
GOVERNMENT NOTICES • GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF HEALTH**NO. 1476****22 DECEMBER 2017****GUIDANCE FOR THE ISSUING OF LICENCES FOR PHARMACY PREMISES**

The Director-General: Health intends to issue the following guidance for the issuing of licences for pharmacy premises in terms of the Regulations relating the ownership and licensing of pharmacies (the Regulations) published in terms of the Pharmacy Act, 1974 (Act No. 53 of 1974) (the Act) to be used:

- By persons submitting an application for a licence for pharmacy premises;
- In the evaluation of applications for such licences.

This document must be read in conjunction with the Act and the Regulations published in terms of this Act.

Interested persons are invited to submit any substantiated comments on this document, or any representations they may wish to make in regard thereto, to the Director-General: Health, Private Bag X828, Pretoria, 0001 for the attention of Mr Gavin Steel, within 45 days of the publication of this notice.

GUIDANCE FOR THE ISSUING OF LICENCES FOR PHARMACY PREMISES

1. Introduction

A Pharmacy Licensing Committee is appointed by the Director-General to evaluate applications and make recommendations for the issuing of licences for pharmacy premises in terms of the Regulations relating to the Ownership and Licensing of Pharmacies, issued in terms of the Pharmacy Act, 1974 (Act No. 53 of 1974), hereinafter referred to as the Act, published under Government Notice No. R. 553 Government Gazette No. 24770 of 25 April 2003.

2. Definitions

In this guidance document any word or expression defined in the Act, and not defined herein bears the same meaning as in the Act or the Regulations published in terms of the Act unless the context otherwise indicates;

“Change of ownership” means any change in the owner of a pharmacy whether a natural person or body corporate and includes a change in the directors of a company or the members of a close corporation;

“District” means a district municipality as defined in the Municipal Structures Act, 1998 (Act No 117 of 1998) as a municipality that has municipal executive and legislative authority in an area that includes more than one municipality, and which is described in Section 155(1) of the Constitution as a category C municipality;

“Large shopping centre” means a shopping centre that contains 50 or more retail establishments and has customer parking facilities;

“Metropolitan municipality” means a municipality as defined in the Municipal Structures Act, 1998 (Act No. 117 of 1998) that has exclusive executive and legislative authority in its area, and which is described in section 155(1) of the Constitution as a category A municipality;

“Place” means a city, town or area in a metropolitan municipality used by Statistics South Africa (Stats SA) to provide population statistics;

GUIDANCE FOR THE ISSUING OF LICENCES FOR PHARMACY PREMISES

“Regulations” means the Regulations relating to the ownership and licensing of pharmacies published in terms of the Act;

“Retail establishment” means premises in a shopping centre occupied by or likely to be occupied by a shop where goods, food or beverages are sold, a bar, café, restaurant or takeaway, or a business that provides services to customers, but excludes:

- (a) commercial office space;
- (b) a car wash or car parking facilities;
- (c) a library;
- (d) a school; preschool; child care centre or child minding facility, unless the centre or facility is regularly available for use by customers of the shopping centre while the customers are at the shopping centre;
- (e) a storeroom or storage area;
- (f) a temporary selling point; or
- (g) an automatic teller machine or automatic dispensing machine;

“Rural sub-district” means a sub-district where the population is less than 80 people per km²;

“Shopping centre” means a group of retail establishments that is under single management and occupies a gross leasable area (excluding the parking facilities) of at least 5 000m²;

“Single management” for a shopping centre means management of the centre as a whole by one or more managers working cooperatively under an agreement to encourage the use of the centre as a single integrated facility and including management of security, pedestrian and vehicular access, cleaning, signage, trading hours, marketing, and maintenance of buildings, common areas and utilities;

“Small shopping centre” means a shopping centre that contains at least 15 but less than 50 retail establishments and has customer parking facilities; and

“Sub-district” means a local municipality as defined in the Municipal Structures Act, 1998 (Act No. 117 of 1998) as a municipality that shares municipal executive and legislative authority in its area with a district municipality within whose area it falls, and which is described in section 155(1) of the Constitution as a category B municipality.

GUIDANCE FOR THE ISSUING OF LICENCES FOR PHARMACY PREMISES**3. Purpose**

The purpose of this guidance document is to assist:-

- (a) The applicant in submitting an application for a licence for pharmacy premises; and
- (b) In the evaluation of the licence applications.

4. General principles

- 4.1 An application for a licence for a community pharmacy or an institutional pharmacy must comply with Regulations 7(1) and 7(2) of the Regulations;
- 4.2 In the case of an institutional pharmacy in a public health facility or an institutional pharmacy in a private health facility, clauses 6 and 7 of this guidance document are not applicable;
- 4.3 An application for a licence for a manufacturing or wholesale pharmacy must comply with Regulation 7(1) of the Regulations;
- 4.4 In the case of a community pharmacy or an institutional pharmacy where the only service provided is:
 - 4.4.1 conducting of clinical trials; or
 - 4.4.2 supply of veterinary medicines; or
 - 4.4.3 compounding of medicine in accordance with the Medicines and Related Substances Act, 1965 (Act 101 of 1965)

and the service provided in the pharmacy is limited in the conditions of the licence to one or more of the services in 4.4.1, 4.4.2 or 4.4.3 above, clauses 6 and 7 of this guidance document are not applicable;

- 4.5 In an application for a licence for a consultant pharmacy, clauses 6 and 7 of this guidance document are not applicable;
- 4.6 In the case of an application for change of ownership of an existing pharmacy, where no relocation is contemplated, clauses 6 and 7 of this guidance document are not applicable;

GUIDANCE FOR THE ISSUING OF LICENCES FOR PHARMACY PREMISES

- 4.7 A licence for a pharmacy premises may be issued subject to the condition that the pharmacy is operational within 90 days of the issuing of such licence;
- 4.8 Where a new licence is issued, the current licence of the pharmacy premises shall be deemed as cancelled and must be returned to the Director-General before a new licence is issued for the premises in question;
- 4.9 Only one licence may be in existence for a single pharmacy premises.

5. Information to be submitted with the pharmacy premises licence application**5.1 New Pharmacies:**

The following information must be included in the application for a licence for pharmacy premises:

- 5.1.1 The name and contact details (address, telephone numbers, fax and email) of the applicant;
- 5.1.2 Details of the exact location of the proposed pharmacy premises, including the physical address, an accurate indication of the location of the premises on a street map and/or on a geographical information system (GIS) map;
- 5.1.3 The Global Positioning System (GPS) co-ordinates of the proposed location using the WGS84 form of GPS co-ordination;
- 5.1.4 The district and sub-district or metropolitan municipality and place where the proposed pharmacy premises will be located;
- 5.1.5 The location of the population to whom a pharmaceutical service will be provided;
- 5.1.6 The population of the sub-district or place that will be served by the proposed pharmacy, according to the latest available population statistics provided by Stats SA;
- 5.1.7 In the case of a community pharmacy, the relationship between the proposed pharmacy and the number and proximity of existing health care services and

GUIDANCE FOR THE ISSUING OF LICENCES FOR PHARMACY PREMISES

facilities, including the distance between the proposed pharmacy and other community pharmacies;

- 5.1.8 The nature and extent of the service that is envisaged to be provided by the proposed pharmacy;
- 5.1.9 The extent of the provision of services to persons outside the sub-district or place in which the proposed pharmacy is to be situated;
- 5.1.10 Where applicable, any special care needs of the community to be served based on demographics and/or health status; and
- 5.1.11 Information as required in terms of Regulation 7(1) of the Regulations that the applicant will comply with Good Pharmacy Practice, Good Manufacturing Practice or Good Distribution Practice (as applicable).

5.2 Change of Ownership:

The following information must be included in an application for change of ownership of a pharmacy:

- 5.2.1 The name and contact details (address, telephone numbers, fax and email) of the previous owner (seller) or the representative thereof;
- 5.2.2 The name and contact details (address, telephone numbers, fax and email) of the prospective owner (buyer) or the representative thereof;
- 5.2.3 Details of the exact location of the premises, including the physical address, an accurate indication of the location of the premises on a street map and/or on a Geographical Information System (GIS) map;
- 5.2.4 The Global Positioning System (GPS) co-ordinates of the proposed location using the WGS84 form of GPS co-ordination;
- 5.2.5 The district and sub-district or metropolitan municipality and place where the pharmacy premises is located;

GUIDANCE FOR THE ISSUING OF LICENCES FOR PHARMACY PREMISES

- 5.2.6 Recently certified copies (not older than 3 (three) months) of the identity documents of the current owner(s) and the prospective owner(s) (as applicable), in the case of natural persons;
- 5.2.7 In the case where the pharmacy is owned by more than one natural person or by a body corporate, proof that the person submitting the application is duly authorised to do so and has been designated as the contact person for any queries relating to the application in question;
- 5.2.8 A copy of the pharmacy licence in the case of pharmacies licensed in terms of the Regulations, as well as a copy of the certificate of recording of the pharmacy with the South African Pharmacy Council;
- 5.2.9 In the case of a body corporate, the latest (not older than 3 (three) months) certificate of registration proving change of ownership obtained from the Companies and Intellectual Property Commission (CIPC) and recently certified copies (not older than 3 (three) months) of the identity documents of the members or directors (as applicable);
- 5.2.10 Where applicable, a sale agreement between the buyer and seller, or other valid proof of change of ownership signed by all parties, or a duly authorised agent of such party. Additional information in this regard may be requested;
- 5.2.11 Where the change of ownership is related only to changes in the founding statement of a close corporation or the directors of a company, valid documentary proof of such change must be submitted.

5.3 Relocation of existing premises

Only the owner of a pharmacy may submit an application for the relocation of a pharmacy. Such an application must include the following information:

- 5.3.1 The name and contact details (address, telephone numbers, fax and email) of the owner of the pharmacy;

GUIDANCE FOR THE ISSUING OF LICENCES FOR PHARMACY PREMISES

- 5.3.2 Details of the exact location of the current premises of the pharmacy to be relocated, including the physical address, an accurate indication of the location of the premises on a street map and/or geographical information system (GIS) map;
- 5.3.3 Details of the exact location of the proposed location to which the pharmacy will be relocated, including the physical address, an accurate indication of the location of the premises on a street map and/or on a geographical information system (GIS) map;
- 5.3.4 The Global Positioning System (GPS) co-ordinates of the proposed new location using the WGS84 form of GPS co-ordination;
- 5.3.5 The district and sub-district or metropolitan municipality and place to which the pharmacy premises will be relocated;
- 5.3.6 A valid lease agreement between the applicant and the owner of the proposed new premises, except where the applicant is the owner of the premises;
- 5.3.7 The distance between the current and proposed location of the pharmacy premises. Distances are based on the shortest possible lawful route that can be followed on foot, from the entrance of the current pharmacy premises to the entrance of the proposed pharmacy premises;
- 5.3.8 In the case where the proposed new premises is more than 250 (two hundred and fifty) metres from the current pharmacy premises, the applicant must provide the population of the sub-district or place that will be served by the pharmacy according to the latest available population statistics provided by Stats SA.

5.4 Change of ownership and relocation of pharmacy premises

The following information must be included in an application for change of ownership of a pharmacy, where the intention is to relocate the pharmacy premises:

- 5.4.1 The name and contact details (address, telephone numbers, fax and email) of the previous owner (seller) or the representative thereof;

GUIDANCE FOR THE ISSUING OF LICENCES FOR PHARMACY PREMISES

- 5.4.2 The name and contact details (address, telephone numbers, fax and email) of the prospective owner (buyer) or the representative thereof;
- 5.4.3 Details of the exact location of the current premises of the pharmacy, including the physical address, an accurate indication of the location of the premises on a street map and/or geographical information system (GIS) map;
- 5.4.4 The Global Positioning System (GPS) co-ordinates of the current location using the WGS84 form of GPS co-ordination;
- 5.4.5 The district and sub-district or metropolitan municipality and place where the pharmacy premises is located;
- 5.4.6 Recently certified copies (not older than 3 (three) months) of the identity documents of the current owner and the prospective owner(s) in the case of natural persons;
- 5.4.7 In the case where the pharmacy is owned by more than one natural person or body corporate, proof that the person submitting the application is duly authorised to do so and has been designated as the contact person for any queries relating to the application in question;
- 5.4.8 A copy of the pharmacy licence in the case of pharmacies licensed in terms of the Regulations, as well as a copy of the certificate of recording of the pharmacy with the South African Pharmacy Council;
- 5.4.9 In the case of a body corporate the latest (not older than 3 (three) months) Certificate of Registration proving change of ownership obtained from the Companies and Intellectual Property Commission (CIPC);
- 5.4.10 Where applicable, a sale agreement between the buyer and seller, or other valid proof of change of ownership signed by all parties, or a duly authorised agent of such party. Additional information in this regard may be requested;
- 5.4.11 Where the change of ownership is related only to changes in the founding statement of a close corporation or the directors of a company, valid documentary proof of such change must be submitted;

GUIDANCE FOR THE ISSUING OF LICENCES FOR PHARMACY PREMISES

- 5.4.12 Details of the exact location of the proposed location to which the pharmacy will be relocated, including the physical address, an accurate indication of the location of the premises on a street map and/or on a geographical information system (GIS) map;
- 5.4.13 The Global Positioning System (GPS) co-ordinates of the proposed location using the WGS84 form of GPS co-ordination;
- 5.4.14 The district and sub-district or metropolitan municipality and place to which the pharmacy premises will be relocated;
- 5.4.15 A valid lease agreement between the applicant and the owner of the proposed new premises, except where the applicant is the owner of the premises;
- 5.4.16 The distance between the current and proposed location of the pharmacy premises. Distances are based on the shortest possible lawful route that can be followed on foot, from the entrance of the current pharmacy premises to the entrance of the proposed pharmacy premises;
- 5.4.17 In the case where the proposed new premises is more than 250 (two hundred and fifty) metres from the current pharmacy premises, the applicant must provide the population of the sub-district or place that will be served by the pharmacy according to the latest available population statistics provided by Stats SA.

6. Norms for granting of licences for pharmacy premises**6.1 New Pharmacy Premises**

The following norms are applied in the consideration of applications for new pharmacy premises:

- 6.1.1 There should be at least one community pharmacy in each sub-district or place;
- 6.1.2 Based on population, the ratio applied is 1 (one) pharmacy per 5000 (five thousand) population, except in rural sub-districts where the ratio is 1 (one) pharmacy per 2 500 (two thousand five hundred) population. This ratio does not apply in the case of an institutional pharmacy situated in a public health facility, an institutional pharmacy situated in a private health facility and the pharmacies mentioned in clauses 4.4 and

GUIDANCE FOR THE ISSUING OF LICENCES FOR PHARMACY PREMISES

4.5. In rural sub-districts, exceptions to the population norm may be considered where the proposed pharmacy is more than 20 (twenty) kilometres from an existing pharmacy;

- 6.1.3 In the case of an application for a licence for a new community pharmacy, such premises may not be located less than 500 (five hundred) metres from an existing community pharmacy. In rural sub-districts, exceptions to this norm may be considered based on the availability of premises for commercial purposes;
- 6.1.4 Distances are based on the shortest possible lawful route that can be followed on foot, from the entrance of the existing pharmacy premises to the entrance of the proposed pharmacy premises;
- 6.1.5 In the case of applications for the location of a pharmacy in a shopping centre, the number of retail establishments is considered. The norm is 1 (one) pharmacy in a small shopping centre, 2 (two) pharmacies in a large shopping centre with up to 100 retail establishments, 3 (three) pharmacies in a large shopping centre with up to 150 retail establishments, with 1 (one) additional pharmacy permissible for each additional 100 (one hundred) retail establishments thereafter. A letter specifying the number of retail establishments in the shopping centre must be provided by the management of the shopping centre or the developer in the case of a new centre or an extension to an existing centre. Such letter must be on the official letter head of the management of the shopping centre or the developer (as applicable) and must include a signed declaration verifying the correctness of the information provided.

6.2 Change of ownership

- 6.2.1 If there is a proposed change of ownership of a pharmacy, an application for change of ownership must be submitted to the Director-General;
- 6.2.2 In the case where a change of ownership of a pharmacy is to be accompanied by a relocation of premises, one application for change of ownership and relocation must be submitted to the Director-General;

GUIDANCE FOR THE ISSUING OF LICENCES FOR PHARMACY PREMISES

- 6.2.3 If the pharmacy remains in the same premises, norms relating to population, proximity and location as contemplated in clauses 6.1.2, 6.1.3, 6.1.4 and 6.1.5 will not be considered in the evaluation of the application; and
- 6.2.4 In the case of a change of ownership, once the new licence has been issued, the current licence of the pharmacy premises shall be deemed as cancelled and must be returned to the Director-General before a new licence is issued for the premises in question.

6.3 Relocation of pharmacy premises

- 6.3.1 In the case of a relocation of a pharmacy premises, an application for a licence for the new premises must be submitted to the Director-General;
- 6.3.2 In the case where a relocation of a pharmacy premises is to be accompanied by a proposed change of ownership, one application for relocation and change of ownership must be submitted to the Director-General;
- 6.3.3 In the case of any relocation of a pharmacy premises, a licence may be granted if the proposed new premises are within 250 (two hundred and fifty) metres, by the shortest possible lawful route that can be followed on foot, from the entrance of the current pharmacy premises to the entrance of the proposed pharmacy premises. The norms relating to proximity as contemplated in clauses 6.1.3 and 6.1.4 will be considered in the evaluation of the application;
- 6.3.4 If a pharmacy is to be relocated to new premises which are more than 250 (two hundred and fifty) metres by the shortest possible lawful route that can be followed on foot, from the entrance of the current pharmacy premises to the entrance of the proposed pharmacy premise, the norms relating to population, proximity and location as contemplated in clauses 6.1.2, 6.1.3, 6.1.4 and 6.1.5 will be considered in the evaluation of the application;
- 6.3.5 Norms relating to distance are not applicable in the case of the relocation of an institutional pharmacy in a public health facility, or an institutional pharmacy in a private health facility where the pharmacy is relocating within the institution in which the pharmacy is located;

GUIDANCE FOR THE ISSUING OF LICENCES FOR PHARMACY PREMISES

- 6.3.6 Where a pharmacy relocates into a shopping centre, the norms relating to shopping centres will apply;
- 6.3.6 In the case of relocation, once the new licence has been issued, the current licence of the pharmacy premises shall be deemed as cancelled and must be returned to the Director-General before a new licence is issued for the premises in question.

7. Basis for evaluation of applications

- 7.1 Applications will be dealt with in chronological order of receipt of a complete application;
- 7.2 An application for a licence for a pharmacy premises will be deemed to be complete when all documents required in terms of the relevant application form, including compliance with Good Pharmacy Practice as contained in rules published in terms of Section 35A of the Act and, where applicable, a licence issued in terms of Section 22C of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), have been received by the Director-General;
- 7.3 In the case of a new site where a licence issued in terms of Section 22C of the Medicines and Related Substances Act, 1964 (Act No. 101 of 1965), is required this licence must be obtained prior to the issuing of a licence for the pharmacy premises;
- 7.4 The applicant may be requested to provide additional information in support of a complete application;
- 7.5 In the case of an application which is incomplete, any outstanding information or documentation must be received by the Director-General within 30 (thirty) days of a request being submitted to the applicant. In cases where the requested information or documentation is not received by the Director-General within the required 30 (thirty) days the application will lapse. The applicant will be required to submit a new application accompanied by the applicable fee;

GUIDANCE FOR THE ISSUING OF LICENCES FOR PHARMACY PREMISES

- 7.6 Applications are evaluated on the basis of the population of the sub-district or place to be served by the proposed pharmacy and the distance between the proposed pharmacy premises and existing community pharmacies;
- 7.7 The population figures used will be based on the latest available statistics provided by Stats SA;
- 7.8 In the case of applications for a pharmacy in a shopping centre, the number of retail establishments in the centre is considered;
- 7.9 In considering applications, the norm relating to the population to be served is considered first, followed by the norm relating to proximity to other community pharmacies. In the case of a pharmacy to be located in a shopping centre, the population and proximity to other community pharmacies is not taken into consideration;
- 7.10 Other factors which may be considered in the evaluation of applications include, but are not limited to the provision of services to patients with special needs or disabilities, the age of the population, as well as factors which may affect the number of people passing the premises;
- 7.11 In the case of an application for the relocation of a pharmacy within the same sub-district or place only the norms relating to proximity as contemplated in clauses 6.3.3 and 6.3.4 will be considered;
- 7.12 In the case of an application for the relocation of a pharmacy to a different sub-district or place norms relating population as contemplated in clause 6.1.2 and proximity as contemplated in clauses 6.1.3, 6.3.3 and 6.3.4 will be considered.

8. Title

This document is called Guidance for the Issuing of Licences for Pharmacy Premises 2017.

MS MP MATSOSO
DIRECTOR-GENERAL: HEALTH
DATE