



Republic of Namibia
Annotated Statutes

REGULATIONS

REGULATIONS MADE IN TERMS OF

Pharmacy Act 9 of 2004

section 35(26)

Regulations relating to Conducting of Business as Wholesale Pharmacist

Government Notice 9 of 2022

(GG 7728)

came into force on date of publication: 21 January 2022

The Government Notice which publishes these regulations notes that they were made on the recommendation of the Pharmacy Council of Namibia

ARRANGEMENT OF REGULATIONS

1. Definitions
2. Application for registration of business as a wholesale pharmacist
3. Granting of provisional registration by Council
4. Responsibilities of managing director of business as a wholesale pharmacist
5. Conducting of business as wholesale pharmacist by a company
6. Appointment of responsible pharmacist
7. Duties of responsible pharmacist
8. Consideration of application for registration of business as a wholesale pharmacist
9. Approval of registration of business as a wholesale pharmacist and issuing of registration certificate
10. Refusal of application for registration of business as a wholesale pharmacist
11. Services to be provided by a business conducted as a wholesale pharmacist
12. Register of business as a wholesale pharmacist
13. Period of registration
14. Revocation of registration of business as a wholesale pharmacist
15. Notification of change
16. Application for alteration to business premises as a wholesale pharmacist
17. Application for relocation of business as a wholesale pharmacist
18. Notification of commencement of business after alteration or relocation

REGULATIONS
Pharmacy Act 9 of 2004

Regulations relating to Conducting of Business as Wholesale Pharmacist

[In the text below, the word “alteration” in the heading is plural:
“Notification of commencement of business after alterations or relocation”.]

19. Requirements to conduct a business as a wholesale pharmacist
 20. Transitional provision
-

Definitions

1. In these regulations, a word or expression to which a meaning has been assigned in the Act has that meaning, unless the context otherwise indicates -

“architect” means an architect as defined in section 1 of the Architects’ and Quantity Surveyors’ Act, 1979 (Act No. 13 of 1979);

“business as a wholesale pharmacist” means a private company or public company registered and incorporated in terms of the Companies Act, 2004 (Act No. 28 of 2004), and registered by the Council under these regulations to -

- (a) conduct business as a wholesale pharmacist; and
- (b) provide the services specified in regulation 11;

“business premises” means a building or a structure, used or intended to be used for purposes of conducting a business as a wholesale pharmacist;

“hospital pharmacy” means a hospital pharmacy referred to in regulation 2 and registered as a hospital pharmacy in terms of regulation 9 of the Regulations Relating to Ownership of Pharmacy by Private Hospital, published under Government Notice No. 101 of 25 July 2014;

“managing director” means a person referred to in regulation 4;

“Medicines and Related Substances Control Act” means the Medicines and Related Substances Control Act, 2003 (Act No. 13 of 2003);

“responsible pharmacist” means a pharmacist appointed under regulation 6;

“registration certificate” means a certificate issued by the Council in terms of these regulations authorising a business to be conducted as a wholesale pharmacist business;

“sell” means sell as defined in section 1 of the Medicines and Related Substances Control Act; and

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

Application for registration of business as a wholesale pharmacist

2. (1) A public company or a private company registered and incorporated in terms of the Companies Act, 2004 (Act No. 28 of 2004), with the intention to conduct a business as a wholesale pharmacist must submit to the Council in a form approved by the Council an application for registration of a business as a wholesale pharmacist.

- (2) The application referred to in subregulation (1) must be accompanied by -

REGULATIONS
Pharmacy Act 9 of 2004

Regulations relating to Conducting of Business as Wholesale Pharmacist

- (a) a description of the business premises at which the business is to be conducted;
- (b) a plan of the building showing the location of the business premises in relation to adjoining or surrounding business premises and access to and from the business premises and this must show compliance with regulation 19(2), (3), (4) and (5);
- (c) a copy of the floor plan drawn by an architect showing the actual layout of the business premises drawn to scale with exact measurements to show that the business premises meet the requirements for the conducting of business set out in regulation 19(2), (3), (4) and (5);
- (d) a list setting out the following information about each person who owns or holds a proprietary interest in the conducting business as wholesale pharmacist -

[The closing phrase may have been intended to refer to “a proprietary interest in the company conducting business as a wholesale pharmacist”; alternatively, the provision may have been intended to refer to “a proprietary interest in the business as a wholesale pharmacist”.]

- (i) the nature and extent of the interest held by the person;
 - (ii) the name, postal address and physical address of the person;
 - (iii) a telephone number and email address of the person; and
 - (iv) details of any proprietary interest the person holds in any other business as a wholesale pharmacist, including the nature and extent of the person’s interest in that business, the name and address of such other business, and the names and addresses of every other person who holds a proprietary interest in that other business;
- (e) a letter of appointment of the responsible pharmacist for the conducting of business as a wholesale pharmacist as well as a letter of acceptance of that appointment by the responsible pharmacist;
 - (f) a certified copy of the memorandum of association of the company;
 - (g) a certified copy of the sales agreement or the lease agreement for the business premises;
 - (h) the application fee determined by the Council in terms of section 28 of the Act;
 - (i) a statement setting out the standard operating procedures to be applied at the business as a wholesale pharmacist in relation to the -
 - (i) procurement of medicine;
 - (ii) receipt and storage of medicine, including the monitoring of expiry dates and temperature control of the medicine;
 - (iii) dispatch of medicine;
 - (iv) control of documents;

**REGULATIONS
Pharmacy Act 9 of 2004****Regulations relating to Conducting of Business as Wholesale Pharmacist**

- (v) security and access control; and
- (vi) measures to be applied in respect of a refrigerator, air conditioner or any other area where medicine is stored, if there is a power failure.

Granting of provisional registration by Council

3. (1) The Council may, on application made in terms of regulation 2, provisionally approve an application for the registration of a business as a wholesale pharmacist, if -

- (a) the applicant does not at the time of making an application in terms of regulation 2 have proof of ownership or lease referred to in regulation 2(2)(g); and
- (b) is satisfied that the applicant has made the necessary arrangements to secure ownership or lease of business premises.

(2) The provisional registration granted under subregulation (1) is valid for a period of three months, which period the Council on a written application may extend for a further period of three months and after that period the Council may not grant any further extension and provisional registration expires at the end of initial period or in case of an extension at the end of the period of extension.

[The word “the” appears to have been omitted before the phrase “initial period”.]

(3) A holder of a provisional registration issued in terms of this regulation may not conduct business as a wholesale pharmacist.

(4) If the holder of the provisional registration granted in terms of this regulation during the period of provisional registration meets the requirements of regulation 2 relating to business premises and has proof of ownership or lease of business premises, the person must apply for registration to conduct business as a wholesale pharmacist in terms of regulation 2, and the provisional registration expires on the date that the Council makes a decision in respect of the application and communicates the decision to the applicant.

Responsibilities of managing director of business as a wholesale pharmacist

4. (1) The business conducted as wholesale pharmacist must appoint a pharmacist who complies with the provisions of subregulation (2) as the managing director of the business.

[The word “a” appears to have been omitted before the phrase “wholesale pharmacist”.]

(2) The managing director of a public company or private company conducting the business as a wholesale pharmacist -

- (a) must be a pharmacist who is registered and who is engaged in active practice as a pharmacist in Namibia, for at least three years;
- (b) must be -
 - (i) a Namibian citizen and be ordinarily resident in Namibia; or

REGULATIONS
Pharmacy Act 9 of 2004

Regulations relating to Conducting of Business as Wholesale Pharmacist

- (ii) lawfully admitted to Namibia for permanent residence and be ordinarily resident in Namibia; and
- (c) may not be appointed as a managing director and may not act as a managing director in any other business of a wholesale pharmacist or pharmacy practice that does not belong to the company concerned, unless the Council on a written application made by the managing director to the Council, grants the application, if the Council is satisfied that it is in the public interest to authorise the managing director to act as managing director of any other business conducted as a wholesale pharmacist business.
- (3) The managing director referred to in subregulation (2) may -
 - (a) be a director of any company, other than the company of which he or she is the managing director.

[The full stop at the end of paragraph (a) should be a semi-colon.]

- (b) be a member, other than the managing director of a close corporation which conducts business as a pharmacist.

[There should be a comma after the phrase "other than the managing director" to offset that phrase properly.]

(4) The managing director referred to in subregulation (2) may not perform, in respect of a company referred to in subregulation (3)(a) or a close corporation referred to in subregulation (3)(b) and of which he or she is not the managing director, any acts pertaining to the profession of a pharmacist.

Conducting of business as wholesale pharmacist by a company

5. (1) A public company or private company may not conduct business as a wholesale pharmacist, unless the managing director manages and controls the business as a wholesale pharmacist.

(2) The managing director is responsible to the Council in respect of any act done by or on behalf of the company concerned and which may result in disciplinary action by the Council in terms of Part VI of the Act, unless that managing director satisfies the Council that the act was committed by another pharmacist without his or her knowledge.

Appointment of responsible pharmacist

6. (1) The business conducted as a wholesale pharmacist must appoint a responsible pharmacist in respect of each business conducted as a wholesale pharmacist.

(2) The managing director of the business as a wholesale pharmacist may be appointed as the responsible pharmacist.

(3) A person appointed to be the responsible pharmacist of business as a wholesale pharmacist -

[The word "a" appears to have been omitted before the phrase "business as a wholesale pharmacist".]

REGULATIONS
Pharmacy Act 9 of 2004

Regulations relating to Conducting of Business as Wholesale Pharmacist

- (a) must be a pharmacist and be engaged in active practice as a pharmacist for at least three years; and
- (b) may not be appointed as a responsible pharmacist for another pharmacy or another wholesale pharmacist business.

(4) If for any reason a person ceases to be the responsible pharmacist in terms of these regulations, the holder of the registration certificate in respect of that wholesale pharmacist must, within seven days from the date on which the person ceases to be the responsible pharmacist, give written notice to the Council specifying the name and address of another pharmacist to be appointed as the responsible pharmacist for the wholesale pharmacist business.

(5) Within 30 days after a written notice is given to the Council under subregulation (4), the holder of the registration certificate must give Council another written notice specifying the date from which the appointment of the responsible pharmacist was appointed as such.

[The phrase “the appointment of” is superfluous.]

(6) The written notice given to the Council in subregulation (5) must be accompanied by a letter of acceptance of the appointment by the responsible pharmacist.

Duties of responsible pharmacist

7. (1) The responsible pharmacist for a business as a wholesale pharmacist must comply the provisions of the Act, these regulations any other applicable regulations and law that apply to the responsible pharmacist.

[There are several apparent omissions and grammatical problems in the closing phrase, which appears to have been intended to read “must comply with the provisions of the Act, these regulations or any other regulations and laws that apply to the responsible pharmacist”.]

(2) The holder of the registration certificate must ensure that the general physical security of the business premises is secure and that the control of keys or other entry devices are restricted to the responsible pharmacist.

[The verb “are” should be “is” to be grammatically correct (“control... is”).]

- (3) The responsible pharmacist must -
 - (a) be regularly in charge of the business as a wholesale pharmacist when it is open for business;
 - (b) ensure that access to the storage area of the business premises is restricted to authorised staff only and that the storage area is under the direct supervision of the responsible pharmacist;
 - (c) oversee, supervise and monitor all other pharmacists providing pharmacy services in the business as a wholesale pharmacist and all other staff who assist in the provision of pharmacy services;
 - (d) make the arrangements to ensure that -
 - (i) medicines are dispatched in accordance with orders received;

**REGULATIONS
Pharmacy Act 9 of 2004****Regulations relating to Conducting of Business as Wholesale Pharmacist**

- (ii) written or electronic records are kept of all medicines received, destroyed or dispatched and the records are kept confidential and secured;
 - (iii) the selling of medicines which are particularly known to be abused or misused are supervised and monitored;
 - [The closing phrase should be “is supervised and monitored”
to accord with the singular subject “selling”.]
 - (iv) the selling of medicines is made only to persons authorised in terms of these regulations;
 - (v) dispatching is carried out according to good pharmaceutical practice;
 - (vi) the identity of a medicine being dispatched remains confidential, other than to the knowledge of a pharmacist or a member of the staff of the business.
- (f) ensure that records of orders and dispatch are in English and include -
- (i) the name and address of the person to whom the medicine is dispatched;
 - (ii) the date the medicine is dispatched;
 - (iii) the name and dose form of the medicine dispatched;
 - (iv) the strength or identifying formula of the medicine;
 - (v) the quantity of doses;
 - (vi) applicable transport and storage conditions;
 - (vii) a unique number to allow identification of the delivery order; and
 - (viii) batch number and expiry date of the products.
- (g) ensure that adequate arrangements are put in place to ensure that records of orders are -
- (i) retained in a secure place at the business for a period of not less than three years;
 - (ii) made at the time of dispatching or in the case of an emergency within 24 hours after the dispatching;
 - (iii) certified by the responsible pharmacist who dispatched the order with his or her handwritten signature within 30 days after the dispatching;
 - (iv) readily retrievable by reference to the name and address of the person to whom the medicine was dispensed dispatched and, the date of dispatching.

- [There is a grammatical problem with subparagraph (iv),
which may have been intended to read as follows;
“(iv) readily retrievable by reference to the name and address of the person
to whom the medicine was **dispatched and** the date of dispatching;”.]

**REGULATIONS
Pharmacy Act 9 of 2004****Regulations relating to Conducting of Business as Wholesale Pharmacist**

- (h) ensure that the records of temperature monitoring data are kept for the shelf-life of the stored medicine and are kept for an additional year after the shelf life of the medicine; and

[The words “shelf-life and “shelf life” are inconsistent with respect to hyphenation in the *Government Gazette*, as reproduced above.]

- (i) ensure that the temperature mapping of the warehouse where medicines are stored is carried out to show uniformity of the temperature across the storage area.

Consideration of application for registration of business as a wholesale pharmacist

8. (1) For the purpose of considering an application made in terms of regulation 2 for registration as a wholesale pharmacist, the Council must inspect the business premises.

(2) The inspection made in terms of subregulation (1), is at the cost of the applicant and the fee payable for inspection is as determined by the Council in terms of section 28 of the Act.

(3) The inspection referred to in subregulation (1) must be conducted by a person appointed by the Council and be conducted in the presence of the managing director or in the presence of a registered person appointed by the managing director.

(4) A person appointed by the Council to inspect the business premises must report in writing to the Council on all findings and observations of the inspection.

(5) The Council after considering the report contemplated in subregulation (4) may invite the applicant to appear before the Council, or a committee of the Council, and make representations in relation to the application, including any matter contained in the inspection report referred to in subregulation (4).

Approval of registration of business as a wholesale pharmacist and issuing of registration certificate

9. The Council may approve an application for registration of a business as a wholesale pharmacist made in terms of regulation 2 and issue a registration certificate to the applicant to conduct such business if the Council is satisfied that -

- (a) the applicant complies with the Act and these regulations; and
- (b) the application for registration is duly made and all required information for consideration of the application is provided.

Refusal of application for registration of business as a wholesale pharmacist

10. The Council may refuse an application for registration of a business as a wholesale pharmacist, if -

- (a) the applicant does not comply with the Act and these regulations;
- (b) the applicant has been convicted of an offence in terms of the Act; or

**REGULATIONS
Pharmacy Act 9 of 2004****Regulations relating to Conducting of Business as Wholesale Pharmacist**

- (c) the applicant has been convicted of an offence in terms of the Medicines and Related Substances Control Act.

Services to be provided by a business conducted as a wholesale pharmacist

11. Subject to the provisions of the Medicines and Related Substances Control Act, the person registered by the Council in terms of these regulations to conduct business as a wholesale pharmacist is authorised to provide the following services -

- (a) the selling of medicines to -
- (i) a community pharmacy;
 - (ii) a hospital pharmacy;
 - (iii) a person licensed in terms section 31(2) of the Medicines and Related Substances Control Act, 2003 (Act No. 13 of 2003) and who is responsible for the running of the Central Medical Stores under the Ministry responsible for health;
 - (iv) any person, other than the person referred to in subparagraph (iii), licensed in terms section 31 of the Medicines and Related Substance Control Act, 2003 (Act No. 13 of 2003)

[There is no punctuation at the end of paragraph (a) in the Government Gazette; there are no additional words.]

- (b) the wholesale distribution of any medicine or scheduled substance through the purchasing, acquiring, keeping, possessing, supplying or selling of any medicine or scheduled substance;
- (c) the furnishing of information and advice to any authorised person with regard to medicine distributed;
- (d) re-packaging of medicines, which means the removing of a medicine from its original container and placing it into a patient ready pack;
- (e) provision of other services approved by the Council in terms of the Act.

Register of business as a wholesale pharmacist

12. (1) The Council must in terms of section 25(2) of the Act, keep a register in respect of a business conducted as a wholesale pharmacist.

- (2) The register referred to in subregulation (1) must include the -
- (a) details of each person having a proprietary interest in the business;
 - (b) registration status of the business as conducted as a wholesale pharmacist;
 - (c) name, address and contact details of the managing director for a private company or a public company conducting business as a wholesale pharmacist; and

**REGULATIONS
Pharmacy Act 9 of 2004**

Regulations relating to Conducting of Business as Wholesale Pharmacist

- (d) name, address and contact details of the responsible pharmacist.

Period of registration

13. The period of registration of a business as a wholesale pharmacist ends on 31 March following the date on which it is granted and after that on 31 March of each year for which the registration is renewed.

Revocation of registration of business as a wholesale pharmacist

14. (1) Subject to subregulation (2) the Council may revoke the registration of a business as a wholesale pharmacist if -

- (a) the holder of the registration certificate does not comply with the Act or the Medicines and Related Substances Control Act; or
- (b) the Council, after conducting an inquiry in terms of Part VI of the Act, determines that there has been a failure by the holder of the registration certificate to comply with requirements set out in regulation 19.

(2) If the Council intends to revoke the registration of a business as a wholesale pharmacist the Council must -

- (a) notify the holder of the registration certificate of the intention and reasons as to why the Council intends to revoke the registration certificate;
- (b) at least 30 days before the intended revocation of the registration certificate, deliver a written notice to the holder of the registration requesting the holder of the registration certificate to make written presentations to the Council within a period determined by Council;

[The word “the” appears to have been omitted before the final word “Council” in paragraph (b).]

- (c) consider the presentations made in terms of paragraph (b), if any; and
- (d) decide whether or not to revoke the registration certificate and in writing notify the holder of the registration certificate of its decision.

(3) A person who is aggrieved by the decision of the Council in subregulation (2), may appeal against that decision or finding to the appeal committee or comply with such penalty imposed in terms of section 63 of the Act.

(4) The appeal made in terms of subregulation (3) must be in the form and manner prescribed in the applicable appeal regulations made in terms of section 66 of the Act.

Notification of change

15. The holder of a registration certificate must inform the registrar in writing within a period of 30 days after an occurrence of any change in the particulars furnished in an application for registration in terms of regulation 2.

Application for alteration to business premises as a wholesale pharmacist

REGULATIONS
Pharmacy Act 9 of 2004

Regulations relating to Conducting of Business as Wholesale Pharmacist

16. (1) The holder of the registration certificate may not cause or permit alterations to be made to the business premises that affects the structure, layout or floor area of the business premises without the prior written approval of the Council.

[The verb “affects” should be “affect” to be grammatically correct (“alterations... that affect”).]

(2) If the holder of a registration certificate intends to make alterations to the business premises, the holder of such certificate must in writing apply to Council for approval and must submit the application at least six weeks before the alterations are made.

(3) The application for approval made in subregulation (1) must be accompanied by -

- (a) specifications and floor plans drawn to scale by a registered architect relating to the proposed alteration; and
- (b) the application fee determined by the Council in terms of section 28 of the Act.

(4) The Council may, for the purposes of considering an application for approval of alterations proposed to be made to the business premises, require that the business premises be inspected by a person appointed by the Council.

(5) The inspection referred to in subregulation (4) be done in the presence of the managing director or a responsible pharmacist.

(6) The inspection made in terms of subregulation (4), is at the cost of the applicant and the fee payable is as determined by the Council in terms of section 28 of the Act.

(7) A person appointed by the Council to perform an inspection as contemplated in subregulation (4) must submit a report in writing on -

- (a) the effect that the alterations would have on the business as a wholesale pharmacist, if carried out in accordance with the plans and specifications submitted to the Council; and
- (b) the suitability of the business premises for the conducting of business as a wholesale pharmacist.

(8) The Council, after considering the report contemplated in subregulation (7), may in writing request the holder of the registration certificate, to appear before the Council or a committee of the Council to make representations in relation to the application, including any matter contained in the inspection report.

(9) The Council may -

- (a) approve the application for alteration of business premises if the applicant complies with this regulation and must give the holder of registration certificate a document indicating the approval; or
- (b) refuse the application and in that case must in writing notify the applicant with its decision and the reasons for the refusal.

**REGULATIONS
Pharmacy Act 9 of 2004****Regulations relating to Conducting of Business as Wholesale Pharmacist**

Application for relocation of business as a wholesale pharmacist

17. (1) The holder of a registration certificate who intends to relocate the business as a wholesale pharmacist to another business premises must apply to the Council for approval.

(2) An application for relocation 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 new business premises and a copy of the floor plan; and

[There is no paragraph (b) in the Government Gazette.]

- (c) the fee determined by the Council in terms of section 28 of the Act and the regulations.

(3) For purpose of considering an application in terms of this regulation, the Council may inspect the business premises to which the business is to be relocated, and subregulations (5), (6), (7) of regulation 16 apply with changes required in the context in respect of such an inspection.

- (4) The Council may -

- (a) approve the application for relocation if the applicant complies with this regulation and must give the holder of registration certificate a document indicating the approval; or

[The word “the” appears to have been omitted before the term “registration certificate”.]

- (b) may refuse the application and in that case must in writing notify the applicant with its decision and the reasons for the refusal.

Notification of commencement of business after alterations or relocation

[In the ARRANGEMENT OF REGULATIONS, the word “alterations” in the heading is singular: “Notification of commencement of business after alteration or relocation”.]

18. (1) The holder of a registration certificate must give written notice to the Council, of the date of commencement of a business as a wholesale pharmacist at the business premises altered or relocated in terms of these regulations.

(2) As soon as may be practical after the commencement of business as a wholesale pharmacist at the business premises that was altered or relocated in terms of these regulations, a person appointed by the Council must inspect the business premises in the presence of the managing director of the business or a pharmacist appointed by the managing director in terms of regulation 6.

(3) A person appointed by the Council to inspect the business premises under subregulation (2) must report to the Council in writing on the suitability of the business premises for the conducting of business as a wholesale pharmacist after alteration or relocation of business premises.

Requirements to conduct a business as a wholesale pharmacist

REGULATIONS
Pharmacy Act 9 of 2004

Regulations relating to Conducting of Business as Wholesale Pharmacist

19. (1) A holder of registration certificate must ensure that the business conducted as a wholesale pharmacist have -

- (a) a tracing system for purchasing of medicines;
- (b) a procedure on handling instructions for medicines requiring special storage when selling and dispatching the medicine;
- (c) a procedure including monitoring of medicines to be stored according to the manufacturer's recommended storage conditions;
- (d) a procedure for returned medicines to be placed under quarantine and returned after the approval and quality evaluation by a responsible pharmacist;
- (e) an effective manual or digital system to control medicines;
- (f) a reconciliation of medicines to be performed at least twice a year, comparing the actual and recorded product quantities;
- (g) a procedure for the removal of expired medicines and storage in a designated area for destruction by incineration or the return of the expired medicines to the supplier;
- (h) a record keeping system of all disposed medicines;
- (i) separate fridges for storage and receiving of medicines for use by human beings and veterinary medicines, in terms of which the fridges are connected to an automatic standby generator or an emergency power system in case of power failure;
- (j) a freezer for vaccines and medicines with temperature regulated at below 0 degrees or as recommended by the manufacturer and the freezer must be connected to an automatic standby generator or other emergency power system in case of power failure; and
- (k) transportation system of medicines which prevent exposure of the medicines to conditions that could affect their stability, packaging integrity and to prevent contamination.

[The verb "prevent" should be "prevents" to be grammatically correct. The word "or" should appear in place of the comma between "stability" and "packaging integrity".]

(2) The holder of the registration certificate must ensure that the interior floor area of the receiving warehouse and dispatch areas of the business premises -

- (a) is at least 100 square meters;
- (b) is secured against unauthorised entry; and
- (c) have sufficient shelving with smooth washable and impermeable material capable of being maintained in a hygienic condition and for keeping of medicines in a manner that will allow for orderly arrangement and proper rotation of medicine.

[The verb "have" should be "has" to be grammatically correct.]

**REGULATIONS
Pharmacy Act 9 of 2004****Regulations relating to Conducting of Business as Wholesale Pharmacist**

(3) The holder of the registration certificate must ensure that the interior floor area of the business premises referred to in subregulation (2) have -

[The verb “have” should be “has” to be grammatically correct (“floor area... has”).]

- (a) adequate pallets for bulk medicines that cannot fit on shelves;
- (b) shelves or pallets suitably placed to allow for cleaning;
- (c) adequate lighting and ventilation with air conditioners to effectively control temperature at below 25°C in all areas where medicines are stored;
- (d) a clearly demarcated separate receiving area, shielded from adverse weather conditions, with direct access for delivery vehicles;
- (e) a clearly demarcated dispatch area, separate from the receiving area with direct access to delivery vehicles and is shielded from adverse weather conditions;

[The word “is” before the phrase “shielded from adverse weather conditions” is superfluous.]

- (f) adequate cold storage with temperature regulated between two degrees Celsius and eight degrees Celsius, or in accordance with the information on the product label; and
- (g) calibrated temperature monitoring devices.

(4) The holder of the registration certificate must ensure that the business premises referred to in subregulation (2) is laid out in such manner that is properly demarcated, and must include -

- (a) a staff rest room, a kitchen and toilet facilities for staff with adequate hand washing facilities;
- (b) secured access restricted to authorised personnel only;
- (c) a secured designated area for the storage of psychotic medicine or for narcotics substances;
- (d) special and segregated areas for storage of flammable and explosive substances;
- (e) additional safety and security measures for combustible liquids, solid and pressurised gases;

[While the intended meaning is not entirely clear, this provision may have been intended to refer to “combustible liquids and solids, and pressurised gases” or “combustible liquids, solids and pressurised gases”.]

- (f) washable and durable floor finish which can withstand movement of heavy loads;
- (g) storage area for cleaning materials;
- (h) separate storage spaces for veterinary medicines and medicines used by human beings' medicines;

**REGULATIONS
Pharmacy Act 9 of 2004**

Regulations relating to Conducting of Business as Wholesale Pharmacist

[This provision was probably intended to refer to either “medicines used by human beings” or “human beings’ medicines”.]

- (i) physically segregated storage areas for rejected, expired, recalled, returned and suspected counterfeits;
- (j) where electronic systems are used, storage areas for rejected, expired, recalled, returned and suspected counterfeits should be validated and clearly identified; and

[It appears that paragraphs (i) and (j) may have been intended to refer to “rejected, expired, recalled, returned and suspected counterfeit medicines”.]

- (k) the business premises is secured against direct access by persons from any adjoining premises where activities other than that of the business as a wholesale pharmacist are carried out.

(5) The holder of the registration certificate must ensure that the business as a wholesale pharmacist has a refrigerator of adequate capacity for the exclusive storage of thermo labile medicines and products only, which refrigerator must be connected to a standby generator or other emergency power system to ensure uninterrupted supply in the event of a power failure.

[The word “thermolabile” should be written as one word.]

(6) The holder of registration certificate must ensure that the following publications are kept on the business premises and are accessible by electronic means -

[The word “a” appears to have been omitted before the term “registration certificate”.]

- (a) the Act, the regulations, rules and notices made or published under that Act in so far as they relate to medicines and the conduct of a business as a wholesale pharmacist, including all amendments to the Act, regulations and rules and notices published under that Act;
- (b) the Medicines and Related Substances Control Act, the regulations and rules made or published in the Act in so far as they relate to medicines and the conduct of a business as a wholesale pharmacist, including all amendments to the Act, regulations and rules and notices published under that Act;

[The phrase “in the Act” should be “under that Act” as in paragraph (a).]

- (c) the latest editions of the relevant international extra pharmacopoeia, a handbook on toxicology and poisoning, and a handbook on pharmacology; and

[The term “Extra Pharmacopoeia” refers to a specific publication and so should be capitalised.]

- (d) 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.

Transitional provision

20. (1) A business registered as a wholesale pharmacist before the date of commencement of these regulations is regarded as a business as a wholesale pharmacist registered

REGULATIONS
Pharmacy Act 9 of 2004

Regulations relating to Conducting of Business as Wholesale Pharmacist

in terms of these regulations or for a period of 12 months from the date commencement and may continue to conduct business as a wholesale pharmacist for that period.

(2) The holder of the registration contemplated in subregulation (1), must within 12 months from the date of commencement of these regulations apply in accordance with these regulations, for registration to conduct business as a wholesale pharmacist, if the holder of that registration intends to continue conducting business as a wholesale pharmacist.

(3) If the holder of the registration referred to in subregulation (1) fails to submit its application for registration of business as a wholesale pharmacist within the period referred to in subregulation (2) the registration concerned lapses and such holder may not continue to conduct business as a wholesale pharmacist after that period.

(4) A person who contravenes subregulation (3) and continues to conduct a business as a wholesale pharmacist after registration has lapsed is on conviction liable to a fine not exceeding N\$20 000 or to imprisonment for a period not exceeding five years, or to both such fine and such imprisonment.