



# GOVERNMENT GAZETTE

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## Government Notice

### MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 101

2014

#### REGULATIONS UNDER THE PHARMACY ACT, 2004 ON THE OWNERSHIP OF PHARMACIES BY PRIVATE HOSPITALS AND REQUIREMENTS FOR REGISTRATION AND CONDUCT OF PHARMACY PRACTICES

In terms of section 66 of the Pharmacy Act, 2004 (Act No. 9 of 2004), and on the recommendation of the Pharmacy Council of Namibia, I -

- (a) have made the regulations set out in the Schedule; and
- (b) repeal the Regulations Relating to Ownership of Pharmacy by Private Hospital, promulgated under Government Notice No. 198 of 18 August 2008.

**R. N. KAMWI**  
**MINISTER OF HEALTH AND SOCIAL SERVICES**

Windhoek, 9 July 2014

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## Definitions

1. In these regulations, unless the context otherwise indicates, a word or expression defined in the Act has that meaning, and -

“architect” means a person registered as an architect in terms of any provision of section 11(i) of the Architects’ and Quantity Surveyors’ Act, 1979 (Act No. 13 of 1979);

“close corporation” means a close corporation as defined in section 1 of the Close Corporations Act, 1988 (Act No. 26 of 1988);

“company” means a company as defined in section 1 of the Companies Act, 2004 (Act No. 28 of 2004);

“hospital pharmacy” means a pharmacy referred to in regulation 2 conducted in a private hospital;

“medicine” means a drug or other preparation for the treatment or prevention of disease;

“pharmacy practice” means -

- (a) a community pharmacy providing pharmacy services, including any part of the business where goods other than medicine are sold or offered to be sold; or
- (b) a hospital pharmacy;

“pharmacy services” include -

- (a) the supply, compounding or dispensing of medicines;

(b) advice and counseling on the effective and safe use of medicines;

“private hospital” means a private hospital registered under section 23 of the Hospitals Health Facilities Act, 1994 (Act No. 36 of 1994);

“proprietary interest”, in relation to a pharmacy practice, means a legal or beneficial interest, either as -

- (a) a sole owner;
- (b) a partner;
- (c) a director or shareholder of a company; or
- (d) a member of a close corporation;

“registration” means registration of a community pharmacy practice under regulation 5 or a hospital pharmacy under regulations 6;

“registration certificate” means a registration certificate in force under these regulations in respect of a pharmacy practice;

“responsible pharmacist”, in relation to a pharmacy practice, means the pharmacist appointed to have overall responsibility for the community pharmacy practice or the hospital pharmacy; and

“the Act” means the Pharmacy Act, 2004 (Act No. 9 of 2004).

### **Establishment of hospital pharmacy by private hospital**

**2.** Under section 37 of the Act, and subject to section 38 thereof and to these regulations, the registered owner of a private hospital may establish and carry on a hospital pharmacy in part of the premises of the private hospital, set aside and operated as a pharmacy for supplying, compounding or dispensing medicines on prescription exclusively to patients of that hospital, including medicines prescribed for such patients to take out.

### **Pharmacy practice to be registered**

**3.** (1) A person may not have a proprietary interest in a community pharmacy practice, or a hospital pharmacy unless a registration certificate has been issued under these regulations authorising such pharmacy practice to be carried on.

(2) A person who contravenes subregulation (1) commits an offence and on conviction is liable to a fine not exceeding N\$4 000 or to imprisonment for a period not exceeding 12 months or to both such fine and imprisonment.

### **Eligibility for registration of pharmacy practice**

**4.** The following persons are eligible to apply for, and be granted, a registration certificate to carry on a pharmacy practice:

- (a) in relation to a community pharmacy practice -
  - (i) a registered pharmacist who wishes to carry on a pharmacy practice as sole owner and who has been registered and engaged in active practice as a pharmacist in Namibia continuously for a period of not less than three years immediately before the date of the application for registration;

- (ii) persons who are all registered pharmacists who wish to carry on a pharmacy practice in partnership, all of whom have been registered and engaged in active practice as pharmacists in Namibia continuously for a period of not less than three years immediately before the date of the application for registration and in which practice no person other than a pharmacist has an interest;
  - (iii) a private company registered in terms of section 35 of the Act to conduct business as a pharmacist, each shareholder of which has been registered and engaged in active practice as a pharmacist in Namibia continuously for not less than three years immediately before the date of the application for registration; or
  - (iv) a close corporation registered in terms of section 36 of the Act to conduct business as a pharmacist, each member of which has been registered and engaged in active practice as a pharmacist in Namibia continuously for not less than three years immediately before the date of the application for registration, and
- (b) in relation to a hospital pharmacy, the owner of the private hospital where the pharmacy is to be conducted.

#### **Application for registration of community pharmacy practice**

**5.** An application for registration of a community pharmacy practice must be submitted to the Council in writing in a form approved by the Council and must be accompanied by -

- (a) a description of the premises at which the community pharmacy practice is to be established and carried on and, unless the premises comprise the whole of a building, a plan of the building showing the location of the pharmacy premises in relation to adjoining or surrounding businesses and access to and from the pharmacy premises;
- (b) a copy of floor plan drawn by an architect showing the actual layout of the pharmacy premises drawn to scale with exact measurements to show that the premises meet the requirements for the minimum standards of fitness for the competent and safe practice of a pharmacy set out in Parts 1, 2 and 3 of Annexure A;
- (c) a statement setting out the following information about each person who owns or holds a proprietary interest in the community pharmacy practice that is to be carried on at the premises -
  - (i) the nature and extent of the interest held by the person;
  - (ii) the name and address of the person;
  - (iii) a telephone number and email address for the person;
  - (iv) details of any proprietary interest the person holds in any other pharmacy practice including the nature and extent of the person's interest in such pharmacy practice, the name and address of such other pharmacy practice, the names and addresses of every other person who holds a proprietary interest in that other pharmacy practice;
  - (v) details of any proprietary interest the person holds in any pharmaceutical wholesale business including the nature of the person's interest in such

wholesale business, the name and address of such wholesale business, the names and addresses of every other person who holds a proprietary interest in that pharmaceutical wholesale business;

- (d) a letter of appointment of the responsible pharmacist for the community pharmacy as well as a letter of acceptance of that appointment by the responsible pharmacist;
- (e) the following documents in respect of the premises or the community pharmacy practice that is to be carried on at the premises -
  - (i) a copy of any sale agreement or lease agreement for the premises or the pharmacy practice; and
  - (ii) a copy of any partnership agreement for the pharmacy practice or any other agreement under which any person has or will have a proprietary interest in the pharmacy practice;
  - (iii) a copy of any agreement between persons who hold a proprietary interest in the pharmacy business that makes provision for any rights the persons possess by virtue of having the proprietary interests; or
  - (iv) if the pharmacy practice is to be carried on by a company registered under section 35 of the Act or a close corporation registered under section 36 of the Act to conduct business as a pharmacist, a copy of the relevant memorandum of association of the company or the relevant founding statement of the close corporation;
- (f) a statement setting out the standard operating procedures to be applied at the community pharmacy practice in relation to at least the following:
  - (i) procurement of medicine;
  - (ii) receipt and storage of medicine, including the monitoring of expiry dates and temperature control;
  - (iii) dispensing and record keeping of prescriptions and patient information;
  - (iv) document control;
  - (v) security and access control; and
  - (vi) measures to be applied in the event of a power supply failure to any refrigerator where medicine is stored or any air conditioner controlling temperature in the dispensary or any other area where medicine is stored;
- (g) the relevant application fee determined by the Council in respect of an application for registration of premises as a community pharmacy practice; and
- (h) any other information or document that the Council may require to consider the application.

#### **Application for registration of hospital pharmacy**

6. An application for registration of a hospital pharmacy must be submitted to the Council in writing in a form approved by the Council and must be accompanied by -

- (a) plans of the premises of the private hospital that show the location of the pharmacy within the hospital;
- (b) a copy of the floor plan drawn by an architect showing the actual layout of the pharmacy premises drawn to scale with exact measurements to show that the premises meet the requirements for the minimum standards of fitness for the competent and safe practice of a pharmacy set out in Parts 1, 2, and 3 of Annexure A;
- (c) a copy of the current registration certificate issued in relation to the private hospital under the Hospitals and Health Facilities Act, 1994 (Act No. 36 of 1994);
- (d) a statement setting out the following information about each person who holds a proprietary interest in the hospital pharmacy that is to be carried on in the private hospital -
  - (i) the nature and extent of the interest held by the person;
  - (ii) the name and address of the person;
  - (iii) a telephone number and email address for the person;
  - (iv) details of any proprietary interest the person holds in any other pharmacy practice, including the nature and extent of the person's interest in such other pharmacy practice, the name and address of such other pharmacy practice, the names and addresses of every other person who holds a proprietary interest in that other pharmacy practice;
  - (v) details of any proprietary interest the person holds in any pharmaceutical wholesale business, including the nature of the person's interest in such wholesale business, the name and address of such wholesale business, the names and addresses of every other person who holds a proprietary interest in that pharmaceutical wholesale business;
- (e) a letter of appointment of the responsible pharmacist for the hospital pharmacy as well as a letter of acceptance of that appointment by the responsible pharmacist;
- (f) a statement setting out the standard operating procedures to be applied at the hospital pharmacy in relation to at least the following:
  - (i) procurement of medicine;
  - (ii) receipt and storage of medicine, the monitoring of expiry dates and temperature control of medicines so stored, including medicines stored in any emergency cupboard or ward or any other area where medicine is stored in the hospital, as well as temperature mapping and deviations;
  - (iii) dispensing of medicine to in and out patients and patients in wards, and record keeping of prescriptions and patient information;
  - (iv) document control;
  - (v) security and access control of all areas where medicine is stored;
  - (vi) measures to be applied in the event of any power supply failure to any refrigerator where medicine is stored or any air conditioner controlling temperature in the dispensary or any other area where medicine is stored.

**Appointment of responsible pharmacist**

7. (1) Subject to subregulation (3), for each community pharmacy practice or hospital pharmacy required to be registered in terms of these regulations there must be appointed a pharmacist to be the responsible pharmacist for the pharmacy practice.

(2) The person in whose name a community pharmacy practice is registered as sole owner is the responsible pharmacist for that pharmacy practice unless another pharmacist is appointed by the owner to be the responsible pharmacist.

(3) A person appointed to be the responsible pharmacist for a pharmacy practice -

(a) must be a pharmacist who has been registered and engaged in active practice as a pharmacist continuously for at least two years; and

(b) may not be appointed as responsible pharmacist for more than one pharmacy practice.

(4) If for any reason a person ceases to be the responsible pharmacist for a pharmacy practice, the holder of the registration certificate in respect of that pharmacy practice must, within seven days of the date the person ceases to be the responsible pharmacist, give written notice to the Council -

(a) specifying the name and address of another pharmacist appointed to be the responsible pharmacist for the pharmacy practice; and

(b) specifying the date from which the appointment of the pharmacist commenced; and

(5) The notice referred to in subregulation (4) must be accompanied by a letter of acceptance of that appointment by the responsible pharmacist.

(6) The holder of a registration certificate who fails to comply with subregulation (4) commits an offence and on conviction is liable to a fine not exceeding N\$ 4000 or to imprisonment for a period not exceeding 12 months or to both such fine and imprisonment

**Consideration of application for registration of pharmacy practice**

8. For the purpose of considering an application for registration of a community pharmacy practice or a hospital pharmacy, the Council may -

(a) require that the premises where the community pharmacy practice or hospital pharmacy is to be established be inspected, at the cost of the applicant, by a person appointed by the Council whom the Council considers appropriately qualified to carry out such inspection and report to the Council on the suitability of the premises for the provision of pharmacy services; or

(b) invite the applicant or if the applicant is a company or close corporation, the managing director or manager of the company or close corporation, to attend before the Council or a committee of the Council to make representations to the Council or committee in relation to the application, including any matter contained in the inspection report.

**Approval of registration of pharmacy practice and issue of registration certificate**

9. (1) The Council may approve an application for registration of a pharmacy practice and issue a registration certificate to carry on the community pharmacy practice or hospital pharmacy concerned if the Council is satisfied that -

- (a) the applicant is eligible to be granted a registration certificate in terms of these regulations;
- (b) the application for registration is duly made and all required information for consideration of the application is provided;
- (c) the facilities, equipment, security, management and operation of the community pharmacy practice or hospital pharmacy at the premises at which it is to be carried on comply with -
  - (i) good pharmacy practice; and
  - (ii) without limiting subparagraph (i), the minimum requirements set out -
    - (aa) in Parts 1, 2 and 3 of Annexure A with respect to the premises, equipment and appliances;
    - (bb) in Annexure B with respect to the control of a pharmacy practice; and
  - (iii) any other requirements that are prescribed by or under the Act.
- (2) A registration certificate is to be issued -
  - (a) in relation to a community pharmacy practice, in the name of the sole owner, partnership, company or close corporation to whom or to which the registration is approved;
  - (b) in relation to a hospital pharmacy, in the name of the owner of the private hospital in respect of which the registration is approved.

### **Grounds for refusal of registration**

**10.** The Council must refuse an application for registration if the Council is not satisfied with respect to the matters referred to in regulation 8 and may also refuse the application if the Council is satisfied that any person who has or is to have a proprietary interest in the pharmacy practice -

- (a) has failed to carry on a pharmacy practice in accordance with these regulations;
- (b) has been convicted of an offence in terms of the Act or these regulations;
- (c) has been convicted of any offence that affects the suitability of that person to provide pharmacy services and the Council believes it is not in the public interest for the pharmacy practice to be registered with such person holding a proprietary interest in the pharmacy practice; or
- (d) is of a character such that it would not be in the public interest to register the pharmacy practice.

### **Notice of decision on application**

**11.** (1) The Council must cause written notice to be given to the applicant of its decision on an application for registration.



(2) If the decision is a refusal of the application, the Council must set out in the notice the reasons for its decision.

### **Particulars in register in respect of pharmacy practices**

**12.** The register kept by the Council in relation to pharmacy practices in terms of section 25(2)(e) of the Act must include the following particulars:

- (a) the name of each person having a proprietary interest in each pharmacy practice;
- (b) the registration status of the pharmacy practice; and
- (c) the name, address and contact details of the responsible pharmacist appointed for the community pharmacy practice or the hospital pharmacy.

### **Period of registration**

**13.** The period of registration of a pharmacy practice ends on 31 March following the date on which it is granted and thereafter on 31 March of each year for which the registration is renewed.

### **Renewal of registration**

**14.** (1) An application to renew an existing registration of a pharmacy practice must be made before 31 March of each year.

(2) An application under subregulation (1) must be made to the Council in writing in a form approved by the Council and must -

- (a) contain the information required by the Council to determine the application; and
- (b) be accompanied by the renewal fee determined by the Council.

(3) If an application for registration renewal has been made but not determined before the date on which the registration expires, the registration certificate continues in force until the application for renewal is determined.

(4) The grant of a renewal of registration takes effect from the date of expiry of the previous registration certificate.

### **Expiry of registration**

**15.** If no application for the renewal of a registration is made on or before the date on which the registration would otherwise expire, the registrar must record the expiry in the register as soon as practicable after that date.

### **Restoration of expired registration**

**16.** (1) The holder of a registration certificate which has expired may apply to the Council, within two months after the expiry, for restoration of the registration certificate.

(2) An application for restoration of a registration certificate must be submitted to the registrar in a form approved by the Council and must -

- (a) contain the information required by the Council to determine the application; and

- b) be accompanied by -
  - (i) the amount payable in respect of the annual registration renewal fee; and
  - (ii) the restoration fee as determined by the Council.

(3) Despite subregulation (1), the Council may accept an application for restoration of a registration certificate made more than two months after expiry of the registration certificate if the Council is satisfied that it would be reasonable considering all the circumstances to accept the application.

(4) The applicant must provide any further information reasonably required by the Council to decide the application.

(5) In deciding the application, the Council may have regard to the same matters required to be taken into account when considering an application for registration of a community pharmacy practice or a hospital pharmacy.

(6) If the Council decides to restore the registration certificate, the registrar must issue a new registration certificate to the applicant.

- (7) If the Council decides to refuse to restore the registration certificate it must -
  - (a) provide the applicant notice of the reasons for the decision; and
  - (b) refund to the applicant the annual registration renewal fee that accompanied the application for restoration.

#### **Community pharmacy practice at separate premises**

**17.** Each community pharmacy practice carried on at separate premises, including a pharmacy practice carried on by the same person, whether under the same name or a different name as another community pharmacy practice of that person, is to be treated as a separate community pharmacy practice for the purposes of these regulations.

#### **Notification of change**

**18.** (1) The holder of a registration certificate must inform the registrar in writing within a period of 30 days after occurrence of any change in the particulars furnished in an application for registration in terms of regulation 5 or 6 relating to the pharmacy practice registered under that registration certificate after the issue thereof.

(2) The holder of registration certificate who fails to comply with subregulation (1) commits an offence and on conviction is liable to a fine not exceeding N\$4 000 or to imprisonment for a period not exceeding 12 months or to both such fine and imprisonment.

#### **Alteration to premises of a pharmacy to be approved**

**19.** (1) The holder of a certificate of registration of a pharmacy practice must not cause or permit any alteration to be made to the premises of the pharmacy that affects the construction, structure, layout or floor area of the pharmacy without the prior written approval of the Council.

(2) An application for approval to make any alteration to a pharmacy of a nature referred to in subregulation (1) must be made in writing and submitted to the Council at least two months before the commencement of the alteration and must be accompanied by -

- (a) all relevant plans, specifications and floor plan drawn to scale by an architect relating to the proposed alteration; and
  - (b) the relevant application fee determined by the Council for an application of approval of alterations.
- (3) The Council may, by notice in writing given to an applicant, request that the applicant provide to the Council such further information as the Council reasonably requires to decide the application.
- (4) For the purpose of considering an application for approval of alterations proposed to be made to the premises of a pharmacy practice, the Council may -
- (a) require that the premises of the community pharmacy practice or hospital pharmacy where alterations are proposed to be made be inspected, at the cost of the applicant, by a person appointed by the Council who the Council considers appropriately qualified to carry out such inspection, and make a report to the Council on the effect the alterations would have, if carried out in accordance with the plans and specifications submitted to the Council, on the suitability of the premises for the provision of pharmacy services; and
  - (b) invite the applicant or, if the applicant is a company or close corporation the managing director or manager of the company or close corporation, to attend before the Council or a committee of the Council to make representations to the Council or committee in relation to the application, including any matter contained in the inspection report.
- (5) The Council may not withhold approval under this regulation unless it is satisfied that if the alterations were carried out in accordance with the plans and specifications given to the Council the pharmacy would cease to meet the requirements for the minimum standards of fitness for the competent and safe practice of pharmacy prescribed under these regulations.
- (6) The Council must give written notice to the holder of the registration certificate concerned of its decision on an application for approval of alterations in terms of subregulation (1), and if the decision is to refuse the application set out the reasons for its decision.
- (7) A person who fails to comply with subregulation (1) commits an offence and on conviction is liable to a fine not exceeding N\$4000 or to imprisonment for a period not exceeding 12 months or to both such fine and imprisonment.

### **Application for relocation of pharmacy practice**

- 20.** (1) The holder of a registration certificate in respect of a community pharmacy practice or a hospital pharmacy may apply to the Council for relocation of the registration certificate -
- (a) in the case of a community pharmacy practice, from the premises in respect of which the registration certificate was granted to other premises; or
  - (b) in the case of a hospital pharmacy, from the area of location of the pharmacy within the hospital in respect of which the registration certificate was granted to another area within that hospital.
- (2) An application for relocation must be submitted to the Council in writing in a form approved by the Council and must be accompanied -

- (a) in the case of relocation of a community pharmacy practice, in relation to the new premises where the pharmacy practice is to be relocated, by the description of the premises and a copy of a floor plan referred to in regulation 5(a) and (b) and a copy of any sale agreement or lease agreement referred to in paragraph (e)(i) of that regulation; or
- (b) in the case of relocation of a hospital pharmacy, in relation to the new area of location of the pharmacy within the hospital, by the plans of the hospital premises and a copy of a floor plan of the layout of the pharmacy premises referred to in regulation 6(a) and (b); and
- (c) by the relocation fee determined by the Council.

#### **Notification of commencement of business or completion of alterations**

**21.** (1) Where the Council granted an application for -

- (a) the registration of a pharmacy practice in terms of regulation 5 or 6;
- (b) the approval of alterations to the premises of a pharmacy practice in terms of regulation 19; or
- (c) the relocation of a pharmacy practice in terms of regulation 20,

the holder of the relevant registration certificate must give written notice to the Council of the -

- (i) date of commencement of business of the pharmacy practice at the premises;
- (ii) new relocated premises of the community pharmacy;
- (iii) new area of location within a hospital of the hospital pharmacy; or
- (iv) date of completion of alterations to the pharmacy premises,

not later than seven days after the date of such commencement, relocation or completion of alterations.

(2) As soon as may be practical after the commencement of business of a pharmacy practice, including a relocated pharmacy practice or hospital pharmacy or the completion of changes to the premises of a pharmacy practice as contemplated in subregulation (1), the Council may cause the premises of the relevant community pharmacy practice or hospital pharmacy to be inspected; at the cost of the holder of the registration certificate of the pharmacy practice, by a person appointed by the Council whom the Council considers appropriately qualified to carry out such inspection and to report to the Council on the suitability of the premises for the provision of pharmacy services and the compliance by the holder of the registration certificate with the requirements of these regulations in respect of such pharmacy practice.

(3) The holder of registration certificate referred to in subregulation (1) who fails to comply with that subregulation commits an offence and on conviction liable to a fine not exceeding N\$4 000 or to imprisonment for a period not exceeding 12 months or to both such fine and imprisonment.

**Grounds for revocation or refusal of renewal of registration of community pharmacy practice**

**22.** (1) The Council may revoke or refuse to renew the registration certificate of a community pharmacy practice carried on by a person if -

- (a) any person who has a proprietary interest in the community pharmacy practice to which the certificate relates is no longer eligible to be registered;
- (b) the person carrying on the community pharmacy practice has failed to carry on the practice in accordance with the Act or these regulations or any other regulations made under the Act relating to the conduct of a pharmacy practice or in accordance with the Medicines and Related Substances Control Act, 2003 (Act No. 13 of 2003) or regulations made under that Act;
- (c) there has been a failure of security at the community pharmacy practice that presents a serious risk to public health and safety;
- (d) the premises of the community pharmacy practice are unhygienic or no longer suitable for use for the conduct of a pharmacy practice; or
- (e) if there has been a failure of good pharmaceutical practice at the premises of the community pharmacy practice that presents a serious risk to public health and safety.

(2) If the Council proposes to cancel or refuse to renew the registration of a community pharmacy practice under subregulation (1), the Council must give the holder of the registration certificate in respect of that pharmacy practice notice in writing of the proposal to cancel or refuse to renew the registration and the reasons for the proposal.

(3) A notice given under subregulation (2) must state that within 14 days after the notice is given the person to whom it is given may make representations in writing to the Council concerning the matter, and the Council must not take a decision on the matter without considering any representations received within that period.

**Non-compliance by holder of registration certificate of hospital pharmacy**

**23.** If any concern that may constitute a ground for revocation or refusal of renewal of the registration of a community pharmacy practice in terms of regulation 22, exists in relation to the holder of a registration certificate in respect of a hospital pharmacy or the premises of such pharmacy, the Council must submit a report on the matter to the Minister for the purposes of section 38(3) of the Act.

**Duties of responsible pharmacist**

**24.** (1) The responsible pharmacist for a pharmacy practice must ensure that the requirements set out in Annexure B are complied with in relation to the pharmacy practice for which he or she is the responsible pharmacist.

(2) A responsible pharmacist who contravenes or fails to comply with any of the requirements referred to in subregulation (1) commits an offence and on conviction is liable to a fine not exceeding N\$4 000 or to imprisonment for a period not exceeding 12 months or to both such fine and imprisonment.

**Transitional provision**

**25.** (1) Despite regulation 3, the owner of a private hospital where, immediately before the date these regulations come into force, an hospital pharmacy was carried on, may continue

to carry on the pharmacy in that hospital without being the holder of a registration certificate in respect of the hospital pharmacy until 31 March of the year following the year in which these regulations come into force.

(2) If, immediately before the day on which these regulations come into force, a pharmacy registered under the Act was not in compliance with the requirement for the minimum standard of fitness for the competent and safe practice set out in paragraph A of Annexure A -

- (a) item 3(a), with respect to the required minimum sizes for the dispensing area; or
- (b) item 3(b), with respect to the consulting area,

then that requirement applies in respect of such a pharmacy only after any alteration to that pharmacy that affects the construction, layout or floor area of the pharmacy is completed.

**ANNEXURE A****REQUIREMENTS IN RELATION TO PREMISES, EQUIPMENT AND APPLIANCES****PART 1****REQUIREMENTS: PREMISES OF A PHARMACY PRACTICE**

1. The interior floor area of the pharmacy premises must be at least 100 square metres, or such lesser area as the Council may approve in a particular case.
2. The premises must -
  - (a) have at least one doorway allowing direct public access to the premises;
  - (b) have no direct access to persons from any adjoining premises where a business or activities other than that of providing pharmacy services are carried out.
3. The premises are to be laid out in a manner consistent with safe pharmacy practices and in such manner that the different parts of the premises are properly situated and are secure and suitable for the purposes for which they are to be used, which must include -
  - (a) a dispensing area of at least 12 square metres or such lesser area as the Council may approve in a particular case, which -
    - (i) is to have adequate facilities for dispensing and compounding medicine;
    - (ii) is to be equipped with a stainless steel or similarly impervious basin that has an impervious surround and is supplied with hot and cold running water;
    - (iii) is to have a working surface with impervious covering, providing not less than one square meter of free working space;
    - (iv) is to have a semi private area at the dispensing counter where medicines can be handed over to a patient and discussions between a pharmacist and the patient can take place in privacy;
  - (b) a separate room or suitably secluded area for private consultation with patients;
  - (c) a room or area separate from the dispensing area where the manufacturing or compounding of medicine is to be carried out, at least one square meter working space;
  - (d) adequate storage areas secured against unauthorised entry and provided with sufficient shelving of smooth washable and impermeable material for the keeping of medicines in a manner that will allow for orderly arrangement and proper rotation of stock, except that any veterinary medicines must be stored separate from human medicines;
  - (e) a waiting area with suitable seating facilities for at least two patients, which is to be located in such position that it is not reasonably likely that discussions between a pharmacist and a patient at the dispensing counter can be overheard by a person in the waiting area;
  - (f) a receiving area with sufficient space for receiving the delivery of stock in an orderly and secure manner;

- (g) any kitchen and toilet facilities provided for staff within the pharmacy premises must be located distinct from any part of the premises to which the public will have access.
- 4. The premises must be well lit and adequately ventilated and be provided with air conditioners to effectively control temperature, particularly in areas where medicines are stored and where temperatures are to be recorded twice daily.
- 5. The premises are to have such devices and systems provided and maintained in good working order as may be necessary to ensure that the premises are reasonably secure against burglary, robbery, theft and unexplained loss.

PART 2  
REQUIREMENTS IN RESPECT OF EQUIPMENT AND APPLIANCES TO BE  
PROVIDED IN A PHARMACY PRACTICE

A pharmacy practice must be provided with at least the following equipment and appliances:

- (a) a refrigerator of adequate capacity for the storage exclusively of thermo labile medicine and products and no other products or articles, which is to be connected to a standby generator or other emergency power system to ensure uninterrupted supply in the event of a power failure and the proper functioning of which is to be checked periodically, except that any veterinary medicines must be stored in a refrigerator separate from human medicines;
- (b) a lockable safe for the storage of Government Notice 180 of 25 July 2008 Schedule 4 substances;
- (c) a dispensing balance or digital scale that is calibrated annually;
- (d) the following dispensing measures:
  - (i) one x 200 ml measure;
  - (ii) one X 100 ml measure;
  - (iii) one x 10 ml measure;
  - (iv) one x 5 ml measure or graduated pipette;
- (e) a funnel;
- (f) two mortars and pestles (one, at least, of glass);
- (g) a stirring rod;
- (h) two spatulas;
- (i) an ointment slab;
- (j) a tablet counting tray.



PART 3  
PUBLICATIONS AND REFERENCE MATERIAL TO BE AVAILABLE IN  
PHARMACY PRACTICE

The following publications must be kept in the premises of a pharmacy practice or must be accessible by electronic means from the premises:

- (a) The Pharmacy Act, 2004 (Act No. 9 of 2004) and the regulations and rules made or published under that Act in so far as they relate to medicine and the conduct of a pharmacy practice, including all amendments of that Act or those regulations or rules.
- (b) The Medicines and Related Substances Control Act, 2003 (Act No. 13 of 2003), and the regulations or government notices made or published under that Act, including all amendments of that Act or those regulations or notices.
- (c) The latest available last editions of the relevant international extra pharmacopoeia, a handbook on toxicology and poisoning, and a handbook on pharmacology, as determined by the Council from time to time.
- (d) Brochures and other informative material, as the Council may determine from time to time, on the proper use of medication and on other health related matters.
- (e) The latest Namibia Guidelines as published by the Ministry of Health and Social Services including the Namibia Standard Treatment Guidelines, HIV Guidelines, Malaria Guidelines and TB Guidelines.

**ANNEXURE B****CONTROL OF PHARMACY PRACTICE**

1. The general physical security of the premises of the pharmacy practice must be secure and the control of keys or other entry devices must be restricted to pharmacists authorised by the responsible pharmacist.
2. The pharmacist appointed to act as the responsible pharmacist for a pharmacy practice is to be regularly and usually in charge of the community pharmacy practice or hospital pharmacy when it is open for business.
3. When the responsible pharmacist is absent or unavailable, another pharmacist must be appointed to act as the pharmacist in charge of the pharmacy when it is open for business.
4. No person is allowed access to the dispensing area of the pharmacy except under the direct supervision of a pharmacist.
5. A pharmacist must oversee the area of the pharmacy practice where pharmacy services are provided.
6. The responsible pharmacist must oversee, supervise and monitor all other pharmacists providing pharmacy services in the pharmacy practice and all other staff who assist in the provision of pharmacy services.
7. Adequate arrangements must be in place to ensure that-
  - (a) medicines are dispensed in accordance with a prescription as far as the dispensing is consistent with the safety of the person who is to use the medicines;
  - (b) written or electronic records are kept of all medicines supplied, compounded or dispensed and the records are kept confidential and secure;
  - (c) the sale of medicines which is particularly known to be abused or misused must be supervised and monitored;
  - (d) therapeutic goods are not removed from the premises except with the express permission of the pharmacist in charge of the pharmacy practice;
  - (e) distance dispensing is carried out according to good pharmaceutical practice;
  - (f) the identity of a medicine being dispensed to a client of the pharmacy must remain confidential other than to the knowledge of a pharmacist or a member of the staff of the business.
8. Adequate arrangements must be in place to ensure that records of prescriptions are in English and must include -
  - (a) the name and address of the person to whom the medicine is dispensed;
  - (b) the date the medicine is dispensed;
  - (c) the name and dose form of the medicine dispensed;
  - (d) the strength or identifying formula;

- (e) the quantity or number of doses ordered;
  - (f) the directions for the use of the medicine;
  - (g) any other ancillary written instructions supplied on the label;
  - (h) the name, address and telephone number of the prescriber;
  - (i) any alteration to the original prescription;
  - (j) any other information concerning the medicine and its use.
9. Adequate arrangements must be in place to ensure that records of prescriptions are -
- (a) retained in a secure place at the pharmacy practice for a period of not less than three years;
  - (b) made at the time of dispensing or in the case of an emergency within 24 hours after the dispensing;
  - (c) certified by the pharmacist who dispensed the prescription with his or her handwritten signature within 24 hours after the dispensing -
    - (i) in the prescription record; or
    - (ii) if the prescription record is made in a manner which precludes handwritten endorsement, in a separate record kept for that purpose;
  - (d) readily retrievable by reference to the name and address of the person to whom the medicine was dispensed, the date of dispensing and from information on the label on the container.
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