326-1496 or email BN@sapc.za.org.

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 –

   (a) Minimum Standards for Unit Dose Dispensing

TA MASANGO
REGISTRAR

MINIMUM STANDARDS FOR UNIT DOSE DISPENSING

1. Definitions

Unit dose dispensing (UDD) is a process where individual doses of medicines are packed into a container (UDC), ready for administration to patients, involving a manual or an automated system.

Unit dose container (UDC) – are containers used for packing of medicines according to administration times for a specific patient and/or a caregiver to administer.

2. Preamble

The use of original packs of medicines, supported by appropriate pharmaceutical care, is recommended as the preferred intervention for the supply of medicines in the absence of a specific need for a unit dose container (UDC). There is evidence to indicate that UDCs may be of value for some patients who have been assessed as having practical problems in managing their medicines and/or maintaining independent healthy living. Each patient's needs must be assessed on an individual basis and any intervention must be tailored to the patient's specific requirements.

The removal of a medicine from the manufacturer's original packaging and packed into a UDC can affect its stability. Pharmacists and pharmacy support personnel must recognise that any re-packaging of medication from the manufacturer's original packaging may involve risks and must take responsibility for the decisions made.

3. Purpose

The purpose of this standard is to provide guidelines to pharmacists and pharmacy support personnel when medicines are dispensed as individual unit doses for a particular patient, to facilitate administration with the aim of improving adherence to therapy. Medicines are dispensed and packed in unit dose containers according to administration times for use by the patient and/or caregiver.

Minimum standards specifically relating to Unit Dose Dispensing are intended to guide pharmacists and pharmacy support personnel on the legal requirements to be taken into consideration in ensuring that the stability of medicines is not compromised for each medicine when packed together in a container as individual unit doses.

4. General considerations

(a) All relevant legislative requirements for dispensing must be met when UDD is applied.

(b) UDD may only be performed in community and institutional pharmacies.

(c) In the absence of stability data, medicines packed into an UDC may only be packaged in a quantity not exceeding 30 consecutive days from the date of packing. The expiry date of the medicine must be taken into consideration.

(d) Only dispense the quantity that is intended to be used by a patient alternatively for not more than 30 consecutive days from the day of dispensing, provided that the date of dispensing and the statement "Use within 30 days" are clearly indicated on the label.

(e) Medicines which are considered unstable or unsuitable when packed together should not be packed into a UDC.

5. Specific Considerations

5.1 The clinical needs and supportive care of the patient

(a) In the case of a child under the age of 12, the guardian must give their consent, prior to the supply of medicines using the UDC.

(b) In the case where a person is subjected to curatorship, in terms of the Mental Health Care Act 17 of 2002, the curator must give their consent. Such a curator will be expected to give consent, prior to the supply of medicines using the UDC.

(c) The patient must give informed consent prior to the supply of medicines using UDC.

(d) The patient, or his or her agent or caregiver must be able to manage the medication and ensure adherence to the treatment regimen.

5.2 The type of medicines used

(a) The following should be considered when determining the suitability of medicines for dispensing in UDC:

(i) the stability of the medicine;
(ii) cross-contamination;
(iii) potential for chemical and physical interactions between medicines and/or the container; and
(iv) the length of time that the medicines will be packed together.

(b) The pharmacist remains responsible for any decisions to pack medicines in the UDC. The following is a general guideline of solid dosage forms which should NOT be packed into a UDC - the list is not comprehensive:

(i) Soluble, effervescent and or dispersible tablets;
(ii) Chewable, sub-lingual and buccal tablets;
(iii) Soft gel and oil filled capsules;
(iv) Moisture sensitive and hygroscopic preparations;
(v) Medicines whose dose may vary frequently depending on test results, e.g. unstable INR with warfarin;
(vi) Medicines that may be harmful when handled e.g. cytotoxics
(vii) Medicines which are stored in the fridge/ thermolabile medicines and medicines with special storage requirements;
(viii) Medicines intended for “as required” use; and
(ix) Medicines that have special administration instructions and must be identified individually in order to do this safely e.g. alendronate.

5.3 The packing of UDC

(a) The packing of UDC must be undertaken by pharmacists and pharmacy support personnel (PSP), operating under the direct supervision of a pharmacist;

(b) There must be a system to check and control the quality of packing of medicines into a UDC;

(c) The premises and layout of the facility in which packaging occurs must adhere to and be conducted in accordance with GPP;

(i) If an automated or semi-automated system is used, the equipment must be operated according to a relevant SOP(s); and
(ii) The packaging material must be water-proof, airtight, and tamper-evident.

5.4 Labelling

(a) The label for each unit dose container must:

(i) be clear, legible and indelible;
(ii) include a statement ‘keep out of reach of children’
(iii) comply with Regulation 10(6) of the General Regulations published in terms of the Medicines Act; and
(iv) include any cautionary and advisory instructions.

(b) Each medicine must be clearly identifiable;

(c) The instructions for use of the container must be simple and unambiguous;

(d) In cases where it is not possible to include all information on the label, additional information must be provided in a separate information pamphlet.

5.5 Record keeping

(a) A record of each UDC prepared for the patient must include:

(i) the name, dosage form, strength and dose of each medicine **packed into each section or compartment of the unit dose container;**
(ii) the name of the person/s who dispensed the prescription and packed the unit dose container;
(iii) the date of dispensing;
(iv) the date of packing the UDC; and
(v) the reference number linking the medicines packed into the UDC to a particular patient.

5.6 Disposal of unused medicines

Patients must be advised that medicines that have been packed into an UDC and that have not been used within 30 days should be returned to the pharmacy for destruction in accordance with legislation.

5.7 Standard operating procedures

the following, must be included in an SOP, but may not be limited to:

(a) assessment of patient selection;
(b) assessment of suitable medicine selection;
(c) describing the use of the packing instrument, including cleaning, maintenance and error records;
(d) packaging of medicines including quality assurance procedures;
(e) managing returned and unused medicines;
(f) uncollected, spoilt and damaged medicine;
(g) recall of medicine(s) packed into UDCs;
(h) handling of complaints related to UDCs;
(i) refilling of bulk containers on completion of filling of UDCs; and
(j) recording of changes to medicines, doses and frequency of dosing.

6. **Knowledge**

Pharmacists and/or pharmacy support personnel must ensure that they have adequate knowledge of UDD as well as the ability to demonstrate the use of the UDC to any person as the need arises