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

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.