

**BOARD NOTICE 272 OF 2013****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](mailto: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 rules of Annexure A of the *Rules relating to good pharmacy practice* are amended:
  - (a) Rule 1.2.1;
  - (b) Rule 2.13.5.5;
  - (c) Rule 2.13.5.8;
  - (d) Rule 4.3.6; and
  - (e) Annexure A: Scope of practice of Pharmacy Personnel – Authority, duties and responsibilities of the Responsible Pharmacist.
3. The following minimum standards as published herewith shall constitute additional 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) Minimum standards for the procurement, storage and distribution of thermolabile pharmaceutical products;
  - (b) Minimum standards relating to courier services; and
  - (c) Minimum standards relating to automated dispensing units for the purpose of dispensing medicines and medical devices.



**TA MASANGO**  
**REGISTRAR**

**MINIMUM STANDARD FOR PHARMACY PREMISES, FACILITIES AND EQUIPMENT****Rule 1.2.1: Appearance of pharmacy premises, is amended as follows:****Paragraph (d) and paragraph (e) which read as follows:**

- (d) The name 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) on duty must wear a name tag or badge indicating his/her name and designation for the purposes of identification of such person by the public.

**Be replaced with:**

- (d) The name of the pharmacist(s) and pharmacy support personnel 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 and designation for the purposes of identification of such person by the public.

**MINIMUM STANDARDS FOR THE PERFORMANCE OF HIV TESTS****Rule 2.13.5.5: Interpretation of results, Tests performed in pharmacies, is amended as follows:****Paragraph (a) which read as follows:**

- (a) The wide availability of rapid tests enables pharmacists to contribute to the important measure of voluntary counselling and testing (VCT). Rapid tests have the advantage that the patient can receive the result virtually immediately and does not have to return to the pharmacy later. A major disadvantage is that the short time interval between the performance of the test and the receipt of the result poses challenges for counselling. Only rapid tests which use a blood sample must be performed in a pharmacy.

**Is replaced by:**

- (a) The wide availability of rapid tests enables pharmacists to contribute to the important measure of voluntary counselling and testing (VCT). Rapid tests have the advantage that the patient can receive the result almost immediately and does not have to return to the pharmacy later. A major disadvantage is that the short time interval between the performance of the test and the receipt of the result poses challenges for counselling.

**Rule 2.13.5.8: Ethical aspects is amended as follows:****Paragraph (h) which read as follows, is deleted:**

- (h) Pharmacists must not sell HIV tests for patients to perform at home.

## **MINIMUM STANDARDS FOR CONTINUOUS SUPPLY OF MEDICINES**

**Rule 4.3.6 Minimum standards for continuous supply of medicines is amended as follows:**

- (a) Pharmacist practising in community and institutional pharmacies must be available to provide a pharmaceutical service to the public on a 24 hour basis.
- (b) If a pharmacy is not open on a 24 hour basis, a designated pharmacist(s) must be available for the emergency supply of pharmaceutical services.
- (c) Contact details of the pharmacist-on-duty must be displayed conspicuously at the pharmacy premises.

**Replaced with sub-rules 4.3.6.1 and 4.3.6.2 below:**

### **4.3.6.1 MINIMUM STANDARDS FOR CONTINUOUS SUPPLY OF MEDICINES – COMMUNITY PHARMACY**

- (a) Pharmacist(s) practising in community pharmacies must be available to provide a pharmaceutical service to the public on a 24 hour basis.
- (b) If a pharmacy is not open on a 24 hour basis, a designated pharmacist must be available for the emergency supply of pharmaceutical services.
- (c) Contact details of the pharmacist-on-duty must be displayed conspicuously at the pharmacy premises.

### **4.3.6.2 MINIMUM STANDARDS FOR CONTINUOUS SUPPLY OF MEDICINES – INSTITUTIONAL PHARMACY**

- (a) Pharmacist(s) practising in institutional pharmacies must be available onsite to provide a pharmaceutical service on a 24 hour basis.

## **ANNEXURE A**

### **SCOPE OF PRACTICE OF PHARMACY PERSONNEL**

## **2. AUTHORITY, DUTIES AND RESPONSIBILITIES OF A RESPONSIBLE PHARMACIST**

**Rule 2.1.1: Circumstances and conditions under which a responsible pharmacist may be absent from his/her pharmacy is amended as follows:**

**The following is added:**

#### **Preamble**

The GPP rules provide that a pharmacy must be run under the personal continuous supervision of a pharmacist.

The standard provides for exceptional circumstances upon which the responsible pharmacist may be absent from his or her pharmacy. The exceptions are to provide for the case where there is only one pharmacist and will have to take care of operational and pharmacy business

issues; and family emergencies. This should not be construed to mean that the responsible pharmacist may be absent from the pharmacy on a regular, continuous and or repetitive basis.

**Rule 2.1.1.2: Condition, is amended as follows:**

**Paragraph (i) is deleted, and paragraph (ii) which read as follows:**

- (ii) schedule 2 to 6 substances were locked away in an area of which the key must be in the personal possession of the responsible pharmacist.

**is replaced with paragraph (i) below:**

- (i) 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.

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

**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 the corresponding meaning.

Storage, supply and distribution forms part of the supply chain management of thermolabile pharmaceutical products. All pharmacies are responsible for the effective, efficient, 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, 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. 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*.

### 3. STORAGE AREA

#### 3.1 General principles

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 which temperature must be maintained at all times.
- (b) No domestic refrigerators shall be deemed suitable for the storage of thermolabile pharmaceutical products.
- (c) 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.
- (d) 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).
- (e) 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.
- (f) Condensation from chillers must not be collected inside the storage area, and no condensation from chillers may collect or drip onto the products.
- (g) A suitable number of WHO approved temperature recording instruments, 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. WHO approved monitors must be adequate to maintain all parts of the area within the specified temperature range.
- (h) 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.
- (i) 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.
- (j) 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.
- (k) 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.

- (l) The refrigerator, cold room or freezer must be connected to an alarm system that will alert the pharmacist in the event of a power failure or if the storage area temperature limits are exceeded.
- (m) Any recording devices/instruments must be calibrated annually against a certificated standard.
- (n) The refrigerator, cold room or freezer must be clearly designated and appropriately signed to store thermolabile pharmaceutical products exclusively.
- (o) Within a community, institutional or courier 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.
- (p) Within a health facility (other than a pharmacy), any storage area for thermolabile pharmaceutical products must be easily accessible to the authorised healthcare professionals.

#### **4. DISTRIBUTION**

##### **4.1 General principles**

4.1.1 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.

4.1.2 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.

##### **4.2 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 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 WHO approved data loggers, refrigeration tags, or lock tags 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 WHO temperature monitoring device.
- (i) Personnel transporting thermolabile pharmaceutical products must be appropriately trained, in terms of the 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.

## 5. RECEIVING

### 5.1 General principles

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 and freezer tags monitor to ensure the temperature history of the transport and the temperature history of the thermolabile pharmaceutical product being transported.
- (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 product 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 manufacturer or wholesale 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 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.

## **6. DOCUMENTATION**

### **6.1 General principles**

- (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.

## **7. PERSONNEL**

### **7.1 General principles**

- (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, similar in nature to that of chemotherapy products.
- (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.

## **8. DISRUPTION IN THE PROCUREMENT, STORAGE AND DISTRIBUTION OF THERMOLABILE PHARMACEUTICAL PRODUCTS (COLD CHAIN)**

### **8.1 General principles**

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, and then such products must be used before any other stock.

#### **MINIMUM STANDARDS SPECIFICALLY RELATING TO COURIER PHARMACIES**

Courier dispensing service entails dispensing and transportation of medicines and medical devices to a patient who may not be in close physical proximity to the pharmacy. Provision of pharmaceutical services via courier must comply with the requirements of the GPP Rule 2.7.1.3 to ensure that there is face to face contact with the patient or their care-giver. The pharmacy providing courier services must deliver all medicines to a selected community pharmacy/institutional pharmacy in close proximity to the geographical area of the patient and/or caregiver of the patient's choice or as determined by the state in case of the state healthcare system. The receiving pharmacy

will then complete phase 3 of the dispensing process in accordance with the provisions of Rule 2.7.1.3 of the GPP.

The proportion of the dispensing fee due to both the courier pharmacy and the selected pharmacy shall be calculated in accordance with the provisions of *Rules relating to services for which a pharmacist may levy a fee* (Government Gazette No: 33898, published in Board Notice 193 of 2010 on 20 December 2010) and in accordance with Regulation 10 of the *Regulations relating to a transparent pricing system for medicines and scheduled substances* (GNR. 1102 of 11 November 2005 as amended).

1. The pharmacists at both the courier and community/institutional pharmacies must be accessible to respond to inquiries or requests pertaining to all medicines and medical devices dispensed from a community/institutional pharmacy that forms part of the courier system.
2. A pharmacy offering courier services must have adequate security systems and procedures, evidenced by written policies and procedures. These would specifically include but are not limited to minimum standards for pharmacy premises, facilities and equipment; face to face (via video link) or interactive telephonic communication must be encouraged.
3. If the courier pharmacy is not within a reasonable distance from the patient/caregiver, and in compliance with the patient/caregiver's choice, the medicines can be delivered to a designated community pharmacy, institutional pharmacy, Community Healthcare Clinic /Primary Healthcare Clinic or alternative site as approved by Council.
4. In instances where a community or institutional pharmacy offers courier dispensing services as a major service the following is also required:
  - (a) inbound and outbound clinical call centres:
    - (i) inbound and outbound clinical call centres, with a pharmacist available at all times, must be in place. Communication between a patient and pharmacist must occur and be in accordance with GPP Rule 1.2.13. and the minimum standards for supervision of pharmacy support personnel;
    - (ii) the inbound clinical call centre must be separate from the outbound call centre;
    - (iii) all personnel working in the clinical call centres should be persons registered with the Council, with a pharmacist being available at all times;
    - (iv) all communication with patients and/or caregivers including telephonic conversation must be monitored for agent's communication and technical skills, and must be recorded and such records shall be retained in line with legislative requirements;
    - (v) Call centre agents must be continuously trained to improve knowledge and skills to assist patients;
    - (vi) Call centre operations are to be assessed daily;

- (b) pre-dispensing phase, which includes but is not limited to:
  - (i) receipt of prescriptions, the creation of a patient profile and loading of personal information must be done by a pharmacist or pharmacy support personnel in line with the relevant scope/s of practice;
  - (ii) adequate procedures must be in place for:
    - (aa) daily recording of prescriptions received via mail (normal and registered post) which must be stamped with a receipt date;
    - (bb) daily recording of prescriptions received via fax which must be stamped with a receipt date;
    - (cc) daily collection of hand-delivered documents to reception areas which must be signed for and stamped with a received stamp;
    - (dd) daily monitoring and checking of electronic prescriptions, including acknowledging receipt of prescriptions and follow up of outstanding verbal prescriptions.
- (c) Dispensing (phase 1 and 2):
  - (i) phase 1 and 2 of dispensing as provided in Rule 2.7.1.1 and 2.7.1.2 of the GPP shall happen at the premises of the pharmacy where the courier services are performed;
  - (ii) the pharmacists involved in dispensing must ensure that a faxed, e-mailed, telephonic or other electronically transmitted prescription or order is followed by the original prescription or order within seven working days as stated in Rule 2.7.1.1(a) (iv) of the GPP and Regulation 28 of the *General Regulations* under the Medicines and Related Substances Act, 101 of 1965;
  - (iii) prescriptions received must be handed over to a pharmacist to perform phase 1 and to perform or supervise the performance of phase 2 of dispensing;
  - (iv) there must be sufficient pharmacists and pharmacy support personnel to handle prescriptions and any other pharmacy related service at all times and comply with Rule 2.7 specifically Rule 2.7.1.1(c) and Rule 2.7.3.2;
  - (v) the medicine label must comply with the provisions of Regulation 8 (*General Regulations – Medicines Act*) and shall clearly indicate the name of the pharmacist that performed phase 1 and 2 of the dispensing process;
  - (vi) Patients must be advised on a monthly basis as to how many repeat prescriptions are left;

- (vii) Personnel who are not registered with Council must not be involved in this phase;
- (d) Dispatch/ Delivery of medicines to institution handling final phase of process:
- (i) Systems and policies must be in place to ensure that the patient receives his/her medicines as prescribed at all times; in compliance with Rule 2.7.5 (b); (c) and (d) of the GPP;
  - (ii) Should delivery of medicines to the institution be outsourced to a third party which is either an established business within the pharmacy or elsewhere, the responsible pharmacist of the courier pharmacy remains accountable to Council and must ensure that this process, complies with Rule 1.2.2 GPP;
  - (iii) The delivery period for the first issue of any prescription after diagnosis or amendment/intervention must be within 24 hours from the time of receipt of the prescription in order to achieve continuity of treatment;
  - (iv) Proof of delivery (signed by the receiving pharmacy must be presented within 24 hours of delivery to ensure that the patient does not miss a dose;
  - (v) The package must contain a copy of the original prescription (not computer generated copy, and the original must remain with the courier pharmacy), to enable the pharmacist to confirm the correctness of the medication prepared;
  - (vi) The package must also contain a copy of the prescription (computer generated copy), which acts as a checklist for the patient and which serves as confirmation of what has been, dispense, claimed for and/or invoiced;
  - (vii) Cold chain management must be observed in validated packaging and delivery must prove compliance with the minimum standards for thermolabile pharmaceutical products. A system must be in place for all participants (including the patient) to easily confirm the security of the cold chain management system;
  - (viii) Transportation of medicine must comply with the provisions of the minimum standard for the delivery of medicines.
- (e) Dispensing: phase 3
- (i) Phase 3 of dispensing shall happen at the premises of the community or institutional pharmacy in accordance with Rule 2.7.1.3 of the GPP;
  - (ii) the medicine label must comply with the provisions of Regulation 8(4)(c) (*General Regulations* under the Medicines

Act) and, in addition, shall indicate clearly the name of the pharmacist that performed phase 3 of the dispensing process;

(f) Patient service

- (i) There must be evidence that every patient medicine pack has sufficient information regarding the efficacy, safety and quality of the medicines, as well as information regarding a toll-free contact number of the responsible pharmacist of the courier pharmacy, and the contact details of the pharmacist performing phase 3 of the dispensing process so that the patient can directly interface with the pharmacist at all times. Provision of information must be in accordance with Rule 2.8 of the GPP;
- (ii) The patient must be encouraged to give feedback regarding the service and such evidence should be available;
- (iii) Appropriate action must be taken to address the patient's concerns and or complaints and such evidence must be available.

(g) Record keeping procedures

Records must be kept in accordance with Rule 2.9 of the GPP.

## **MINIMUM STANDARDS RELATING TO AUTOMATED DISPENSING UNITS FOR THE PURPOSE OF DISPENSING MEDICINES AND MEDICAL DEVICES**

### **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 referred to as automated dispensing cabinets (ADCs), automated dispensing devices (ADDs), automated dispensing machines (ADMs), automated pharmacy systems (APS), or unit-based cabinets (UBC). As such, this standard serves to address all such systems.

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.

### **2. Purpose**

The purpose of this standard is to regulate the use of ADUs in community pharmacies, institutional pharmacies, primary health care dispensaries, courier pharmacies and medicine rooms of licensed dispensers. Minimum standards specifically relating to ADUs are intended to guide pharmacists and licensed dispensers on the use of ADUs.

Where ADUs are utilised, all relevant legislation is applicable. The following standards specifically relate to ADUs:

### 3. General considerations

- (a) ADUs may be installed in a pharmacy or medicine rooms of licensed dispensers for the purpose of assisting with phase 2 of the dispensing process.
- (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 / caregiver / patient's agent and/or unauthorised persons.
- (c) In instances where the ADU is used in the activities of phase of 2 of dispensing processes the prescription must be signed in person by the pharmacist or licensed dispenser.
- (d) Phase 1 and Phase 3 of dispensing must be done by the pharmacist, pharmacy support personnel or licensed dispenser.
- (e) A pharmacy or medicine rooms of licensed dispensers utilising the ADU must have a documented contingency plan to ensure continuous supply of medicines and medical devices in an event of power or system failure.

#### 3.1 Minimum standards specifically relating to ADUs in community and institutional pharmacies

- (a) The responsible pharmacist of a pharmacy wishing to install the ADU must apply to Council in a prescribed manner and pay the applicable fees prior to installation of the ADU.
- (b) The pharmacist must be accessible to respond to inquiries or requests pertaining to all medicines and medical devices dispensed from the ADU.
- (c) All relevant standards and legislation must be maintained in the pharmacy that utilises the ADU.
- (d) The ADU must have adequate security systems and procedures, evidenced by written policies and procedures, to:
  - (i) prevent unauthorized access;
  - (ii) comply with legislation; and
  - (iii) prevent the illegal use or disclosure of protected health information (confidentiality).
- (e) Records and/or electronic data kept by the pharmacist using the ADU must meet the following requirements.
  - (i) All events involving medicines and medical devices stored in the ADU must be recorded electronically;
  - (ii) Records must be maintained by the pharmacy and must be readily available to Council. Such records must meet all the requirements of

Regulations 11 and 30 of the *General Regulations* under the Medicines Act and shall include but not limited to:

- (aa) identity of the ADU accessed;
  - (bb) identification of the registered person utilising the ADU;
  - (cc) type of transaction;
  - (dd) name, strength, dosage form, and quantity of the medicine and/or medical devices accessed;
  - (ee) name of the patient for whom the medicine and/or medical devices were ordered; and
  - (ff) such additional information as the responsible pharmacist may deem necessary.
- (f) The responsible pharmacist has the sole responsibility to:
- (i) assign, discontinue, or change access to the ADU;
  - (ii) ensure that access to the medicines and medical devices in the ADU comply with the applicable legislation;
  - (iii) ensure that only registered persons handle medicines and medical devices in the ADU;
  - (iv) ensure that the ADU is filled/stocked accurately and in accordance with established, written policies and procedures;
  - (v) ensure that in the process of picking, re-packaging, packing and cross-contamination is avoided at all times;
  - (vi) 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
  - (vii) 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) The filling/stocking of all medicines and medical devices in the ADU must be done by the pharmacist, pharmacist intern or relevant pharmacy support personnel under the supervision of the pharmacist.
- (h) A record of medicines and medical devices filled/stocked in to the ADU must be maintained and must include identification of the registered persons filling/stocking and checking for accuracy.
- (i) 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.
- (j) All aspects of handling Schedule 6 medicines must meet the requirements of all applicable legislation.



- (k) The ADU must have a 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.
- (l) The ADU must have a mechanism for securing and accounting for damaged or expired medicines and medical devices in accordance with the applicable legislation.

### **3.2 Minimum standards specifically relating to ADUs in a Primary Healthcare Clinic**

- (a) The supervising pharmacist of the primary healthcare clinic dispensary (PHCD) wishing to install the ADU must apply to Council in a prescribed manner and pay the applicable fees prior to installation of the ADU.
- (b) The supervising pharmacist of the PHCD must be accessible to respond to inquiries or requests pertaining to all medicines and medical devices dispensed from the ADU.
- (c) All policies and procedures pertaining to the ADU must be maintained by the supervising pharmacist of the PHCD.
- (d) The ADU must have adequate security systems and procedures, evidenced by written policies and procedures, to:
  - (i) prevent unauthorized access;
  - (ii) comply with legislation; and
  - (iii) prevent the illegal use or disclosure of protected health information (confidentiality).
- (e) Records and/or electronic data kept by the ADU must meet the following requirements:
  - (i) All events involving the medicines and medical devices stored in the ADU must be recorded electronically;
  - (ii) Records must be maintained by the pharmacy and must be readily available to Council. Such records must include:
    - (aa) identity of the ADU accessed;
    - (bb) identification of the authorised person utilising the ADU;
    - (cc) type of transaction;
    - (dd) name, strength, dosage form, and quantity of the medicine and/or medical devices accessed;
    - (ee) name of the patient for whom the medicine and/or medical devices were ordered; and
    - (ff) such additional information as the supervising pharmacist of the PHCD may deem necessary.

- (f) The supervising pharmacist of the PHCD has the sole responsibility to:
  - (i) assign, discontinue, or change access to the ADU;
  - (ii) ensure that access to the medicines and medical devices in the ADU comply with the applicable legislation;
  - (iii) ensure that only registered persons handle medicines and medical devices in the ADU;
  - (iv) ensure that the ADU is filled/stocked accurately and in accordance with written policies and procedures;
  - (v) 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
  - (vi) 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) The filling/stocking of all medicines and medical devices in the ADU must be done by the relevant pharmacy support personnel under indirect supervision of the pharmacist.
- (h) A record of medicines and medical devices filled/stocked into the ADU must be maintained and must include identification of the registered persons filling/stocking and checking for accuracy.
- (i) All medicines and medical devices stored in the ADU must be packaged and labelled in accordance with the applicable legislation.
- (j) The ADU must have a mechanism for securing and accounting for medicines and medical devices and medical devices removed from and subsequently returned to the ADU, all in accordance with the applicable legislation.
- (k) The ADU must have a mechanism for securing and accounting for damaged or expired medicines and medical devices in accordance with the applicable legislation.

### **3.3 Minimum standards specifically relating to ADUs in medicine rooms of licensed dispensers**

- (a) 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.
- (b) The licensed dispenser must be accessible to respond to inquiries or requests pertaining to all medicines and medical devices dispensed from the ADU.
- (c) All relevant legislation and standards must be maintained in the medicine room that utilises the ADU.
- (d) The ADU must have adequate security systems and procedures, evidenced by written policies and procedures, to:

- (i) ensure that only the licensed dispenser(s) have access to the ADU;
  - (ii) comply with legislation; and
  - (iii) prevent the illegal use or disclosure of protected health information (confidentiality).
- (e) The licensed dispenser has the sole responsibility to:
- (i) assign, discontinue, or change access to the ADU;
  - (ii) ensure that access to the medicines and medical devices in the ADU comply with the applicable legislation;
  - (iii) ensure that only licensed dispensers handle medicines and medical devices in the ADU;
  - (iv) ensure that the ADU is filled/stocked accurately and in accordance with established, written policies and procedures;
  - (v) ensure that in the process of picking, re-packaging, packing and cross-contamination is avoided at all times;
  - (vi) 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
  - (vii) ensure that the ADU is tested on a periodic basis in accordance with the manufactures' specifications to ensure that the ADU is operating properly.
- (f) The filling/stocking of all medicines and medical devices in the ADU must be done by the licensed dispenser.
- (g) A record of medicines and medical devices filled/stocked into the ADU must be maintained and must include identification of the licensed dispenser filling/stocking and checking for accuracy.
- (h) All medicines and medical devices stored in the ADU must be packaged and labelled in accordance with the applicable legislation.
- (i) All aspects of handling Schedule 6 medicines must meet the requirements of all applicable legislation.
- (j) The ADU must have a 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.
- (k) The ADU must have a mechanism for securing and accounting for damaged or expired medicines and medical devices in accordance with the applicable legislation.

#### **4. INFORMATION TO BE SUBMITTED IN SUPPORT OF AN APPLICATION FOR THE INSTALLATION OF THE ADU IN A PHARMACY**

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

- (a) a professionally drawn floor plan and site plans of the pharmacy premises indicating the location of the ADU;
  - (b) name and address of the pharmacy where the ADU is being used;
  - (c) manufacturer's name and model;
  - (d) description of how the ADU is used in the dispensing process;
  - (e) quality assurance procedures to determine continued appropriate use of the ADU (an affidavit); and
  - (f) policies and procedures for system operation, safety, security, accuracy, patient confidentiality, access, and malfunction (an affidavit).
-