



health

Department:  
Health  
REPUBLIC OF SOUTH AFRICA

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

**LU-PL1.0, Rev 0**

### **AFFORDABLE MEDICINES: Licensing Unit**

AB Xuma Building, 112 Voortrekker Road, Pretoria Townlands 351-Jr, Pretoria, 0187

Contacts Us: 012 395 8500

Email: [pharmapps@health.gov.za](mailto:pharmapps@health.gov.za)

Effective: 01 Jan 2022

### I: GENERAL INFORMATION

- **FIRST TIME APPLICANTS** – **APPLY ONLINE** on the website of the South African Pharmacy Council ([www.sapc.za.org](http://www.sapc.za.org) – *Members of the Public tab – Apply for a Pharmacy Licence*). **NO PHYSICAL APPLICATIONS** will be required to be submitted. All supporting documents and the physical application **must** be uploaded on the website.
  - **APPLICANTS APPLYING FOR A SECOND OR MORE TIME:** LOGIN into your online owner profile and submit an application. **NO PHYSICAL APPLICATIONS** will be required to be submitted. All supporting documents and the physical application **must** be uploaded on the website.
  - 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. Applicants are advised to familiarise themselves with the Criteria for Licensing as published on the Department of Health website.
  - Categories of pharmacies that may be licensed are:
    - Community
    - Institutional – private and state owned
    - Consultant
    - Manufacturing
    - Wholesale
- NOTE: For Manufacturing and Wholesale Licences** – a separate application, in terms of Section 22C of the Medicines and Related Substances Act 101 of 1965, must be made to the South African Health Products Regulatory Authority (see [www.sahpra.com](http://www.sahpra.com)). Your licence application will only be finalised once you send the Department a copy of the licence issued to you by SAHPRA.
- 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)
    - **PL05** – Affidavit confirming change of ownership by previous licence holders
  - The **non-refundable application fee** for Pharmacy Premises Licence is R1,000 (published in Government Gazette 25056, Notice 760), 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 Trading Title (Name) / Y-Number



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## II: THE LICENSING PROCESS

- Applicants are required to apply online on the website [www.sapc.za.org](http://www.sapc.za.org) (go to the “Members of the public tab”, Select “Apply for pharmacy licence”)
- **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);
- The application will be reviewed by the Department for the need to establish a pharmacy, and by the South African Pharmacy Council for compliance to Good Pharmacy Practice (GPP) requirements.
- The premises in respect of an application to licence a new community pharmacy premises, or the relocation of an existing community pharmacy may be subjected to a site inspection by the Department;
- The application will be reviewed by a Committee - taking into account all the information provided in the application, the inspection report by the Department, the Criteria for Licensing and the GPP recommendation of Council. The Committee recommendation will be submitted to the Director-General or delegated senior official of the Department for final decision. **Applicants are required to familiarise themselves with the Criteria for Licensing published on the Department of Health website ([www.health.gov.za](http://www.health.gov.za));**
- Further information may be required from the applicant in respect of their application;
- 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;
- The applicant will be informed collect the original document stating the outcome of their application or to send a courier (at own cost) to collect it;
- The licensing process takes approximately **90 days** from receipt of ALL required documents (including the GPP recommendation from the SAPC and GMP/GWP licence from SAHPRA) to finalise.  
**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 (whether intentional or unintentional) forms ground for declining or subsequent withdrawal and cancellation of a licence**

### **LEGISLATIVE CONSIDERATIONS:**

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.**
- 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 of Health and the South African Pharmacy Council; and return the original licence to the Department.

**The Checklists below may be used to ensure that all documents required for the online application are ready before applications are submitted.**



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### III: CHECKLISTS

**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.

#### A: CHECKLIST FOR NEW PHARMACY APPLICATION

i. PL01: Form Completed in Full		Y	N	N/A
A	Completed in full ( <b>Alternative trading title compulsory for new pharmacy</b> )			
B	The category of pharmacy is indicated on the form			
C	The classification of the application is marked ( <b>Note – only one may be selected</b> )			
D	Not applicable for new pharmacy licence applications			X
E or F	Relevant section completed to confirm owner of pharmacy (i.e. Sole Trader, Partnership or Company)			
G	Details of person responsible for the application completed in full			
H	Services and activities completed in full ( <b>Not applicable to institutional pharmacies</b> )			
I & J	Statutory declaration completed, signed and commissioned			
ii. PL02: Responsible Pharmacist Sections Completed in Full		Y	N	N/A
A	Details of pharmacist appointed as Responsible Pharmacist (RP) completed in full			
B	Details of person authorised to appoint RP completed in full			
C	Declaration completed and signed by both RP and authorised person			
iii. PL03: Premises Information Completed in Full		Y	N	N/A
	The name of the pharmacy premises indicated			
	The square meters of the pharmacy premises indicated			
	The Good Pharmacy Practice checklist for the premises is completed in full			
	The PL03 is signed			
iv. PL04: Affidavit By Owner Completed in Full		Y	N	N/A
	The PL04 is completed and signed by the owner / delegated person			
Attachments for New Pharmacy Premises Application		Y	N	N/A
	Certified copy of <b>signed</b> lease agreement/intent to lease of the pharmacy premises <b>or</b> proof of ownership of premises where premises are owned by applicant			
	Proof of payment of non-refunded application fee of R1,000-00			
	Certified copy of registration documents of Company as issued by the Company and Intellectual Property Commission (CIPC) (for company owners only)			
	Certified copy of Identity Documents (ID) of all directors appearing on CIPC registration document			
	Certified copy of ID(s) of Sole Traders (where applicable)			
	Certified copy of Identity Document of Responsible Pharmacist (RP)			
	Certified copy of registration card of RP South African Pharmacy Council			
	Duly signed resolution/mandate where person responsible for application is not owner			
	Letter of appointment of RP signed by owner or delegated person			
	Letter of acceptance signed by Responsible Pharmacist			
	Professionally drawn site plans, indicating the location of the pharmacy			
	Professionally drawn ( <b>to scale</b> ) floor plans of the pharmacy* <i>*Refer to Good Pharmacy Practice Requirements, Fourth Edition, 2010</i>			
	<b>Institutional Pharmacies ONLY</b> - Copy of hospital licence issued by the relevant Provincial Department of Health (if already issued) or proof of application for a hospital licence			
Manufacturing and Wholesale Pharmacy Licence Applications ONLY – in addition to the above		Y	N	N/A
	Copy of Site Master File			
	Copy of licence issued in terms of Section 22C of the Medicines and Related Substances Act 101 of 1965, as issued by South African Health Products Regulatory Authority (where already available)			



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<b>A: CHECKLIST FOR CHANGE IN OWNERSHIP OR CHANGE IN OWNERSHIP AND TRADING TITLE</b>				
<b>i. PL01: Form Completed in Full</b>		<b>Y</b>	<b>N</b>	<b>N/A</b>
<b>A</b>	Completed in full ( <b>Note:</b> Alternative Title not applicable for Change in ownership only)			
<b>B</b>	The category of pharmacy is indicated on the form			
<b>C</b>	The classification of the application is marked ( <b>Note – only one may be selected</b> )			
<b>D</b>	Details pertaining to the existing pharmacy are completed in full			
<b>E or F</b>	Relevant section completed to confirm new/prospective owner of pharmacy (i.e. Sole Trader or Partnership or Company)			
<b>G</b>	Details of person responsible for the application completed in full			
<b>H</b>	Services and activities completed in full ( <b>Not applicable to institutional pharmacies</b> )			
<b>I &amp; J</b>	Statutory declaration completed, signed and commissioned			
<b>ii. PL02: Responsible Pharmacist Sections Completed in Full</b>		<b>Y</b>	<b>N</b>	<b>N/A</b>
<b>A</b>	Details of pharmacist appointed as Responsible Pharmacist (RP) completed in full			
<b>B</b>	Details of person authorised to appoint RP completed in full			
<b>C</b>	Declaration completed and signed by both RP and authorised person			
<b>iii. PL03: Premises Information Completed in Full</b>		<b>Y</b>	<b>N</b>	<b>N/A</b>
	The name of the pharmacy premises indicated			
	The square meters of the pharmacy premises indicated			
	The Good Pharmacy Practice checklist for the premises is completed in full			
	The PL03 is signed			
<b>iv. PL04: Affidavit By Owner Completed in Full</b>		<b>Y</b>	<b>N</b>	<b>N/A</b>
	The PL04 is completed and signed by the owner / delegated person			
<b>v. PL05: Affidavit By Owner Completed in Full</b>		<b>Y</b>	<b>N</b>	<b>N/A</b>
	The PL05 is completed in full by previous owner and commissioned			
<b>Attachments for Change in Ownership or Change in Ownership and Trading Title</b>		<b>Y</b>	<b>N</b>	<b>N/A</b>
	Covering letter indicating the details and reasons for the change in ownership of the pharmacy			
	Certified copy of <b>signed</b> lease agreement/intent to lease of the pharmacy premises <b>or</b> proof of ownership of premises where premises are owned by applicant <b>with prospective owner details</b>			
	Proof of payment of non-refunded application fee of R1,000-00			
	Certified copy of registration documents of Company as issued by the Company and Intellectual Property Commission (CIPC) of the <b>current owner</b> (where applicable)			
	Certified copy of registration documents of Company as issued by CIPC of the <b>prospective new owner</b> (where applicable)			
	Certified copy of Identity Documents (ID) of all Directors appearing on CIPC registration document or Sole Trader or Partners of <b>current owner</b>			
	Certified copy of Identity Documents (ID) of all Directors appearing on CIPC registration document or Sole Trader or Partners of <b>prospective new owner</b>			
	Certified copy of ID of Responsible Pharmacist (RP)			
	Certified copy of registration card of RP South African Pharmacy Council (SAPC)			
	Letter of appointment of RP signed by owner or delegated person			
	Letter of acceptance signed by Responsible Pharmacist			
	Certified copy of Department of Health Premises Licence ( <b>Not applicable to pharmacies established Pre-May 2003</b> )			
	Proof of current registration/recording of the pharmacy with SAPC			
	Professionally drawn site plans, indicating the location of the pharmacy			
	Professionally drawn ( <b>to scale</b> ) floor plans of the pharmacy* <i>*Refer to Good Pharmacy Practice Requirements, Fourth Edition, 2010</i>			
	Duly signed resolution/mandate for person responsible for application ( <b>Note:</b> Required for partnerships, more than 1 director in a Company or if the elected person is not the owner)			
	<b>Institutional Pharmacies ONLY</b> - Copy of hospital licence issued by the relevant Provincial Department of Health (if already issued) or proof of application for a hospital licence			
<b>Manufacturing and Wholesale Pharmacy Licence Applications ONLY – in addition to the above</b>		<b>Y</b>	<b>N</b>	<b>N/A</b>
	Copy of Site Master File			
	Copy of licence issued in terms of Section 22C of the Medicines and Related Substances Act 101 of 1965, as issued by South African Health Products Regulatory Authority (where already available)			



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### **A: CHECKLIST FOR RELOCATON ONLY OR RELOCATION AND CHANGE IN TRADING TITLE**

<b>i. PL01: Form Completed in Full</b>		<b>Y</b>	<b>N</b>	<b>N/A</b>
<b>A</b>	Completed in full ( <b>Note:</b> Alternative Title not applicable for Relocation only applications)			
<b>B</b>	The category of pharmacy is indicated on the form			
<b>C</b>	The classification of the application is marked ( <b>Note – only one may be selected</b> )			
<b>D</b>	Details pertaining to the existing pharmacy are completed in full			
<b>E or F</b>	Relevant section completed to confirm new/prospective owner of pharmacy (i.e. Sole Trader or Partnership or Company)			
<b>G</b>	Details of person responsible for the application completed in full			
<b>H</b>	Services and activities completed in full ( <b>Not applicable to institutional pharmacies</b> )			
<b>I &amp; J</b>	Statutory declaration completed, signed and commissioned			
<b>ii. PL02: Responsible Pharmacist Sections Completed in Full</b>		<b>Y</b>	<b>N</b>	<b>N/A</b>
<b>A</b>	Details of pharmacist appointed as Responsible Pharmacist (RP) completed in full			
<b>B</b>	Details of person authorised to appoint RP completed in full			
<b>C</b>	Declaration completed and signed by both RP and authorised person			
<b>iii. PL03: Premises Information Completed in Full</b>		<b>Y</b>	<b>N</b>	<b>N/A</b>
	The name of the pharmacy premises indicated			
	The square meters of the pharmacy premises indicated			
	The Good Pharmacy Practice checklist for the premises is completed in full			
	The PL03 is signed			
<b>iv. PL04: Affidavit By Owner Completed in Full</b>		<b>Y</b>	<b>N</b>	<b>N/A</b>
	The PL04 is completed and signed by the owner / delegated person			
<b>Attachments for Relocations only or Relocations and Change in Trading Title</b>		<b>Y</b>	<b>N</b>	<b>N/A</b>
	Covering letter indicating the details of the relocation and reasons for relocation of the pharmacy			
	Certified copy of <b>signed</b> lease agreement/intent to lease of the pharmacy premises <b>or</b> proof of ownership of premises where premises are owned by applicant			
	Proof of payment of non-refunded application fee of R1,000-00			
	Certified copy of registration documents of Company as issued by the Company and Intellectual Property Commission (CIPC) of the owner (where applicable)			
	Certified copy of Identity Document(s) (ID) of all Directors appearing on CIPC registration document or Sole Trader or Partners of owner			
	Certified copy of ID of Responsible Pharmacist (RP)			
	Certified copy of registration card of RP South African Pharmacy Council (SAPC)			
	Letter of appointment of RP signed by owner or delegated person			
	Letter of acceptance signed by Responsible Pharmacist			
	Certified copy of Department of Health Premises Licence ( <b>Not applicable to pharmacies established Pre-May 2003</b> )			
	Proof of current registration/recording of the pharmacy with SAPC			
	Professionally drawn site plans, indicating the location of the pharmacy			
	Professionally drawn ( <b>to scale</b> ) floor plans of the pharmacy*			
	<i>*Refer to Good Pharmacy Practice Requirements, Fourth Edition, 2010</i>			
	Duly signed resolution/mandate for person responsible for application ( <b>Note:</b> Required for partnerships, more than 1 director in a Company or if the elected person is not the owner)			
	<b>Institutional Pharmacies ONLY</b> - Copy of hospital licence issued by the relevant Provincial Department of Health (if already issued) or proof of application for a hospital licence			
<b>Manufacturing and Wholesale Pharmacy Licence Applications ONLY – in addition to the above</b>		<b>Y</b>	<b>N</b>	<b>N/A</b>
	Copy of Site Master File			
	Copy of licence issued in terms of Section 22C of the Medicines and Related Substances Act 101 of 1965, as issued by South African Health Products Regulatory Authority (where already available)			

