



health

Department:  
Health  
REPUBLIC OF SOUTH AFRICA

## APPLICATION FOR PHARMACY PREMISES LICENCE IN TERMS OF SECTION 22 OF THE PHARMACY ACT 53 OF 1974

**Please return to:**

**AFFORDABLE MEDICINES: Licensing Unit**

4th Floor Civitas South Building, Cnr Thabo Sehume & Struben Streets, Pretoria, 0001; or  
Private Bag X828, Pretoria, 0001  
Contacts Us: 012 395 8201/2/3/4

Email: [pharmapps@health.gov.za](mailto:pharmapps@health.gov.za) Fax: 086 621 0829

### I: GENERAL INFORMATION

- The licensing of pharmacy premises is governed by the Pharmacy Act, 1974 (Act 53 of 1974) and its Regulations:
  - i. Section 22 and 22A of the Pharmacy Act, 1974 (Act 53 of 1974)
  - ii. Regulations Relating to the Ownership and Licensing of Pharmacies
- An application for a pharmacy premises licence is made to the Director-General: Health, who may issue or refuse such licence on such conditions as he or she may deem fit.
- Categories of pharmacies that may be licensed are:
  - Community
  - Institutional – private and state owned
  - Consultant
  - Manufacturing
  - Wholesale

**NOTE: For Manufacturing and Wholesale/Distributor Licences** – a separate application, in terms of Section 22C of the Medicines and Related Substances Act 101 of 1965, must be made to the Medicines Control Council (see [www.mccza.com](http://www.mccza.com)).

- Only **original** applications must be submitted to the Department. Applications may be posted, couriered or hand delivered. **NO FAXED OR EMAILED COPIES**
- **Incomplete applications will not be processed**
- The application form consists of 4 sections, namely:
  - **PL01** – Pharmacy Premises and Ownership
  - **PL02** – Responsible Pharmacist
  - **PL03** – Compliance of Premises
  - **PL04** – Affidavit for the different sectors (**Note:** Only complete and submit the affidavit relevant to the category of pharmacy you have applied for)
- The non-refundable application fee for Pharmacy Premises Licence is R1,000 (incl VAT), payable to the South African Pharmacy Council using the following banking details:

<b>Bank</b>	: Standard Bank
<b>Account Type</b>	: Cheque Account
<b>Account Number:</b>	011885866
<b>Branch Code</b>	: 010145
<b>Reference</b>	: Pharmacy Name



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### II: THE LICENSING PROCESS (NB! Please submit all applications in duplicate)

- All applications must be submitted **in duplicate (2 original copies)**;
- **Only complete application forms will be processed.** Date of receipt will be taken as the day when all required documents are received (including the application fee);
- A copy of the complete application will be submitted to the South African Pharmacy Council (SAPC) for review of compliance to Good Pharmacy Practice (GPP) Requirements;
- Your application will be acknowledged, in writing, on receipt of a complete application;
- The premises in respect of an application to licence a new community pharmacy premises, or the relocation of an existing pharmacy will be subjected to a site inspection by the Department;
- The application will be assessed by a Committee - taking into account all the information provided in the application, the inspection report by the Department and the GPP recommendation of Council. The recommendation will be forwarded to the Director-General or delegated senior official of the Department for final decision;
- Further information may be required from the applicant after the Committee meeting;
- The Director-General, or delegated senior official, is entitled to issue or decline such a licence application. On approval, a licence shall be issued. If an application is declined, a letter of decline will be issued;
- A copy of the licence/letter will be emailed to the applicant or person responsible for the application. The original will be posted via registered mail. The applicant may collect the original or send a courier (at own cost) to collect it;
- The licensing process will take a **minimum of 30 working days** from receipt of the GPP recommendation from the South African Pharmacy Council where all Departmental processes are finalised. **NOTE:** The process may take longer should there be other processes that must be finalised prior to the issuing of the licence (e.g. withdrawal of existing pharmacy premises licence, request for further information from the applicant).

**NB: Falsification of information or documents required is ground for declining or subsequent withdrawal of a licence**

#### **LEGISLATIVE REQUIREMENTS:**

Please note the following:

- Once a licence is issued, the pharmacy must be recorded **within 30 days** with the South African Pharmacy Council. **Trading may not begin until the pharmacy is recorded** (check [www.sapc.org.za](http://www.sapc.org.za) for application forms).
- In terms of Section 14(h) of the Act, Council may decline to record a person or pharmacy that does not comply with the prescribed conditions.
- The Director-General may withdraw a licence should the licence holder not comply with any applicable Legislation.
- Should you wish to cancel your licence, kindly inform the Department and the South African Pharmacy Council; and return the original licence to the Department.

**NB: The application form is an official document. Only a copy of the original form may be used. The use of replicas or amended forms will render the application null and void.**



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### III: CHECKLIST

**IMPORTANT:** Failure to submit outstanding information within 30 days of being informed will result in your application lapsing. You will then be required to complete and submit a new application for processing.

Attachments for PL01			
<b>i. All Premises:</b>	Y	N	N/A
Copy of duly signed lease agreement/intent to lease for premises			
Proof of ownership of premises (where applicable)			
Copy of hospital licence (institutional pharmacy premises licences only)			
Proof of payment of non-refunded application fee of R1,000-00 (including VAT)			
<b>ii. Changes to existing premises (Change of Ownership/Relocation)</b>	Y	N	N/A
Complete PL01 – Section D			
Certified copy of SAPC recording certificate			
Certified copy of Department of Health Premises Licence			
Copy of signed sale agreement (Change of Ownership ONLY)			
<b>iii. Ownership Changes – Sole Trader or Partnership</b>	Y	N	N/A
Complete PL01 – Section E			
Certified copy of ID document(s) of all partners			
Copy of signed agreement of partnership (where applicable)			
Certified copy of owner(s)' professional registration with relevant statutory body			
<b>iv. Ownership Changes - Companies</b>	Y	N	N/A
Complete PL01 – Section F			
Certificate of incorporation			
Latest CM29 documents			
Proof of current CIPC registration			
Schedules from auditors certifying the shareholdership, where necessary			
Certified copy of each Director's professional registration with relevant statutory body			
<b>v. Ownership Changes – Close Corporation</b>	Y	N	N/A
Complete PL01 – Section F			
Latest CK2 document			
Copy of each member's professional registration with relevant statutory body			
Attachments for PL02 – Responsible Pharmacist			
Certified copy of Identity Document	Y	N	N/A
Proof of current registration with the South African Pharmacy Council			
Letter of appointment of Responsible Pharmacist signed by owner			
Letter of acceptance signed by Responsible Pharmacist			
Attachments for PL03 – Compliance of Premises			
Professionally drawn site plans, indicating the location of the pharmacy	Y	N	N/A
Professionally drawn (to scale) floor plans of the pharmacy* <i>*Refer to Good Pharmacy Practice Requirements, Fourth Edition, 2010</i>			
Letter of appointment of Responsible Pharmacist signed by owner			
Letter of acceptance signed by Responsible Pharmacist			
Copy of Site Master File (Manufacturing and Wholesale Pharmacy Licence Applications ONLY)			
Declarations to be signed in front of Commissioner of Oaths			
PL01 – Statutory Declaration	Y	N	N/A
PL02 – Declaration by Responsible Pharmacist and Owner			
PL04 – Affidavit for category of pharmacy applied for			





**H. Services and Activities (use additional page where required)**

Submit information required in terms of Sub-regulation 7(2) of the Regulations Relating to the Ownership and Licensing of Pharmacies. (Note: This is not required if there is a statutory requirement for the pharmacy in terms of the Regulation 30(h) of Regulations Governing Private Hospitals and Unattached Theatre Units, 1980):

- 1. The population to whom the services will be provided, as provided by the latest published Census results (official Municipal Statistics may also be submitted where Census results are not available):


- 2. The existing pharmaceutical services and facilities in the area where pharmacy is to operate


- 3. The relationship between the proposed pharmaceutical service and existing services and facilities


- 4. The nature and extent of pharmaceutical services to be provided:


- 5. The special care needs of the community to be served


- 6. The benefit to members of the specific community which the pharmacy intends serving


- 7. The extent of the provision of services to persons outside the service area and the extent and nature of the availability of pharmaceutical services in the nearby areas


**I. Statutory Declaration**

I declare that I am the owner / delegated official of the applicant in respect of this application. I am duly authorised to declare that:

The contents and all the statements therein made are true.

All supporting documents are true and accurate.

The owner is eligible to own a pharmacy in terms of the Pharmacy Act, 1974 (Act 53 of 1974).

The owner will ensure to ensure compliance to all applicable legislation, regulations and professional obligations.

1. Title	Mr		Ms		Mrs		Miss		Other	specify
2. Surname										
3. First name/s										
4. Position held in company										

**Signature:**

**Date:**   /   /

**J. Commissioner of Oaths Declaration**

Signed and sworn at \_\_\_\_\_,  
on this \_\_\_\_\_ day of \_\_\_\_\_ in the year \_\_\_\_\_,  
the deponent (applicant) having acknowledged that he/she knows and understands the contents of this declaration.

**Signature:**

**Date:**   /   /

STAMP

Full name, capacity, address and contact details of Commissioner of Oaths



Application to licence a pharmacy premises Appointment of a Responsible Pharmacist

\*\*This form must be filled in by the Responsible Pharmacist and the owner/delegated official of the pharmacy\*\*

A. Responsible Pharmacist \*Attach certified copy of valid registration and Identity Document\*

1. Surname 2. First Name(s) 3. ID Number (attach certified copy) 4. Email address 5. Phone Number 6. Cell Number 7. SAPC Registration

C. Details of Owner

1. Surname 2. First Name(s) 3. Telephone number 4. Cell number 5. Registration number (where applicable)

D. Declaration

Owner (or duly authorised person): I, \_\_\_\_\_, hereby declare that the above-mentioned pharmacist has been offered the position of responsible pharmacist at \_\_\_\_\_ Pharmacy in terms of the requirements Section 22 of the Pharmacy Act, 1974.

Signature: [Signature box]

Date: [dd] / [mm] / [yyyy]

Responsible Pharmacist: I, \_\_\_\_\_, hereby declare that I have accepted the position of responsible pharmacist of \_\_\_\_\_ Pharmacy at the above-mentioned premises in terms of the requirements of Section 22 of the Pharmacy Act, 1974.

Signature: [Signature box]

Date: [dd] / [mm] / [yyyy]





**Application to licence a pharmacy premises  
Compliance of premises**

**\*\*Tick / cross the relevant boxes\*\***

I, the above applicant declare that:			
1. The size of the premises is			m <sup>2</sup>
2. There is/ will be a separate facility for washing hands	Yes	No	N/A
3. There is/ will be a separate facility for cleaning of equipment	Yes	No	N/A
4. The pharmacy will be suitably located in the institution	Yes	No	N/A
5. A responsible pharmacist will be present at all times during business hours.	Yes	No	N/A
6. The premises will be kept clean	Yes	No	N/A
7. The floor surface will be of impermeable material	Yes	No	N/A
8. All working surfaces will be finished with a smooth impermeable and washable material	Yes	No	N/A
9. All cupboards and shelves will be finished with a smooth, impermeable and washable material	Yes	No	N/A
10. A registered pharmacist only will be in possession of the keys to the pharmacy	Yes	No	N/A
11. There will be sufficient and adequate lighting.	Yes	No	N/A
12. The temperature in the dispensary will be below 25°C	Yes	No	N/A
13. The total floor area will be sufficient for the efficient operation of staff	Yes	No	N/A
14. There will be a suitable waiting area, in accordance with Good Pharmacy Practice (GPP) guidelines	Yes	No	N/A
15. There will be a suitable semi-private area for the provision of information And advice in accordance with GPP guidelines	Yes	No	N/A
16. All Scheduled medicines will be stored/displayed in areas inaccessible to the public	Yes	No	N/A
17. The receiving area for deliveries will be clearly defined and effectively separated from the pharmacy	Yes	No	N/A
18. The pharmacy will be suitably situated in the hospital (institutional pharmacies only)	Yes	No	N/A
19. Are security measures in place to prevent unauthorised entry?	Yes	No	N/A
20. A fridge for heat sensitive pharmaceuticals and vaccines will be available.	Yes	No	N/A
21. Access to the premises will be: <i>(tick / cross the box adjacent to the appropriate option)</i>	Via independent entrance to and from the premises		
	Share joint entrance with another/adjoining premises		
	Both independent entrance and shared entrance		
22. The <b>Manufacturer</b> will comply with Good Manufacturing Practices as determined by the Medicines Control Council	Yes	No	N/A
23. The <b>Wholesaler</b> will comply with Good Wholesale Practices as determined by the Medicines Control Council	Yes	No	N/A
24. Will medicines/stock be stored away from the pharmacy premise outlined in Section PL01?  _____			
If yes, please supply details of other premises / storage area where medicines / stock will be stored:  _____  _____  _____			

**AFFIDAVIT FOR COMMUNITY, PRIVATE INSTITUTIONAL & CONSULTANT PHARMACIES ONLY (1 FORM PER DIRECTOR)**



**DEPARTMENT OF HEALTH**  
DIRECTORATE: AFFODABLE MEDICINES  
C/o STRUBEN & THABO SEHUME STREETS, PRETORIA, 0002  
PRIVATE BAG X828, PRETORIA, 0001  
TEL: (012) 395-8202/8204, FAX: 27 (86) 621-0820  
EMAIL: [pharmapps@health.gov.za](mailto:pharmapps@health.gov.za)

**AFFIDAVIT BY AN OWNER (SOLE PROPRIETOR/PARTNER) OF A RETAIL (COMMUNITY, INSTITUTIONAL OR CONSULTANT) PHARMACY REGARDING ELIGIBILITY AND COMPLIANCE WITH STANDARDS AS REQUIRED IN TERMS OF REGULATION 7(1) OF PHARMACIES ACT 53 OF 1974**

**Note:** Proof of authorisation must be provided where authority to sign affidavit is delegated.

I, ..... the owner/duly authorised person (provide authorisation)

ID Number....., do hereby make an oath and declare that:

(a) I am the owner of.....Pharmacy

having its address at.....

(b) I am not an authorised prescriber.

(c) I do not have any direct or indirect beneficial interest in or on behalf of a person contemplated in Regulations 4(a) and (b) of the Regulations Relating to the Ownership and Licensing of Pharmacies in terms of the Pharmacy Act 53 of 1974.

(d) I am not the owner or the holder of any direct or indirect interest in a manufacturing pharmacy.

(e) I am not prohibited by any legislation from owning a pharmacy or having direct or indirect beneficial interest in the pharmacy.

Signature:.....Date...../...../.....

**TO BE COMPLETED BY A COMMISSIONER OF OATHS**

SIGNED AND SWORN TO before me .....

On this ..... day of ..... in the year .....

The deponent, having acknowledged that he/she knows and understands the contents of this declaration.

.....  
**SIGNATURE OF COMMISSIONER OF OATHS**

**STAMP**

(Full name, capacity, address and contact details of Commissioner of Oaths)

**AFFIDAVIT FOR MANUFACTURERS AND WHOLESALERS ONLY**



**DEPARTMENT OF HEALTH**  
DIRECTORATE: AFFORDABLE MEDICINES  
C/o STRUBEN AND THABO SEHUME STREETS, PRETORIA, 0002  
PRIVATE BAG X828, PRETORIA, 0001  
TEL: 27 (012) 395-8204/8202, FAX: 27(86) 621-0820  
EMAIL: [pharmapps@health.gov.za](mailto:pharmapps@health.gov.za)

**AFFIDAVIT BY AN OWNER(S) OF A WHOLESALE/MANUFACTURING PHARMACY REGARDING ELIGIBILITY, OWNERSHIP AND COMPLIANCE WITH STANDARDS AS REQUIRED IN TERMS OF REGULATION 7(1) OF PHARMACIES ACT 53 OF 1974**

I, ..... (as a nominee),  
ID Number..... do hereby make an oath and declare that:

The undersigned directors of .....  
undertake to comply with and abide by the standards required in terms of Regulation 7(1) of the Regulations on Ownership and Licensing of Pharmacies in terms of Act 53 of 1974.

**NAMES:**

- 1. \_\_\_\_\_
- 2. \_\_\_\_\_
- 3. \_\_\_\_\_
- 4. \_\_\_\_\_
- 5. \_\_\_\_\_
- 6. \_\_\_\_\_

**TO BE COMPLETED BY A COMMISSIONER OF OATHS**

SIGNED AND SWORN TO before me .....

On this ..... day of ..... in the year .....

The deponent having acknowledged that he/she knows and understands the contents of this declaration.

.....  
**SIGNATURE OF COMMISSIONER OF OATHS**

**STAMP**

(Full name, capacity, address and contact details of Commissioner of Oaths)

**AFFIDAVIT FOR GOVERNMENT PHARMACIES ONLY**



**DEPARTMENT OF HEALTH**  
DIRECTORATE: AFFORDABLE MEDICINES  
C/o STRUBEN AND THABO SEHUME STREETS, PRETORIA, 0002  
PRIVATE BAG X828, PRETORIA, 0001  
TEL: 27 (012) 395-8204/8202, FAX: 27 (86) 621-0820  
EMAIL: [pharmapps@health.gov.za](mailto:pharmapps@health.gov.za)

**AFFIDAVIT BY THE RESPONSIBLE PHARMACIST / MANAGER OF AN INSTITUTIONAL PHARMACY – ON BEHALF OF THE OWNER - REGARDING ELIGIBILITY, OWNERSHIP AND COMPLIANCE WITH STANDARDS AS REQUIRED IN TERMS OF REGULATION 7(1) OF PHARMACY, 1974 (ACT 53 OF 1974)**

I, ..... (Responsible Pharmacist),

ID Number....., do hereby make an oath and declare that:

The Department of Health ..... (province) undertakes to comply and abide with the standards required in terms of Regulation 7(1) of the Regulations on Ownership and Licensing of Pharmacies in terms of Act 53 of 1974.

**TO BE COMPLETED BY A COMMISSIONER OF OATHS**

SIGNED AND SWORN TO before me .....

On this ..... day of ..... in the year .....

The deponent having acknowledged that he/she knows and understands the contents of this declaration.

.....  
**SIGNATURE OF COMMISSIONER OF OATHS**

**STAMP**  
  
**(Full name, capacity, address and contact details of Commissioner of Oaths)**