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## DEPARTMENT OF HEALTH

NO. 1065

06 NOVEMBER 2015

## PHARMACY ACT, 1974 (ACT NO. 53 OF 1974)

## GUIDELINES FOR THE ISSUING OF LICENCES FOR PHARMACY PREMISES

The Minister of Health intends to publish the following Guidelines to be used by the Director-General in the review and issuing of licences in terms of sections 22 and 22A of the Pharmacy Act, 1974 (Act No. 53 of 1974) in the schedule.

Interested persons are invited to submit any substantiated comments on the proposed Guidelines, 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.

**Schedule****1. Definitions**

In these Guidelines any word or expression defined in the Pharmacy Act, 1974 (the Act No. 53 of 1974), and not defined herein bears the same meaning as in the Act and unless the context otherwise indicates;

**“Act”** means the Pharmacy Act 53 of 1974, ;

**“Body corporate”** means any legal person registered in terms of any Act in operation in the Republic;

**“Change of ownership”** means a change in the ownership of a pharmacy from one natural person or body corporate to another;

**“Community pharmacy”** means a pharmacy as defined in the *Regulations relating to the ownership and licensing of pharmacies* published in terms of the Pharmacy Act 53 of 1974, as amended;

**“District”** means a district municipality as defined in the Municipal Structures Act, 1998 (Act No. 117 of 1998);

**“Institutional pharmacy”** means a pharmacy as defined in the Regulations Relating to the Ownership and Licensing of Pharmacies published in terms of the Pharmacy Act, 1974 (Act No. 53 of 1974) Government Notice R. 553 of 25 April 2003 ;

**“Regulations”** means the Regulations Relating to the Ownership and Licensing Of Pharmacies published in terms of the Pharmacy Act, 1974 (Act No. 53 of 1974),; Government Notice R. 553 of 25 April 2003;

**“Rural sub-district”** means a sub-district where the population is less than 80 people per km<sup>2</sup>; and

**“Sub-district”** means a local municipality as defined in the Municipal Structures Act, 1998 (Act No. 117 of 1998).

## **2. General principles**

- 2.1 An application for a licence for a community pharmacy must comply with Regulations 7(1) and 7(2) of the Regulations.
- 2.2 An application for a licence for an institutional pharmacy must comply with Regulations 7(1) and 7(2) of the Regulations provided that clause 4 of these Guidelines (norms for granting of licences for pharmacy premises) and clause 5 (basis for evaluation of applications) are not applicable in the case of an institutional pharmacy in a private health facility.
- 2.3 An application for a licence for a manufacturing or wholesale pharmacy must comply with Regulation 7(1) of the Regulations.
- 2.4 In the case of community and institutional pharmacies where the only service provided is:
  - 2.4.1 Conducting of clinical trials; or
  - 2.4.2 Supply of veterinary medicines; or
  - 2.4.3 Compounding of oncology products;

and the service provided in the pharmacy is limited in the conditions of the licence to one or more of the services in clauses 2.4.1, 2.4.2 or 2.4.3 above, clause 4 of these Guidelines (norms for granting of licences for pharmacy premises) and clause 5 (basis for evaluation of applications) shall not apply.

- 2.5 In an application for a licence for a consultant pharmacy, clause 4 of these Guidelines (norms for granting of licences for pharmacy premises) and clause 5 (basis for evaluation of applications) shall not apply.
- 2.6 In the case of an application for relocation of an existing community pharmacy, the provisions in clauses 4.5 and 4.6 will apply.
- 2.7 In the case of an application for change of ownership of a pharmacy, clause 4 of these Guidelines (norms for granting of licences for pharmacy premises) and clause 5 (basis for evaluation of applications) shall not apply.
- 2.8 Should the licence contemplated in 2.6 or 2.7 above be granted, the current licence of the pharmacy premises shall lapse and must be returned to the Director-General.

### **3. Information to be submitted with the pharmacy premises licence application**

#### **3.1 New Pharmacies:**

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

- 3.1.1 The name and contact details (address, telephone numbers, fax, email) of the applicant.
- 3.1.2 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.
- 3.1.3 The Global Positioning System (GPS) co-ordinates of the proposed location using the WGS84 form of GPS co-ordination.
- 3.1.4 The district and sub-district where the proposed pharmacy premises will be located.

- 3.1.5 The population of the sub-district or sub-districts that will be served by the proposed pharmacy according to the latest available census information provided by Statistics South Africa (Stats SA).
- 3.1.6 The relationship between the proposed pharmacy and the number and proximity of existing services and facilities such as other community pharmacies.
- 3.1.7 The nature and extent of the service that is envisaged to be provided by the proposed pharmacy.
- 3.1.8 The approximate number and location of the population to whom a pharmaceutical service will be provided.
- 3.1.9 The extent of the provision of services to persons outside the sub-district in which the proposed pharmacy is to be situated.
- 3.1.10 Where applicable, any special care needs of the community to be served based on the demographics and/or health status.
- 3.1.11 In addition, information relating to compliance with Good Pharmacy Practice (GPP) to be submitted in support of an application for a license for a pharmacy premises to be issued in terms of the Regulations as published in the GPP.

## **3.2 Change of Ownership**

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

- 3.2.1 The name and contact details (address, telephone numbers, fax, email) of the previous owner (seller) or the representative thereof.
- 3.2.2 The name and contact details (address, telephone numbers, fax, email) of the prospective owner (buyer) or the representative thereof.

- 3.2.3 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.
- 3.2.4 The Global Positioning System (GPS) co-ordinates of the proposed location as per 3.1.3 above.
- 3.2.5 The district and sub-district where the pharmacy premises is located.
- 3.2.6 Recently certified copies (not older than three months) of the identity documents of the current owner and the prospective owner(s) in the case of natural persons.
- 3.2.7 In the case of a body corporate the latest (not older than three months) Certificate of Registration proving change of ownership obtained from the Companies and Intellectual Property Commission (CIPC).
- 3.2.8 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.
- 3.2.9 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.
- 3.2.10 A valid sale agreement between buyer and seller, or legal document of change of ownership of the pharmacy excluding sworn affidavits.
- 3.2.11 Where the change of ownership is related only to changes in the founding statement of a company (e.g. member resignation in a close corporation, changes in the directors) proof of the changes having been done with the CIPC (e.g. CK2 and CK2A documents).

### 3.3 Relocation of existing premises

The following information must be included in the application for the relocation of the pharmacy:

- 3.3.1 The name and contact details (address, telephone numbers, fax, email) of the applicant.
- 3.3.2 Details of the exact location of the current pharmacy premises 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.
- 3.3.3 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.
- 3.3.4 The Global Positioning System (GPS) co-ordinates of the proposed new location as per cause 3.1.3 above.
- 3.3.5 The district and sub-district to which the pharmacy premises will be relocated.
- 3.3.6 A valid lease agreement between the applicant and the owner of the proposed new premises.
- 3.3.7 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 existing pharmacy premises to the entrance of the proposed pharmacy premises.
- 3.3.8 in the case where the relocation is more than 500m from the existing pharmacy premises, the applicant must provide the population of the sub-district that will be served by the pharmacy according to the latest available census information provided by Statistics South Africa (Stats SA).

#### **4. Norms for granting of licences for pharmacy premises**

##### **4.1 New Pharmacy Premises**

The following Norms are applied in the consideration of an application for new pharmacy premises:

- 4.1.1 There should be at least one community pharmacy in each sub-district.
- 4.1.2 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 excludes institutional pharmacies in public and private health facilities, and pharmacies mentioned in clause 2.4. 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.
- 4.1.3 In the case of an application for a licence for a new 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.
- 4.1.4 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.

##### **4.2 Change of ownership**

- 4.2.1 If there is a change of ownership of a pharmacy, an application for change of ownership must be submitted to the Director-General.
- 4.2.2 In the case where a change of ownership of a pharmacy is accompanied by a proposed change of premises, a separate application for a new licence for the proposed new pharmacy premises must be submitted to the Director-General.

- 4.2.3 If the pharmacy remains in the same premises, norms relating to population and proximity as contemplated in clause 4.1.2 and 4.1.3 will not be considered in the evaluation of the application.
- 4.2.4 In the case of a change of ownership, once the new licence has been issued, the original licence shall be deemed to be cancelled and must be returned to the Director-General prior to, or on collection of, the new licence.

### **4.3 Relocation of existing pharmacy premises**

- 4.3.1 In the case of a relocation of an existing pharmacy premises, an application for a license for a new pharmacy premises must be submitted to the Director-General.
- 4.3.2 In the case where a relocation of an existing pharmacy premises is accompanied by a proposed change of ownership, a separate application for a new licence for the pharmacy premises must also be submitted to the Director-General.
- 4.3.3 In the case of a relocation of an existing 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 existing pharmacy premises to the entrance of the proposed pharmacy premises. The norms relating to proximity as contemplated in section 4.1.3 will be considered in the evaluation of the application.
- 4.3.4 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 existing pharmacy premises to the entrance of the proposed pharmacy premise, the norms relating to population and proximity as contemplated in clauses 4.1.2 and 4.1.3 will be considered in the evaluation of the application.
- 4.3.5 In the case of relocation, once the new licence has been issued, the original licence shall be deemed to be cancelled and must be returned to the Director-General prior to, or on collection of, the new licence.



## **5. Basis for evaluation of applications**


- 5.1 Applications will be dealt with in chronological order of receipt of a complete application.
- 5.2 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 Requirements 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 101 of 1965), have been received by the Director-General.
- 5.3 The applicant may be requested to provide additional information in support of a complete application.
- 5.4 In the case of an application which is incomplete any outstanding information or documentation must be received by the Director-General within thirty (30) 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 thirty (30) days the application will lapse. The applicant will be required to submit a new application accompanied by the applicable fee.
- 5.5 Applications are evaluated on the basis of the population of the sub-district to be served by the proposed pharmacy and the distance between the proposed pharmacy premises and existing community pharmacies.
- 5.6 Population figures are based on the latest available census information provided by Stats SA.
- 5.7 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.
- 5.8 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 including the presence of an airport, taxi rank, bus station and/or train station.

5.9 In the case of an application for the relocation of a pharmacy within the same sub-district only the norms relating to proximity as contemplated in clauses 4.3.3 and 4.3.4 will be considered.

5.10 In the case of an application for the relocation of a pharmacy to a different sub-district norms relating population as contemplated in clauses 4.1.2 and proximity as contemplated in clauses 4.1.3, 4.3.3 and 4.3.4 will be considered.

## 6. Title

These Guidelines are called Guidelines for the Issuing of Licences for Pharmacy Premises 2015.

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**DR A MOTSOLEDI, MP**  
**MINISTER OF HEALTH**  
DATE 19/10/2015