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BOARD NOTICES

BOARD NOTICE 49 OF 2015

THE SOUTH AFRICAN PHARMACY COUNCIL

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 standards as published herewith shall constitute amendments to the existing minimum standards 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) Amendments to Rule 1.4

   Minimum standards for community or institutional pharmacies providing mobile pharmaceutical services;

   (b) Amendments to Rule 1.5

   Minimum standards for community or institutional pharmacies operating internet sites; and

   (c) Amendments to Rule 2.7.5

   Minimum standards relating to the collection and the delivery of medicines to patients from a community or institutional pharmacy.

3. The following minimum standard as published herewith shall constitute additional standard, identified as Rule 1.10 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) Rule 1.10

   Minimum standards for a community pharmacy or institutional pharmacy operating a remote automated dispensing unit (RADU).

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Amendments to Rule 1.4

1.4. MINIMUM STANDARDS FOR COMMUNITY OR INSTITUTIONAL PHARMACY PROVIDING MOBILE PHARMACEUTICAL SERVICES

Rule 1.4.1 and Rule 1.4.2 are hereby inserted as follows:

1.4.1 Purpose

The purpose of this standard is to regulate the provision of mobile pharmaceutical services.

1.4.2 General considerations

(a) Provision of mobile pharmaceutical services must be under the direct control of a registered/ recorded pharmacy which is continuously supervised by a responsible pharmacist.

(b) A community or institutional pharmacy that offers mobile pharmaceutical service, must provide this services in accordance with all relevant legislation.

(c) In instance, where an automated dispensing unit is used to provide this service; the mobile unit must comply with the minimum standards for automated dispensing unit in a community or institutional pharmacy.

Rule 1.4.1 is hereby amended as follows and is renumbered as Rule 1.4.3

1.4.3 Pre-requisites for conducting mobile pharmaceutical services

(a) Mobile pharmaceutical services may only be provided *at or from* a pharmacy licensed by the Director-General of the NDoH and recorded with Council and with the prior approval of Council;

(b) Each mobile pharmacy must be operated by and be under the direct personal supervision of a pharmacist;

(c) A pharmacy may provide mobile pharmaceutical services at a place or places as approved by Council;

(d) Only medicine, medicinal and relevant products and/or approved supplementary services may be sold/provided from a mobile unit;

(e) A pharmacy providing mobile pharmaceutical services must, on yearly basis provide the Council with the intended route, to allow for ease of inspection of the facility, specifying the following:

(i) all the areas where the services will be delivered;

(ii) the period within which those services will be provided.

(f) The approval of a mobile pharmaceutical services unit shall be renewed on an annual basis in the event that the route changes.

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Rule 1.4.2 is hereby amended and renumbered as Rule 1.4.4 *Mobile unit, facilities and equipment within the mobile unit*

Rule 1.4.2 (c) is hereby amended to Rule 1.4.4 (c), and shall now read as follows:

1.4.4 (c) Light conditions, temperature and humidity within the mobile unit must comply with the requirements for the storage of medicine, other pharmaceutical products, raw materials and packaging materials *as well as the minimum standards for procurement, storage and distribution of thermolabile pharmaceutical products;*

Amendments to Rule 1.5

1.5 MINIMUM STANDARDS FOR COMMUNITY OR INSTITUTIONAL PHARMACIES OPERATING INTERNET SITES

Rule 1.5.1 and Rule 1.5.2 are hereby inserted as follows:

1.5.1 Introduction

The sale of medicine via an internet sites must adhere to the principles of dispensing as per the *Rules relating to good pharmacy practice* (GPP).

1.5.2 Purpose

The purpose of this standard is to regulate dispensing activities provided by community or institutional pharmacies by way of internet services, where there is no face to face contact with the patient.

Rule 1.5.3 is hereby substituted for the introductory paragraph as follows:

1.5.3 General considerations

(a) Internet websites which sell medicine (S1-6) directly to the public must be operated by and constitute part of a pharmacy licensed by the National Department of Health (NDOH) and recorded with Council.

(b) Such a website must fall under the authority of the responsible pharmacist of the pharmacy of which it forms a part, and be operated in compliance with all relevant legislation including the Pharmacy Act, the Medicines Act and Good Pharmacy Practice.

(c) An Internet site cannot exist/operate independently of a pharmacy.

(d) A pharmacy may not operate or supervise more than one internet site for the purposes of selling medicines.

(e) Only schedule 1 to 6 medicines may be sold directly to the public through an internet website by a pharmacy in accordance with applicable legislation;

(f) The distribution or delivery of medicine must be done in accordance with applicable legislation.

The remaining standard as numbered (a) – (h) will hereby be amended to be identified as Rule 1.5.4 (a) – (h) and the content thereof will remain the same.

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Amendment to Rule 2.7.5

The title of Rule 2.7.5 is hereby amended to read:

MINIMUM STANDARDS SPECIFICALLY RELATING TO THE COLLECTION AND THE DELIVERY OF MEDICINES TO PATIENTS FROM A COMMUNITY OR INSTITUTIONAL PHARMACY

Rule 2.7.5 is hereby substituted as follow:

2.7.5.1 Purpose

The purpose of this standard is to regulate activities relating to the collection and the delivery of medicines to patients from a community or institutional pharmacy.

2.7.5.2 General considerations

(a) All efforts must be made to enable face-to-face counselling of the patient by a pharmacist;

(b) When a person other than a pharmacist delivers medicines to a patient or a patient's caregiver, the pharmacist must furnish written instructions, that shall include the patient's details and information regarding the correct use of medicine, and a patient information leaflet;

(c) All medicines should, whenever possible, be delivered to patients at an agreed time; and

(d) In the absence of an adult (i.e. a person above 14 years old) to receive the medicine, it must be taken back to the pharmacy.

2.7.5.3 Collection and delivery of medicines

(a) A patient's agent or caregiver may collect medicines and accept information pertaining to a particular patient provided that the pharmacist is satisfied that confidentiality has been maintained and the patient has, where possible, provided written consent;

(b) The patient's agent or caregiver may only collect medicines for a patient or patients who are under their direct care, and in case of multiple patients the pharmacist must satisfy themselves that the patient's agent or caregiver is the appropriate person to give the medicine to by ensuring that:

(i) the identity of the registered facility where the patient's agent is operating from is known and documentary proof is obtained;

(ii) registration documents (e.g. facilities license) of the patient's agent or caregiver or their facility with the relevant authority must be provided and be kept by the pharmacist;

(iii) identity number of the caregiver in case of individual patients must be provided to the pharmacist.

(c) For all acute medicines and first time chronic medicines the patient must be seen by the pharmacist or by pharmacy support personnel in terms of their relevant scope of practice;

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(d) Evidence of the patient/caregiver phase 3 interaction must be documented in line with the provisions of the GPP;

2.7.5.4 Transportation for the delivery of medicines

(a) Transportation of patient ready pack medicines must be in such a way that it is secure and the temperature is maintained to product specifications;

(b) Mode(s) of transportation must be suitable for transporting these medicines. No open vehicles shall be permitted for purposes of transporting pharmaceutical products;

(c) For purposes of transportation, the route must be validated to ensure that delays and/or exposure to extreme temperatures are correctly assessed. Transportation must only be within South Africa and due to large geographical areas; routes must be treated as unique in terms of the range of temperatures that the pharmaceutical products may experience;

(d) The vehicle used for transportation must be clean and free from all forms of pests and contamination, including but not limited to rats, vermin, birds, fungi and mites;

(e) During transportation pharmaceutical products must not be packaged with non-pharmaceutical items or placed in a container with any other goods (for example food and beverages which may also require transportation), which could result in contamination;

(f) The vehicle used for transportation must have a sufficient capacity to allow for orderly storage of pharmaceutical products during transportation;

(g) Cold chain management must be observed, validated packaging and delivery must prove compliance with the minimum standards for thermo labile pharmaceutical products as applicable where relevant;

(h) Temperature data loggers and freezer tags that comply with WHO specifications must be used to monitor the temperature of the loaded area of the transportation throughout the trip, and the validated cooler box packaging must have a temperature monitoring device that complies with or meets WHO specifications;

(i) Personnel transporting pharmaceutical products must be appropriately trained and shall provide the suitable documentation as proof, for this function and they must ensure that the correct procedures are followed to maintain the cold chain within the manufacturer's specification;

(j) At any stage of transportation, a delivery document must show evidence that the transport requirements, *inter alia* temperature control have been met. Damage to containers or any other event or problem which occurs during transit must be reported to and recorded by the responsible pharmacist of the pharmacy from which the pharmaceutical products were sent. Upon arrival the person responsible for the transportation of the pharmaceutical products must inform the patient or patient's agent or caregiver, that the package contains pharmaceutical products and provide information about specific storage requirements (as applicable);

(k) Proof of delivery (signed by the patient or the patient's agent or caregiver) must be presented within 24 hours of delivery to ensure that the patient does not miss a dose;

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Insertion of Rule 1.10

1.10 *MINIMUM STANDARDS FOR A COMMUNITY OR INSTITUTIONAL PHARMACY OPERATING A REMOTE AUTOMATED DISPENSING UNIT (RADU)* is hereby inserted as Rule 1.10

1.10.1 Introduction

Council embraces the use of innovation and technology to improve access to pharmaceutical services. Council is aware of the shortage of human resources in pharmacy and high burden of disease in this country that warrants the profession employing alternative methods of delivery of pharmaceutical services. The introduction of RADU aims to improve access to chronic medicines in rural areas and/or in areas where it might not be economical viable to establish a brick and mortar pharmacy.

1.10.2 Definitions of terms

(a) Enrolled patient – means a patient enrolled by a pharmacy to collect repeat medicine/s prescribed for a chronic condition and or disease at a location where a pharmacy was approved by Council to install or operate a remote automated dispensing unit.

(b) Approved pharmacy – means a pharmacy that obtained a certificate of approval from Council to operate a RADU and which pharmacy is in direct control of the RADU and is responsible for the proper functioning of the RADU in accordance with the minimum standards contained herein.

(c) Stable patient – refers to a patients who has been on medicines prescribed for a chronic condition and or disease for more than 3 months and his condition and or disease is under control on the prescribed treatment regimen.

(d) Remote automated dispensing unit (RADU) - refers to an automated dispensing unit that is remotely operated from an approved pharmacy to dispense medicines and medical devices.

1.10.3 Purpose

The purpose of this standard is to regulate the operation of a remote automated dispensing unit.

1.10.4 General considerations

(a) A pharmacy intending to install a RADU must apply to Council for approval of an installation of a RADU on the form provided by Council and pay the applicable fees, prior to operating a RADU.

(b) A pharmacy may only operate a RADU at the location approved by Council. The site where the RADU is installed must comply with minimum standards for pharmacy premises, facilities and equipment as published in the Rules relating Good Pharmacy Practice.

(c) A pharmacy approved to operate a RADU must:

(i) retain records of all prescriptions filled at the RADU. Such records must be available to Council on request or during an inspection of the pharmacy;

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(ii) have a procedure and a mechanism for securing and accounting for damaged or expired medicines and medical devices at the RADU;

(iii) develop and maintain all policies and procedures regarding the usage of RADU;

(iv) ensure that adequate systems and procedures relating to the RADU are in place and that there is compliance with such systems and procedures.

(d) Only registered pharmacy personnel may have access to the RADU for the purpose of stock management and dispensing medicines and medical devices.

1.10.5 Specific considerations for a community pharmacy

(a) A community pharmacy must not operate more than one remote automated dispensing unit.

(b) A remote automated dispensing unit may not be established within a five kilometer radius of any existing community pharmacy.

(c) A community pharmacy must only use a RADU for the purposes of dispensing repeat prescriptions for medicines and medical devices for chronic conditions or diseases.

(d) A community pharmacy must only give access to enrolled and stable patients to collect their medicines and medical devices from the RADU.

1.10.6 Specific considerations for an institutional pharmacy

(a) An institutional pharmacy may operate more than one remote automated dispensing unit.

(b) An institutional pharmacy may use a RADU for the purposes of dispensing both acute medicines and repeat medicines and medical devices for the treatment of chronic condition and or diseases;

(c) In the case where a RADU is used to dispense a prescription with no repeats, the copy of the prescription must be retained by the unit.

1.10.7 Dispensing of medicines using a RADU

(a) Phase 1 and 3 of the dispensing processes must be performed only by a pharmacist through the audio visual interface, at the time of dispensing.

(b) Dispensing services must be under the direct supervision of a pharmacist and the approved pharmacy must be under the direct continuous supervision of a responsible pharmacist.

(c) A pharmacist may only dispense one prescription at a time, when using a RADU.

(d) All dispensed prescription from RADU must be signed in person by the pharmacist.

(e) All medicines and medical devices dispensed at or by RADU must be labelled in accordance with the requirements of Regulation 8(4) of the General Regulations published in terms of the Medicines and Related Substances Act 101 of 1965 and

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must include the address of the remote dispensing unit and pharmacy that manages the RADU .

(f) If a patient refuses the dispensed medicine by RADU, the medicine must be locked in a secured cabinet by the RADU and not re-dispensed until checked by a pharmacist or pharmacy support personnel for quality assurance purposes;

(g) Only medicines in the original patient ready packs prepared by the manufacturer thereof with the exception of reconstitution of dry powder medicines (where applicable) may be dispensed from a RADU;

(h) No specified schedule 5 and schedule 6 substances shall be dispensed using a RADU;

(i) A pharmacist must be accessible to respond to all enquiries and or requests from a patient utilizing the RADU.

1.10.8 The responsibilities of a responsible pharmacist of the pharmacy from which the RADU is managed

In addition to complying with the requirements of Regulation 28 of the Regulations relating to the practice of pharmacy, the responsible pharmacist must:

(a) ensure that the RADU operates in compliance with all relevant legislation;

(b) ensure that the pharmacy offering dispensing services through a RADU is appropriately staffed;

(c) provide proof to Council, in the form of an assessment certificate from the internet service provider (ISP), that there is adequate connectivity to facilitate communication between the patients and the pharmacist operating the RADU;

(d) assure the integrity of the medicines dispensed from a remote automated dispensing unit;

(e) ensure that there is a proper stock control and only registered pharmacy personnel may stock the RADU;

(f) ensure that stock counts of stock in the RADU are done at the same time as stock counts in the pharmacy;

(g) ensure that pharmacy personnel who operate the RADU are properly trained and document such training;

(h) ensure that written policies and procedures are developed before the unit is operated to:

(i) ensure the safe and effective dispensing of medicines and medical devices;

(ii) ensure that the RADU is operating safely, accurately, and securely; and

(iii) define conditions for access to the RADU and medicines contained in the unit, as well as policies that assign, discontinue, or change access to the remote automatic dispensing unit and medicines;

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(i) ensure that only pharmacist or pharmacy support personnel employed by the pharmacy approved to operate a RADU have secured access to the medicines in the RADU;

(j) ensure that access to the medicines in the remote dispensing unit complies with all applicable legislation.

1.10.9 Record keeping

(a) Records of prescriptions filled at the RADU must be maintained at the pharmacy approved to operate RADU; and

(b) Records must be available for inspection at all times and must include the following,

(i) all prescriptions dispensed at the remote automated dispensing unit;

(ii) all inventory movement at the remote automated dispensing unit; and

(iii) a policy and procedure manual of the remote automated dispensing unit.

1.10.10 Security, location, connectivity and features of a RADU

A remote automated dispensing unit must:

(a) be well secured to prevent unauthorised access at all times and entry must be limited to authorised personnel only;

(b) be located in a place that is adequately secured to ensure that there is a provision of privacy and that the medicines are secured during filling and stocking of the machine;

(c) be connected via live computer, video, and audio link to the pharmacy through the information technology system of the pharmacy approved to operate the RADU;

(d) not be operated if there is no audio-visual link and/or the computer at the RADU or the operating pharmacy is dysfunctional;

(e) have a private area available for communication between the patient and the pharmacist operating the RADU and;

(f) have the following features:

(i) double-locked cabinets to ensure that it is appropriately secured at all times;

(ii) bar-coding or similar technology that effectively recognises the product;

(iii) a cabinet that delivers only bar-coded patient ready pack;

(iv) a scanner that confirms the correctness of the patient ready pack

(v) a printer that performs labelling using a bar coding system;

(vi) a video component that allows the patient to have a "face-to-face" consultation with the pharmacist at the pharmacy.

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1.10.11 Documentation and information displayed conspicuously at the RADU

(a) copies of the license and/or recording/registration certificate of the pharmacy approved to operate RADU;

(b) the original certificate of approval issued by Council for a pharmacy to operate a RADU;

(c) a copy of the registration certificate of the responsible pharmacist; and

(d) contact details of the pharmacy approved to operate RADU.

1.10.12 Information to be submitted in support of an application for installation and operation of a RADU

Documentation as to the type of equipment, serial numbers, content, policies and procedures, must be submitted with an application for review by Council. Such documentation must include but not limited to:

(a) A professionally drawn floor plan and site plans of the pharmacy premises indicating the location of the RADU; if the RADU is attached the outer perimeter wall of a pharmacy;

(b) A professionally drawn floor plan and site plans of the of the RADU if the RADU is located elsewhere other than at the pharmacy;

(c) Name and address of the location where the RADU is being used;

(d) Manufacturer's name and model and or unique identifier of the machine.