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.

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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 (ADMs), 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.

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