

BOARD NOTICE 172 OF 2019
THE SOUTH AFRICAN PHARMACY COUNCIL

RULES RELATING TO GOOD PHARMACY PRACTICE

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

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 rule to Annexure A of the *Rules relating to good pharmacy practice* is hereby added –
 - (a) Minimum Standards for Unit Dose Dispensing



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REGISTRAR

MINIMUM STANDARDS FOR UNIT DOSE DISPENSING

1. Definitions

Unit dose dispensing (UDD) is a process where individual doses of different medicines are dispensed or re-dispensed into a container (UDC; see below), ready for administration to patients, involving a manual or an automated system and that includes but is not restricted to other international definitions e.g. the multi-compartment system.

Unit dose container (UDC) – is a container used for the dispensing or re-dispensing of medicines according to its administration time for a specific patient and/or a caregiver to administer and that includes but is not restricted to other international definitions e.g. multi-compartment compliance aids.

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). UDCs may however 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 it being dispensed into a UDC, can affect its stability. Pharmacists and pharmacy support personnel (PSP) must recognise that any dispensing or re-dispensing of medication from the manufacturer's original packaging into a UDC may involve risks and as such, the dispenser or re-dispenser must take full responsibility for the decision to use UDD.

3. Purpose

The purpose of this standard is to provide guidelines to pharmacists and PSP when medicines are dispensed or re-dispensed as individual unit doses for a particular patient, to facilitate administration with the aim of improving adherence to therapy.

Minimum standards specifically relating to UDD and the use of UDCs are intended to guide pharmacists and PSP on the legal requirements to be taken into consideration when dispensing or re-dispensing medicines 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 NOT be performed in manufacturing pharmacies, wholesale pharmacies and by licensed dispensers.

- (c) Pharmacists must be in possession of either the latest original prescription concerned or a legal copy thereof at the time of dispensing or re-dispensing medicines into UDCs.
- (d) Medicines being dispensed into an UDC may only be dispensed in a quantity that will not exceed the number of doses prescribed for 30 consecutive days from the dispensing date. Further, the expiry date of the medicine must also be taken into consideration.
- (e) The date of dispensing and the statement "Use within 30 days" must be clearly indicated on the label.
- (f) Medicines which are considered to be unstable or unsuitable when dispensed together, should not be packed into a UDC.
- (g) Under no circumstances, may medications intended for different administration times be dispensed into a single compartment (for illustrative purposes, see Fig 1 for an example).

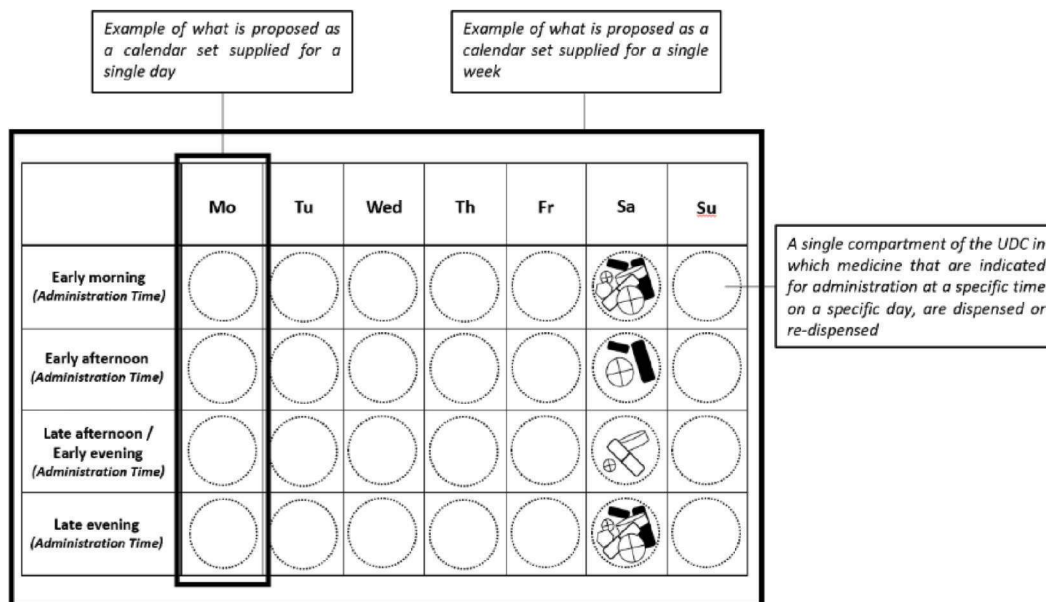


Figure 1 – Schematic layout of a Unit Dose Container (UDC)

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 years, the guardian must give their consent, prior to supplying medicines by means of UDCs.
- (b) In the case where a person is subjected to curatorship in terms of the Mental Health Care Act 17 of 2002, the curator will be expected to give consent, prior to the patient being supplied medicines using UDCs.

- (c) The patient must give his/her informed consent prior to being supplied medicines using UDCs and he/she will have the option to opt out.
- (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 types 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 relative duration of time that the medicines will be packed together, taking into consideration that this time must not exceed 30 days.
- (b) The UDD pharmacist remains responsible for any decisions to dispense medicines into UDCs. The following is a general guideline pertaining to solid dosage forms that should NOT be dispensed into a UDC (the list is not comprehensive and should be elaborated on based on the professional discretion of the UDD pharmacist):
 - (i) Soluble, effervescent and or dispersible tablets;
 - (ii) Chewable, sub-lingual and buccal tablets;
 - (iii) Moisture sensitive and hygroscopic preparations;
 - (iv) Medicines of which the dose may vary frequently depending on test results, e.g. digoxin or unstable INR with warfarin;
 - (v) Medicines that may be harmful when being handled, e.g. cytotoxics;
 - (vi) Medicines that are subject to storage in the fridge, thermolabile medicines, and medicines that require special storage;
 - (vii) Medicines intended for "as required" use;
 - (viii) Medicines that have special administration instructions and that must be identified individually in order to ensure its safe administration, e.g. alendronate, methotrexate, high dose glucocorticoids intended for acute use, etc.; and
 - (ix) Medicines included on the list of non-substitutable medicines.

4.3 Dispensing or re-dispensing medicines into UDCs

- (a) Dispensing or re-dispensing into UDCs must be performed by pharmacists or PSP operating under the direct supervision of a pharmacist in a pharmacy;
- (b) A suitable quality control system must be in place to check and control the quality of the procedures and end results relating to the dispensing or re-dispensing of medicines into a UDC;
- (c) The premises and layout of the facility in which UDD are performed, as well as the process of UDD itself must adhere to and be 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 UDC packaging material must be moisture resistant, airtight, and tamper evident.

5.4 Labelling and patient information

- (a) The label that accompanies a calendar set of UDCs (refer Fig 1), e.g. a UDC set supplied for one day, one week or one month, must:
 - (i) be clear, legible and indelible;
 - (ii) include the 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 that might be relevant.
- (b) Each medicine, as well as its intended time of administration, must be clearly identifiable;
- (c) The instructions for the use of the container must be simple and unambiguous;
- (d) In cases where it is not possible to include all information on the UDC label, additional information must be provided in a separate information leaflet.

5.5 Record keeping

- (a) A record of each UDC prepared for a particular patient must include:
 - (i) the name, dosage form, strength and dose of each medicine **dispensed into each section or compartment of the UDC;**
 - (ii) the name of the person/s who dispensed or re-dispensed the prescription and prepared the UDC;
 - (iii) the date of dispensing or re-dispensing of the medicines into an UDC; and
 - (iv) the reference number linking the medicines dispensed or re-dispensed into the UDC to a particular patient and the relevant prescription.

5.6 Disposal of unused medicines

Patients must be advised that medicines that have been dispensed or re-dispensed into an UDC that have not been used within 30 days of the unit dose dispensing or re-dispensing date, should be returned to the pharmacy for disposal in accordance with legislation.

5.7 Standard operating procedures

The following must be included in an SOP, but will not be limited to:

- (a) an assessment of patient selection and how consent will be recorded;
- (b) an assessment of suitable medicine selection;
- (c) a description for the use of the UDD equipment, including its cleaning, maintenance and error records;
- (d) the quality assurance procedures;
- (e) the management of returned and unused medicines;
- (f) the management of uncollected, spoiled and damaged medicines;
- (g) the recall of medicine(s) packed into UDCs in the event that such a recall must be enacted;
- (h) the handling of complaints related to UDCs;
- (i) the refilling of bulk containers on completion of filling of UDCs, if necessary; and
- (j) recording of changes to the prescribed medicines, doses and frequency of dosing.

6. Knowledge

Pharmacists and/or pharmacy support personnel must ensure that they have adequate knowledge of UDD techniques and UDCs and must be able to demonstrate the use of UDCs if patients require it.