
GOVERNMENT NOTICE

DEPARTMENT OF HEALTH

No. R. 151

28 February 2014

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

PROPOSED CRITERIA FOR THE ISSUING OF LICENCES FOR PHARMACY PREMISES

The Minister of Health has, in terms of sections 22 and 22A of the Pharmacy Act, 1974 (Act No. 53 of 1974), to make the regulations in the schedule.

Interested persons are invited to submit any substantiated comments on the proposed Regulations, or any representations they may wish to make in regard thereto, to the Director-General: Health, Private Bag X828, Pretoria, 0001 (for the attention Mr Gavin Steel) within 3 months of date of publication of this notice.

1. Definitions

“Closed shopping centre” means an area or building which contains a number of retail outlets and which has a defined entry and exit point for pedestrians;

“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;

“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 53 of 1974, as amended;

“Medical centre” means a building where one or more practitioners provide health care services to the community;

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

2. General principles

- 2.1 An application for a licence for a community pharmacy or an institutional pharmacy in a private health facility must comply with both Regulation 7(1) and 7(2) of the *Regulations relating to the ownership and licensing of pharmacies* published in terms of the Pharmacy Act 53 of 1974, as amended.
- 2.2 An application for a licence for a manufacturing or wholesale pharmacy must comply with Regulation 7(1) of the *Regulations relating to the ownership and licensing of pharmacies*. As Regulation 7(2) does not apply, the establishment of the need for the service is not applicable in the case of these categories of pharmacy.
- 2.3 In the case of an application for an institutional pharmacy in a private health facility, the establishment of the need for the service does not apply as it is a statutory requirement that there is a pharmacy located in the health facility (refer Regulation 7(2)(d) of the *Regulations relating to the ownership and licensing of pharmacies*).
- 2.4 In the case of community and institutional pharmacies where the **only** service provided is:
- 2.4.1 the conducting of clinical trials; or
 - 2.4.2 the supply of veterinary medicines; or
 - 2.4.2 the provision of mail order services,
- the criteria relating to population and proximity are not applicable.
- 2.5 In the case of applications for consultant pharmacies, Regulation 7 of the *Regulations relating to the ownership and licensing of pharmacies* is not applicable.
- 2.6 In the case of a change of ownership application, the criteria relating to proximity and population are not applicable.
- 2.7 The application will be deemed to have been received on the date on which all required documents have been received.
- 2.8 Applications are considered in chronological order of receipt as per sub regulation 2.7 above.

- 2.9 The applicant may be requested to provide additional information in support of the application.
- 2.10 The applicant may be requested to provide additional information in support of the application and when the information supplied is incomplete. Should the outstanding information/documentation is not submitted within thirty (30) days of a request being submitted to the applicant via email and/or registered post, the application will lapse. The applicant will be required to submit a new application for consideration.
- 2.11 Where an application has failed to comply with Good Pharmacy Practice Requirements as outlined by the South African Pharmacy Council (SAPC), and a letter of non-recommendation supplied to the applicant by the SAPC, the application shall automatically be rejected by the National Department of Health. The applicant will be required to submit a new application to start the process again.

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 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;
- 3.1.4 the district and sub-district where the proposed pharmacy will be located;
- 3.1.5 the population of the sub-district that will be served by the proposed pharmacy according to the latest available census information provided by Statistics South Africa (Stats SA). This information must have the official stamp of Statistics South Africa as proof of validity;

- 3.1.6 the relationship between the proposed pharmacy and the number and proximity of existing services and facilities such as other private sector 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 (the source of information for population data must 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 cases where it is proposed that a pharmacy is established in a medical centre, proof of the authorised prescribers practicing on a full time basis must be supplied.

3.2 Change of Ownership:

- 3.2.1 the name and contact details (address, telephone numbers, fax, email) of both the previous owner (buyer) and the new owner (seller);
- 3.2.2 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;
- 3.2.3 the Global Positioning System (GPS) co-ordinates of the proposed location;
- 3.2.4 the district and sub-district where the pharmacy is located;
- 3.2.5 recently certified copies of the Identity Documents of both the previous and new owner(s) – in the case of sole proprietary;

- 3.2.6 in the case of companies - the latest (not older than 3 months) Certificate of Registration of the selling and buying companies from the Companies and Intellectual Property Commission (CIPC);
- 3.2.7 in the case where the pharmacy is owned by more than one person, proof that the person submitting the application is duly authorised to do so;
- 3.2.8 a copy of the pharmacy licence (where applicable), as well as a copy of the certificate of recording of the pharmacy with the South African Pharmacy Council;
- 3.2.9 a valid sale agreement between the buyer and the seller, where applicable;
- 3.2.10 proof of the sale agreement undertakings being done (e.g. deposit of the agreed amount to the seller, within the time frames outlined on the sale agreement);
- 3.2.11 where the change of ownership is related to only 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).

4. Basis for evaluation of applications

- 4.1 Applications are evaluated on the basis of the population of the sub-district to be served by the proposed pharmacy and the proximity of the proposed pharmacy to existing private sector services and facilities;
- 4.2 Population figures are based on the latest available census information provided by Stats SA. This must be supplied with the official stamp of Stats SA;
- 4.3 In the case of applications for the location of a pharmacy in a closed shopping centre, the foot count of the existing centre, or the projected foot count in the case of a new centre, or an extension to an existing centre, is considered. An original letter specifying the foot count must be provided by the management of the closed shopping centre or the developer in the case of a new centre or an extension to an existing centre. Such letter must be accompanied by an signed affidavit verifying the correctness of the information submitted;

- 4.4 In considering applications, the norm relating to the population to be served is considered first, followed by the norm relating to proximity to other pharmacies. Exceptions may be applied in rural sub-districts to promote access to pharmaceutical services;
- 4.5 In the case of an application for a pharmacy to be situated in a closed shopping centre, where the foot count exceeds 100 000 (one hundred thousand) per month, the population count and proximity of services on the outside of the centre is not taken into consideration. Where the foot count is less than 100 000, the population and proximity criteria will apply;
- 4.6 In cases where it is proposed that a pharmacy is established in a medical centre, a licence will be considered where there are at least 5 (five) authorised prescribers as defined in terms of the Medicines and Related Substances Act 101 of 1965 as amended, practising on a full time basis in such centre and the centre is open for at least 60 (sixty) hours per week. The population count and the proximity of services on the outside of the medical centre will not be taken into consideration;
- 4.7 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. Norms for granting of licences for pharmacy premises

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

5.1 New Pharmacy Premises:

- 5.1.1 There should be at least one community pharmacy in each sub-district;
- 5.1.2 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. In rural sub-districts, exceptions to the population norm may be considered where the

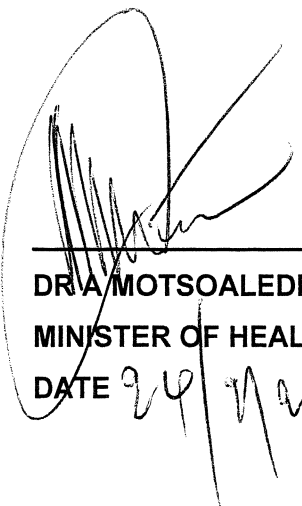
proposed pharmacy is more than 20 (twenty) kilometres from an existing pharmacy;

- 5.1.3 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 pharmacy. In rural sub-districts, exceptions to this norm may be considered based on the availability of premises for commercial purposes;
- 5.1.4 Distances are based on the shortest possible **lawful route** that can be followed **by foot**;
- 5.1.5 In the case of a closed shopping centre, which has a defined entry and exit point/s for pedestrians, the norm is 1 (one) pharmacy for the first 100 000 (one hundred thousand) foot count per month. A second and subsequent licence may be granted in a shopping centre if the foot count exceeds 200 000 (two hundred thousand) per month. A third licence may be granted in cases where the foot count exceeds 300 000 (three thousand) per month;
- 5.1.6 No more than 3 (three) licences will be issued in a closed shopping centre;
- 5.1.7 In cases where the foot count of a shopping centre is less than 100 000 (one hundred thousand) per month the population count and proximity of other pharmacies in the area will be considered.

5.2 Change of ownership

- 5.2.1 If there is a change of ownership of a pharmacy, an application for change of ownership must be submitted to the Department;
- 5.2.2 If there the pharmacy remains in the same premises, norms relating to the population and proximity will not be considered in the evaluation of the application;
- 5.2.3 Should the applicant wish to relocate the premises after the change of ownership is done, a separate application for relocation must be submitted to the Department after the change of ownership has been finalised;

- 5.2.4 Once the new licence for change of ownership has been granted to the new owner, the licence pertaining to the old premises shall be deemed as cancelled, and the applicant must return it to the Department within 30 days of receiving the new licence for the relocation of the pharmacy premises.



DR A MOTSOLEDI, MP
MINISTER OF HEALTH
DATE 24/2/2014
