



Government Gazette Staatskoerant

REPUBLIC OF SOUTH AFRICA
REPUBLIEK VAN SUID-AFRIKA

Vol. 596

Pretoria, 27 February 2015
Februarie

No. 38511

N.B. The Government Printing Works will not be held responsible for the quality of "Hard Copies" or "Electronic Files" submitted for publication purposes



AIDS HELPLINE: 0800-0123-22 Prevention is the cure

IMPORTANT NOTICE

The Government Printing Works will not be held responsible for faxed documents not received due to errors on the fax machine or faxes received which are unclear or incomplete. Please be advised that an "OK" slip, received from a fax machine, will not be accepted as proof that documents were received by the GPW for printing. If documents are faxed to the GPW it will be the sender's responsibility to phone and confirm that the documents were received in good order.

Furthermore the Government Printing Works will also not be held responsible for cancellations and amendments which have not been done on original documents received from clients.

CONTENTS • INHOUD

<i>No.</i>		<i>Page No.</i>	<i>Gazette No.</i>
BOARD NOTICES			
49	Pharmacy Act (53/1974): Rules relating to what constitutes Good Pharmacy Practice: Comments	3	38511
50	do.: Rules relating what constitutes Good Pharmacy Practice: Implementation	13	38511

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).



TA Masango
REGISTRAR

Address: 591 Belvedere Street, Arcadia, Pretoria, 0083, Private Bag X40040, Arcadia, 0007.
Telephone: 0861 7272 00. Facsimile 012-321 1479/92

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.

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.

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;

- (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;

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;

- (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

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;

- (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.

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.

BOARD NOTICE 50 OF 2015**THE SOUTH AFRICAN PHARMACY COUNCIL****RULES RELATING TO GOOD PHARMACY PRACTICE**

The South African Pharmacy Council herewith publishes amendments for implementation to the minimum standards as contained in Annexure A of the *Rules relating to good pharmacy practice* which was published on 17 December 2004 Government Gazette No: 27112, in Board Notice 129 of 2004 (as amended) 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 rules to Annexure A of the *Rules relating to good pharmacy practice* are hereby amended –

(a) Rule 1.2.1, paragraphs (d) and (e);

(b) Amendments to Rule 2.3.5

Minimum standards for the procurement, storage and distribution of thermolabile pharmaceutical products; and

(c) Annexure A: Rule 2.1.1.2.

The following minimum standard as published herewith shall constitute an additional standard as identified as Rule 1.9 to Annexure A of the *Rules relating to good pharmacy practice* in accordance with section 35A(b) (ii) of the Act -

(a) Rule 1.9

Minimum standards relating to automated dispensing units for the purpose of dispensing medicines and medical devices.



**TA MASANGO
REGISTRAR/CEO**

Address: 591 Belvedere Street, Arcadia, Pretoria, 0083; Private Bag X40040, Arcadia, 0007. Tel: 0861 7272 00. Facsimile 012-321 1479/92

Amendments to Rule 1.2.1: Appearance of pharmacy premises

Rule 1.2.1.Paragraphs (d) and (e) are hereby amended as follows:

- (d) The name and surname of the pharmacist(s) on duty must be displayed conspicuously in or outside the pharmacy for purposes of identification of such person(s) by the public.
- (e) The pharmacist(s) and pharmacy support personnel on duty must wear a name tag or badge indicating his/her name, surname and registered designation (e.g. responsible pharmacist, specialist, etc.) for the purposes of identification of such person by the public. This may be combined into a single badge or two separate badges.

Amendments to Rule 2.3.5

Rule 2.3.5 is hereby replaced as follows:

MINIMUM STANDARDS FOR THE PROCUREMENT, STORAGE AND DISTRIBUTION OF THERMOLABILE PHARMACEUTICAL PRODUCTS

2.3.5.1 Introduction

Thermolabile pharmaceutical products are defined as all products which require constant cold storage at product specific temperatures below room temperature. This also includes vaccines which are normally stored between 2 °C and not exceeding 8 °C. "Cold chain products" bears a corresponding meaning.

Storage, supply and distribution forms part of the supply chain management of thermolabile pharmaceutical products. All pharmacists are responsible for the effective, efficient and safe handling, storage and distribution of such products. These standards set out appropriate steps for meeting this responsibility.

Handling and storage of thermolabile pharmaceutical products must be in accordance with procedures, which must be established and designed to prevent contamination, deterioration of the goods, and damage to packs and/or confusion of products. Particular care must be given to maintaining the integrity of ingredients and seals on packs. Attention must be paid to instructions from the manufacturer relating to handling or storage of the goods. Distribution systems chosen to deliver thermolabile pharmaceutical products from the manufacturer/importer to the end user must take into account basic operational parameters, including timeliness and accountability.

Importers must take all reasonable measures to ensure that thermolabile pharmaceutical products are not mishandled or exposed to adverse storage conditions at ports of entry.

Storage, supply and distribution of thermolabile pharmaceutical products must be in accordance with the provisions of the Medicines and Related Substances Control Act, 101 of 1965 and the manufacturer's specification.

2.3.5.2 Procurement

Procurement of thermolabile pharmaceutical products must be performed in terms of the Minimum standards for procurement, storage and distribution as detailed in Rule 2.3 of the *Rules pertaining to good pharmacy practice*.

2.3.5.3 Storage area

Storage areas may include *inter alia* **cold rooms, refrigerators and freezer**. Thermolabile pharmaceutical products require controlled temperature storage and therefore must be identified on receipt and be stored in accordance with written instructions. Temperatures must be monitored and recorded twice daily. Records must be reviewed regularly. Controlled temperature storage areas must be equipped with temperature recorders. Control must be adequate to maintain all parts of the area within the specified temperature range. This control is essential in maintaining the quality of thermolabile pharmaceutical products and in helping to protect the end user from sub-standard or ineffective thermolabile pharmaceutical products as a result of inadequate control.

- (a) Thermolabile pharmaceutical products must be stored in a storage area, refrigerator or cold room, in a temperature regulated environment as per the information on the manufacturer's product label indicating which temperature must be maintained at all times.
- (b) The storage area must be large enough to allow for orderly arrangement of products, to permit air circulation especially between shelving and for proper product rotation. If it is filled to capacity, the effect on temperature distribution must be investigated.
- (c) The storage area must be kept clean. Internal air temperature distribution must be mapped on installation of the storage area while empty and thereafter fully stocked. This must be done annually under conditions of normal use. Thermolabile pharmaceutical products must not be stored in areas shown by temperature mapping to present a risk (e.g. in the airflow from the refrigeration unit).
- (d) All storage areas, such as refrigerators or cold rooms must be properly maintained in order to maintain the factory standards for such storage areas. Proof of maintenance must be provided.
- (e) Condensation from chillers must not be collected inside the storage area, and no condensation from chillers may collect or drip onto the products.
- (f) A suitable number of temperature recording instruments that complies with or meets WHO specifications, being at least a logging device, must be installed to record temperatures and to provide temperature and profiles as per the temperature mapping of the storage area. Monitors that complies with or meets WHO specifications, must be adequate to monitor and record temperature ranges in all parts of the area within the specified temperature range.
- (g) Temperatures must be monitored and recorded at least twice daily, with a minimum of seven hour interval and the records from such monitoring must be reviewed daily.
- (h) Large commercial refrigerators and walk-in cold rooms must be monitored with an electronic temperature-recording device that measures load temperature in one or more location, depending on the size of the unit.

- (i) In the monitoring of large commercial refrigerators and walk-in cold rooms, portable data-loggers that can be downloaded onto a computer may be used instead of a fixed device.
- (j) The refrigerator, cold room or freezer must be connected to a standby generator or other emergency power system to ensure uninterrupted power supply in the event of power failure.
- (k) The refrigerator, cold room or freezer must be connected to an alarm system and/or warning system in the event of a power failure or if the storage area temperature limits are exceeded.
- (l) Any recording devices/instruments must be calibrated annually against a certificated standard.
- (m) The refrigerator, cold room or freezer must be clearly designated and appropriately signed to store exclusively thermolabile pharmaceutical products.
- (n) Within a community or institutional pharmacy the storage area must be inside the pharmacy and must be easily accessible to the pharmacist and pharmacy support personnel and other authorised healthcare professionals.
- (o) Within a health facility (other than a pharmacy), any storage area for thermolabile pharmaceutical products must be easily accessible to the authorised healthcare professionals.

2.3.5.4 Distribution

A distribution system must have in place:

- (a) a comprehensive quality system;
- (b) a process for continual quality improvement;
- (c) an ambient and cold chain distribution strategy;
- (d) a risk assessment programme.

Thermolabile pharmaceutical products must be transported by appropriately specialised means in such a way that they are secure and are not subjected to unacceptable degrees of heat / cold.

- (a) Packaging system of thermolabile pharmaceutical products, for purposes of distribution must be quality assured to ensure that it occurs within the cold room environment, fulfils the manufacturers' specifications requirements, is thermally designed and validated, and is related to Temperature Profile(s)/Logistic history.
- (b) There must be clear, visible labelling on the packaging with instructions regarding storage conditions, special precautions and warnings for the shipment.

2.3.5.5 Transportation

- (a) Transportation of thermolabile pharmaceutical products 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 approved for transporting thermolabile pharmaceutical products. Examples include refrigerator trucks, cars, ships, and containers. Thermolabile pharmaceutical products shall be transported in any mode(s) of transportation which is permanently enclosed and sealed. No open vehicles shall be permitted for purposes of transporting thermolabile pharmaceutical products.
- (c) In the event of the mode(s) of transport not being specific for the transportation of thermolabile pharmaceutical products, the specialised packaging like validated cooler bag packaging must be used.
- (d) For purposes of transportation, the route must be planned and assessed and/or validated to ensure that delays and/or exposure to extreme temperatures are correctly assessed. Transportation between South Africa and other neighbouring countries and within South Africa, due to large geographical areas, must be treated as unique in terms of the range of temperatures that the thermolabile pharmaceutical products may experience.
- (e) The transport must be clean and free from all forms of contamination, *inter alia* rats, vermin, birds, fungi, and mites.
- (f) During transportation thermolabile pharmaceutical products must not be packaged with non-pharmaceutical items or containerised with any other goods (for example food and beverages which may also require refrigeration transportation), which could result in contamination.
- (g) The transport must have a sufficient capacity to allow for orderly storage of thermolabile pharmaceutical products during transportation.
- (h) Temperature data loggers, refrigeration tags, freezer tags, log tags or cold chain monitoring cards that complies with or meets WHO specifications must monitor the temperature of the loaded area of the transportation throughout the trip, and the validated cooler box packaging must have at least a temperature monitoring device that complies or meets with WHO specifications.
- (i) Personnel transporting thermolabile pharmaceutical products must be appropriately trained, in terms of an approved unit standard for cold chain management 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.
- (k) 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 distributing pharmacy. Upon arrival the person responsible for the transportation of the thermolabile pharmaceutical products must inform receiving personnel, pharmacists, or other authorised healthcare professionals, that the package includes thermolabile pharmaceutical products and that they require immediate attention.

2.3.5.6 Receiving

Thermolabile pharmaceutical products must be identified on receipt and be stored in accordance with written instructions for purposes of stock management within the shortest possible time from offloading.

- (a) The receiving area must protect deliveries from bad weather during the unloading of thermolabile pharmaceutical products;
- (b) The receiving area must be separated from the storage area;
- (c) Upon arrival of thermolabile pharmaceutical products, the receiving personnel must do spot checks and inspect the delivery vehicle to ensure product integrity with regards to the following:
 - (i) product security,
 - (ii) that the product has not been tampered with and that there are no damaged containers,
 - (iii) that products were protected from weather,
 - (iv) and that there is no risk for contamination of products.
- (d) The delivery document must be reviewed for evidence that transportation requirements, *inter alia* temperature control, have been met;
- (e) Check temperature data loggers, refrigeration tags, freezer tags, log tags or cold chain monitoring cards to ensure the temperature history of the transport and the temperature history of the thermolabile pharmaceutical product being transported were maintained within in limits.
- (f) If any discrepancies are identified, they must all be documented. In addition the supplier must be notified immediately and the thermolabile pharmaceutical products must be identified and segregated.
- (g) A Standard Operating Procedure for receiving of thermolabile pharmaceutical products must be used to ensure these products are within manufacturer specific temperature range during the receiving process.
- (h) Quality assessment sampling requiring laboratory testing is required for the received thermolabile pharmaceutical products within a manufacturing pharmacy before they are taken to the main store facility.
- (i) Quality assessment sampling requiring observation for damaged products is required for the received thermolabile pharmaceutical products within a wholesale, community or institutional pharmacy before they are taken to the main store facility.

- (j) Delivery documents must be signed off on temperature data and condition of other control devices used.
- (k) The thermolabile pharmaceutical products must be removed from the transportation container or cooler bag prior to storage in the main store area to prevent temperature deviation.

2.3.5.7 Documentation

- (a) Documentation is critical. Each step of the supply chain must follow established protocols in order to maintain proper records.
- (b) Customs delays may occur due to inaccurate or incomplete customs documentation, therefore guidelines for creating a commercial invoice must be followed to ensure the proper verbiage, number of copies, and other details.
- (c) Each time the process does not conform to the procedure, the event must be properly documented, investigated and corrected so that the deviations do not occur on future transportation.

2.3.5.8 Personnel

- (a) All persons involved in the procurement, storage and distribution of thermolabile pharmaceutical products must have the education, training, experience or combination of these elements that will allow them to effectively discharge this responsibility and be capable of meeting these requirements. This training must be documented.
- (b) Procedures and conditions of work for employees and other persons having access to thermolabile pharmaceutical products must be designed and managed to minimise the possibility of such pharmaceutical products being in possession of unauthorised persons.
- (c) All persons involved in the procurement, storage and distribution of thermolabile pharmaceutical products must have the ability/skill appropriate to their responsibility, for ensuring that thermolabile pharmaceutical products are handled, stored and distributed in accordance with the required minimum standards.
- (d) There must be an adequate number of competent persons involved in all stages of the distribution of thermolabile pharmaceutical products in order to ensure that the quality of these products is maintained.
- (e) Persons involved in the procurement, storage and distribution of thermolabile pharmaceutical products must be supplied with appropriate personal protective equipment and with specialised protective garments suitable for the activities that they perform.
- (f) Material safety data sheets must be accessible to any staff member that requires the information. A Spillage Handling Standard Operating Procedure must be available, in accordance with national environment management act (1978) and other related prescripts.
- (g) Appropriate procedures relating to personal hygiene and sanitation, relevant to the activities to be carried out, must be established and observed. Such procedures must cover *inter alia* health, hygiene and clothing of personnel.

2.3.5.9 Disruption in the procurement, storage and distribution of thermolabile pharmaceutical products (cold chain)

When there is a disruption in the storage and or distribution of thermolabile pharmaceutical products or a disruption is reasonably suspected:

- (a) In the event that there is disruption in the cold chain, the designated responsible person must be informed and appropriate steps taken to manage the situation.
- (b) Actions must comply with manufacturer's documented advice, where possible and where available.
- (c) An incident report and root cause analysis investigation must be completed to ensure lessons are learned to prevent reoccurrence.
- (d) Pharmacies and authorised healthcare professionals must have business continuity plans for storing thermolabile pharmaceutical products in the event of refrigerator breakdown, loss of electricity supply, defrosting or other disruptions to the cold chain, which must be implemented immediately to prevent loss.
- (e) Refrigerator temperature must be recorded by noting the current reading and recording the maximum and minimum temperatures.
- (f) If the temperature of the storage area has deviated from the product specific temperature requirement, stock must be moved to an alternative cold storage area.
- (g) In the event of moving stock, the stock so moved must be segregated by packing separately and marked, indicating "Batch Number(s) involved in a potential incident – **do not use until authorised**" and dated to make sure the implicated stock can be identified and kept separate.
- (h) Where immediate removal is not possible, the storage area must be kept closed to maximize temperature control.
- (i) Monitoring of the temperature must be maintained on at least an hourly basis and recorded up until the point of restoration to working order of the storage area or removal and transfer to another cold store.
- (j) Check for evidence of exposure of the thermolabile pharmaceutical products for deviations in temperature and establish how long the products have been stored outside of the specified temperature requirements.
- (k) Refer to the manufacturer for advice on stability as a result of temperature deviation and report the occurrence on an incident report form.
- (l) Where necessary record and quarantine the thermolabile pharmaceutical product for destruction in line with the minimum standards for destruction and disposal of medicines and scheduled substances.
- (m) If advised that the products are safe for use then mark as "**Use first**" and date, such products must then be used before any other stock of the same product.

Amendments to Rule 2.1.1 of Annexure A: Circumstances and conditions under which a responsible pharmacist may be absent from his/her pharmacy:

Rule 2.1.1.2 of Annexure A: Condition, is amended as follows:

Paragraph (i) is repealed, and paragraph (ii) is amended as follows:

- (ii) Schedule 1 to 6 substances are locked away in an area of which the key must be in the personal possession of the responsible pharmacist.

Insertion of Rule 1.9

MINIMUM STANDARDS RELATING TO AUTOMATED DISPENSING UNITS FOR THE PURPOSE OF DISPENSING MEDICINES AND MEDICAL DEVICES is hereby inserted as Rule 1.9

1.9.1 Introduction

Automated dispensing units (ADUs) are mechanical systems that perform operations or activities, other than compounding or administration, relative to the storage, picking, packaging, labelling, and/or giving out medicines and medical devices. They are also called automated dispensing cabinets (ADCs), automated dispensing devices (ADDs), automated dispensing machines (ADM), automated pharmacy systems (APS), or unit-based cabinets (UBC).

Council recognises that ADUs are technology advancements that can improve speed and accuracy of medicine delivery. ADUs can assist pharmacists and licensed dispensers with phase 2 of dispensing, freeing them to focus more on patient care. The role of ADUs in the dispensing process makes it necessary for Council to exercise its ethical and legal commitment to the community by regulating ADUs in order to ensure safe delivery of pharmaceutical services.

1.9.2 Purpose

The purpose of this standard is to regulate the use of ADUs in community pharmacies, institutional pharmacies, dispensaries in primary health care clinics and medicine rooms of licensed dispensers. Minimum standards specifically relating to ADUs are thus intended to guide pharmacists and licensed dispensers on the use of ADUs. Where ADUs are utilised, all relevant legislation is applicable.

1.9.3 General considerations

- (a) ADUs may be installed in a pharmacy or dispensary in a primary health care clinic or medicine rooms of licensed dispensers for the purpose of assisting with phase 2 of the dispensing process in accordance with the applicable legislation.
- (b) The installation and the location of the ADU must be such that medicines and medical devices are not accessed and/or received directly by the patient or his or her caregiver or agent.
- (c) The Responsible Pharmacist wishing to install the ADU must apply to Council and pay the applicable fees prior to installation and operation of an ADU.
- (d) The ADU may be installed in the primary healthcare clinic dispensary that complies with the minimum standards provided in Rule 1.6 of the GPP document.

- (e) The ADU may be installed in the medicine room of a licensed dispenser that complies with the minimum standards provided in Rule 1.7 of the GPP document.
- (f) The Responsible Pharmacist or a licensed dispenser utilising the ADU must have a contingency plan to ensure continuous supply of medicines and medical devices in an event of power or system failure.
- (g) A pharmacy that operates an ADU must still comply to all relevant standards and legislation

1.9.4 Dispensing of medicines using a ADU

- (a) Phase 1 and Phase 3 of dispensing must be done by the pharmacist, pharmacy support personnel or licensed dispenser, within their scope of practice.
- (b) A pharmacist, pharmacy support personnel or licensed dispenser may only operate one ADU at a time and thereby dispense one prescription at a time.
- (c) The pharmacist or licensed dispenser must be accessible to respond to inquiries or requests pertaining to all medicines and medical devices dispensed from an ADU.
- (d) All prescription dispensed from ADU must be signed in person by the pharmacist or licensed dispenser.
- (e) All medicines and medical devices stored in the ADU must be packaged and labelled in accordance with the applicable legislation when dispensed to the patient.

1.9.5 The stocking and management of the ADU

The filling and or stocking of all medicines and medical devices into the ADU must be done by the pharmacist, pharmacist intern, and relevant pharmacy support personnel under the supervision of the pharmacist or licensed dispenser.

1.9.6 The responsibilities of a responsible pharmacist of a pharmacy approved to operate an ADU

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 access to the medicines and medical devices in the ADU comply with the applicable legislation;
- (b) ensure that only registered persons handle medicines and medical devices in the ADU;
- (c) ensure that the ADU is filled/stocked accurately and in accordance with established, written policies and procedures;
- (d) ensure that in the process of picking, re-packaging and packing, cross-contamination is avoided at all times;

- (e) ensure that the ADU is tested prior to initial use in accordance with the manufactures' specifications to ensure that the ADU is operating properly; and
- (f) ensure that the ADU is tested on a periodic basis in accordance with the manufactures' specifications to ensure that the ADU is operating properly.
- (g) assign, discontinue, or change access control of persons to the ADU in line with such persons scope of practice.

1.9.7 Security, location, connectivity and features of an ADU

- (a) The ADU must have adequate security systems and procedures, evidenced by written policies and procedures, to:
 - (i) prevent unauthorised access;
 - (ii) comply with legislation; and
 - (iii) prevent the illegal use or disclosure of protected health information (confidentiality).
- (b) The ADU must have a procedure and physical mechanism for securing and accounting for medicines and medical devices removed from and subsequently returned to the ADU, all in accordance with the applicable legislation.
- (c) The ADU must have a procedure and physical mechanism for securing and accounting for damaged or expired medicines and medical devices in accordance with the applicable legislation.

1.9.8 Record keeping

- (a) A record of medicines and medical devices filled and or stocked into the ADU must be maintained and must include identification of the registered persons filling/stocking and checking for accuracy.
- (b) Records must be maintained and must be readily available to Council. Over and above the requirements of Regulations 11 and 30, such records, must include but are not limited to:
 - (i) Identification of the persons accessing the ADU for purposes stock management;
 - (ii) identification of persons accessing the ADU for purposes of dispensing;
 - (iii) name, strength, dosage form, and quantity of the medicine and/or medical devices;
 - (iv) name of the patient for whom the medicine and/or medical devices were dispensed; and
 - (v) such additional information as the responsible pharmacist may deem necessary.
- (c) All transactions involving medicines and medical devices stored in the ADU must be recorded electronically.

- (d) All aspects of handling specified Schedule 5 and Schedule 6 medicines must meet the requirements of all applicable legislation.

1.9.9 Information to be submitted in support of an application for the installation of the ADU in a pharmacy

Documentation that must be submitted with the application for review by Council must include but is not limited to:

- (a) manufacturer's name and model of the ADU including type of equipment and serial numbers;
- (b) a professionally drawn floor plan and site plans of the pharmacy premises indicating the location of the ADU;
- (c) name and address of the pharmacy where the ADU is to be installed;
- (d) description of how the ADU is used in the dispensing process.
-

Printed by and obtainable from the Government Printer, Bosman Street, Private Bag X85, Pretoria, 0001
Publications: Tel: (012) 748 6052, 748 6053, 748 6058

Advertisements: Tel: (012) 748 6205, 748 6208, 748 6209, 748 6210, 748 6211

Subscriptions: Tel: (012) 748 6054, 748 6055, 748 6057

Gedruk deur en verkrygbaar by die Staatsdrukker, Bosmanstraat, Privaatsak X85, Pretoria, 0001

Publikasies: Tel: (012) 748 6052, 748 6053, 748 6058

Advertensies: Tel: (012) 748 6205, 748 6208, 748 6209, 748 6210, 748 6211

Subskripsies: Tel: (012) 748 6054, 748 6055, 748 6057