



health

Department:
Health
REPUBLIC OF SOUTH AFRICA

APPLICATION FOR A LICENCE TO DISPENSE OR A LICENCE TO COMPOUND AND DISPENSE (HOMEOPATHS) ISSUED IN TERMS OF SECTION 22C(1)(a) OF THE MEDICINES AND RELATED SUBSTANCES ACT 101 OF 1965

AFFORDABLE MEDICINES: LICENSING UNIT

Civitas Building, Cnr Struben & Thabo Sehume Streets, Pretoria, 0001
Email: dispensepps@health.gov.za

LU-FORM-D1.0

Effective Date: 01 November 2019

I: GENERAL INFORMATION

1. Dispensing Licence applications are made to the Director-General: Health, in terms of Section 22C(1)(a) of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), as amended.
2. The Medicines and Related Substances Act, 1965 states,
*“(1) Subject to the provisions of this section-
(a) the Director-General may on application in the prescribed manner and on payment of the prescribed fee issue to a medical practitioner, dentist, practitioner, nurse or other person registered under the Health Professions Act, 1974, a licence to compound and dispense medicines, on the prescribed conditions.”.*
3. Dispensing licences are only issued to nurses in line with Section 56(6) of the Nursing Act, 2005 (Act No. 33 of 2005).
4. All applications must be completed in full, using black ink. Fields marked with * are compulsory. **Incomplete applications will not be processed.**
5. Only **original** applications must be submitted to the Department. Applications may be posted, couriered or hand delivered. **NO FAXED OR EMAILED COPIES WILL BE ACCEPTED.**
6. Before submitting the application form, have the following documents on hand:
 - a. Certified copy of Identity Document
 - b. Certified copy of your registration card with Statutory Council
 - c. Certified copy of certificate of completion of the Dispensing Course with a provider accredited by the South African Pharmacy Council (SAPC)
 - d. Proof of payment of the non-refundable application fee and annual fee
 - e. Nurses only:
 - i. Completed and signed Section H of application form
 - ii. Confirmation of employment on company letter head and signed by an authorised manager
 - iii. Proof of areas of specialisation and protocol competencies (certified)
7. **NOTE:** Applications are processed within 90 days of receipt of all required documents. Applicants will be advised on the collection of the written outcome on applications.



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II: COMPLETING THE APPLICATION FORM

SECTION A to C:

- Complete General Information, Residential Address & Business Address.
- Ensure that you include the Province at which the Dispensing Licence will be utilised.

SECTION D:

- Indicate profession as well as qualification obtained.
- Ensure that the Statutory Council and Registration Number are supplied for each qualification listed.

SECTION E

- This information refers to the requirements to comply with Good Pharmacy Practice Requirements. This is to ensure that the norms and standards as required by the South African Pharmacy Council are complied to. It is mandatory to answer all the questions.

SECTION F:

- This section indicates documentation that must be submitted together with the application form for the dispensing licence.

SECTION G:

- This section is a declaration by the applicant that the information furnished to the Department is true and correct. It also ensures that the applicant is aware that inspections may be done by the Department on the premises, and gives consent to these.

SECTION H (Nurses ONLY):

- This section must be completed by nurses only. It covers authorisation in terms of Section 56(6) of the Nursing Act, 2005 (Act 33 of 2005).
- This section must be accompanied by the required documents.

SECTION I & J:

- Section I is a declaration by the applicant that the information furnished to the Department is true and correct. It also ensures that the applicant is aware that inspections may be done by the Department on the premises, and gives consent to these. This section must be signed in front of the Commissioner of Oaths, who will then proceed to complete section J.



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III: APPLICATION & ANNUAL FEES PAYABLE

- A non-refundable application fee of R1000-00 (as published in the Government Gazette is payable once off on application. **No Cheque payments are accepted.**
- An annual fee of R200-00 per year must be paid on application, and is payable yearly after that on or before 28 February.
- Proof of payment of both amounts must be submitted to together with your application form.
- Your Statutory Council Number (without the Prefix Letters) must be used as the reference when making payments to the Department.
- **Note: Where the Statutory Council Number is less than 8 (eight) numbers – please add zero’s at the end to make up 8 (eight) numbers.**
- Payments to the National Department of Health are payable to the following account:

Banking details:

| | | |
|------------------|---|--|
| Bank | : | ABSA |
| Account Holder | : | National Department of Health |
| Branch | : | Vermeulen Street |
| Branch code | : | 632005 |
| Account No. | : | 405 364 3510 |
| Account type | : | Cheque account |
| Beneficiary Ref. | : | Statutory Council Registration Number ONLY |

IV: DELIVERY ADDRESS

| POSTAL ADDRESS | COURIER/HAND DELIVERY |
|--|--|
| National Department of Health Affordable Medicines: Licensing Unit C/O South African Pharmacy Council 591 Belvedere Street Arcadia Pretoria 0001 | National Department of Health Affordable Medicines: Licensing Unit C/O South African Pharmacy Council 591 Belvedere Street Arcadia Pretoria 0001 |

V: ENQUIRIES

| | | |
|-------------------|---|---------------------------|
| Email (preferred) | : | dispensepps@health.gov.za |
| Telephone | : | 012 395 8314/8315 |
| Facsimile | : | 086 621 0829 |



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REPUBLIC OF SOUTH AFRICA

**DEPARTMENT OF HEALTH
DIRECTORATE: AFFORDABLE MEDICINES - LICENSING UNIT**

**Civitas Building, Cnr Struben & Thabo Sehume Streets, Pretoria, 0001
EMAIL: dispensepps@health.gov.za
TELEPHONE : 012-395-8314/8315**

LU-FORM-D1.0

**APPLICATION FOR A LICENCE TO COMPOUND OR DISPENSE MEDICINES IN TERMS OF
SECTION 22C (1) (a) OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965),
AS AMENDED**

SECTION A: GENERAL INFORMATION

| | | | | | | | | | | | | | | | | | | | | |
|----------------------------------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| 1. Title* | | | | | | | | | | | | | | | | | | | | |
| 2. Surname of Applicant* | | | | | | | | | | | | | | | | | | | | |
| 3. Full names of Applicant* | | | | | | | | | | | | | | | | | | | | |
| 4. Identity Number of Applicant* | | | | | | | | | | | | | | | | | | | | |

SECTION B: RESIDENTIAL ADDRESS

| | | | | | | | | | | | | | | | | | | | | | |
|---------------------------------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| 1. Street Address of Applicant* | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | |
| Code | | | | | | | | | | | | | | | | | | | | | |
| 2. Postal Address of Applicant* | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | |
| Postal Code* | | | | | | | | | | | | | | | | | | | | | |

SECTION C: BUSINESS ADDRESS (where dispensing will take place)

| | | | | | | | | | | | | | | | | | | | | | | | |
|--------------------------------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|---|--|--|--|---|--|--|--|
| 1. Street Address of Premises* | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | |
| Code | | | | | | | | | | | | | | | | | | | | | | | |
| 2. Postal Address of Premises* | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | |
| Postal Code* | | | | | | | | | | | | | | | | | | | | | | | |
| Home Telephone Number | | | | | | | | | | | | | | | | - | | | | - | | | |
| Business Phone Number* | | | | | | | | | | | | | | | | - | | | | - | | | |
| Fax Number of Applicant | | | | | | | | | | | | | | | | - | | | | - | | | |
| Cell Number of Applicant* | | | | | | | | | | | | | | | | - | | | | - | | | |
| E-mail address | | | | | | | | | | | | | | | | | | | | | | | |

SECTION D: QUALIFICATIONS

| | |
|--|--|
| Profession (specify)* | |
| Qualification* | |
| Name of Statutory Council* | |
| Statutory Council Registration Number* | |
| Qualification | |
| Name of Statutory Council | |
| Statutory Council Registration Number | |
| Qualification | |
| Name of Statutory Council | |
| Statutory Council Registration Number | |

SECTION E: DISPENSING COURSE

| | |
|-----------------------------------|--|
| Name of SAPC Accredited Provider* | |
| Name of Course Completed* | |
| Date of Completion* | |

APPLICATION FORM FOR A LICENCE TO COMPOUND OR DISPENSE IN TERMS OF SECTION 22C(1)(a)
OF ACT 101 OF 1965 - AUTHORISED PRESCRIBERS

| *SECTION F: PARTICULARS OF THE PREMISES | | |
|---|-----|----------------|
| I, _____, as the applicant, declare that: | | |
| 1. The size of the premises is | | m ² |
| 2. Key, key card or other device or the combination of any device, which allows access to the dispensary is kept on the person of the authorized prescriber . | Yes | No |
| 3. Only the authorized prescriber has keys to the pharmacy area where schedule 1 – 6 items are kept. | Yes | No |
| 4. There is sufficient security to prevent unauthorised access to medicines. | Yes | No |
| 5. The pharmacy will be suitably located in the consulting rooms. | Yes | No |
| 6. The dispensary is suitably located in the pharmacy. | Yes | No |
| 7. The pharmacy is accessible to persons with disabilities. | Yes | No |
| 8. There is/ will be a separate facility for washing hands | Yes | No |
| 9. There is/ will be a separate facility for cleaning of equipment | Yes | No |
| 10. The premises will be kept clean, orderly and tidy. | Yes | No |
| 11. The floor surface will be of impermeable material. | Yes | No |
| 12. All working surfaces will be finished with a smooth impermeable and washable material | Yes | No |
| 13. All countertops and shelves will be finished with a smooth, impermeable and washable material which is easy to keep clean | Yes | No |
| 14. Walls are finished with a smooth, impermeable and washable material, which is easy to keep clean | Yes | No |
| 15. There will be sufficient and adequate lighting. | Yes | No |
| 16. There is an air conditioner in the pharmacy which is in good working condition. | Yes | No |
| 17. The temperature in the dispensary will be below 25 °C. | Yes | No |
| 18. There is at least one fire extinguisher or fire hose in the pharmacy. | Yes | No |
| 19. There will be a suitable waiting area, in accordance with Good Pharmacy Practice (GPP) guidelines | Yes | No |
| 20. There is a suitable private area for the provision of information and advice, in accordance with GPP standards. | Yes | No |
| 21. There is a suitable area for the screening and performing of tests. | Yes | No |
| 22. The professional image of the dispensing area is not affected by the display of commercial material not directly linked with health. | Yes | No |
| 23. The pharmacy is designated as a non-smoking area. | Yes | No |
| 24. The receiving area for deliveries will be clearly defined and separated from the rest of the pharmacy | Yes | No |
| 25. A fridge for heat sensitive pharmaceuticals and vaccines will be available. | Yes | No |
| 26. A nurse prescriber - only patient ready packs or original packings | Yes | No |
| 27. No bulk stock is kept on premises | Yes | No |

| | | | | | | | | | |
|---|--------------------------|--------------|--|--|--|--|--|--|--|
| SECTION G: SUPPORTING DOCUMENTATION* | | | | | | | | | |
| 1. Certified copy of Certificate of successful completion of a course in dispensing, or compounding and dispensing. | <input type="checkbox"/> | | | | | | | | |
| 2. Certified copy of Proof of current registration with the Statutory Council | <input type="checkbox"/> | | | | | | | | |
| 3. Certified copy of Identity Document | <input type="checkbox"/> | | | | | | | | |
| 4. Proof of payment of application and/or annual fees. | <input type="checkbox"/> | | | | | | | | |
| SECTION H: FOR NURSES ONLY (see page 4)* | | | | | | | | | |
| 1. Section 56(6) authorisation signed by authorising doctor* | <input type="checkbox"/> | | | | | | | | |
| 2. Proof of Areas of Specialisation and Protocol Competencies (certified)* | <input type="checkbox"/> | | | | | | | | |
| 3. Confirmation of employment on company letter head and signed by authorised manager* | <input type="checkbox"/> | | | | | | | | |
| SECTION I: DECLARATION BY THE APPLICANT* | | | | | | | | | |
| <p>1. I hereby give consent for an inspection of the premises in terms of the applicable legislation.</p> <p>2. The information furnished herewith is true and correct.</p> <p>APPLICANT'S SIGNATURE:</p> <p>DATE: <table border="1" style="display: inline-table; border-collapse: collapse;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table> - <table border="1" style="display: inline-table; border-collapse: collapse;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table> - <table border="1" style="display: inline-table; border-collapse: collapse;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table></p> <p style="text-align: center; margin-left: 100px;"> D D M M Y Y Y Y </p> | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| SECTION J: DECLARATION BY COMMISSIONER OF OATHS* | | | | | | | | | |
| <p>SIGNED and SWORN TO before me on this ----- day of ----- in the year -----</p> <p>The deponent (applicant) having acknowledged that he/she understands the contents of this declaration.</p> <p>SIGNATURE OF COMMISSIONER OF OATHS</p> <p>.....</p> <p>DATE:</p> <div style="text-align: center; margin-top: 20px;"> <table border="1" style="margin: auto; border-collapse: collapse;"> <tr> <td style="padding: 5px;">STAMP</td> </tr> <tr> <td style="height: 100px;"></td> </tr> </table> </div> | | STAMP | | | | | | | |
| STAMP | | | | | | | | | |
| | | | | | | | | | |
| <p>This form may be completed and submitted to the Director-General ONLY IF the applicant has completed the supplementary course on dispensing and/or compounding.</p> | | | | | | | | | |



DEPARTMENT OF HEALTH
DIRECTORATE: AFFORDABLE MEDICINES

PRIVATE BAG X828, PRETORIA 0001

EMAIL: dispensepps@health.gov.za

TELEPHONE : 012-395-8314/8315

FACSIMILE : 0866 210 829

SECTION H: AUTHORITY UNDER SECTION 56(6) OF THE NURSING ACT, 2005 (ACT 33 OF 2005)

1. Name of Nurse

2. Name of Clinic/Facility

You are hereby authorised to diagnose prescribe and dispense medicines for the conditions listed in the standing orders of the clinic according to the treatment protocols listed in the standing orders of the clinic according to the treatment protocols listed below subject to the limitations imposed by the Regulations to Section 38A of the Nursing Act.

You are to maintain legible, comprehensive clinical notes in the patient file and to complete the drug register required under the licence issued in terms of section 22C (1) (a) of the Medicines and Related Substances Act (Act 101 of 1965) as amended.

Name of Medical Practitioner in charge:

Signed at on day of 20.....

Signature: Qualification(s):

HPCSA No:

Address:

.....

.....

Tel: (.....)

Note: Attach confirmation of employment on company letter head, signed by the authorised manager.

| Area of Specialisation (Attach proof of completion) | Mark with X | Proof Attached (state YES or NO) |
|--|----------------|--|
| Primary Health Care | | |
| Occupational Health | | |
| Other(specify) | | |
| Protocol Competencies | Mark with X | Proof Attached (state YES or NO) |
| STI | | |
| EPI | | |
| TB | | |
| Diabetes | | |
| Hypertension | | |
| Travel Medicines | | |
| Other(specify) | | |
| Other(specify) | | |