# health Department: Health REPUBLIC OF SOUTH AFRICA

# DEPARTMENT OF HEALTH

#### AFFORDABLE MEDICINES: LICENSING UNIT

Dr AB Xuma Building, 1112 Voortrekker Rd, Pretoria Townlands 351-JR, PRETORIA, 0187 Email: dispensepps@health.gov.za

# Guideline for the completion of the Application Form for:

- A Licence to Dispense Medicines (Authorised Prescribers)
- A Licence to Compound & Dispense Medicines Homeopaths
- A Licence to Compound & Dispense Medicines Traditional Chinese Medicine Practitioners

LU-FORM-D1.1 Effective Date: 01 February 2022

# I: GENERAL INFORMATION

- 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. Applications may be emailed to dispensepps@health.gov.za.
- 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 from the National Department of Health offices.



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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 guestions.

#### **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

# V: ENQUIRIES

Email (preferred) : dispensepps@health.gov.za

Telephone : 012 395 8314/8315 Facsimile : 086 621 0829



**DIRECTORATE: AFFORDABLE MEDICINES** 

Dr AB Xuma Building, 1112 Voortrekker Road, Pretoria Townlands 351-Jr, Pretoria, 0187

**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

Health Professional Mark with X	Medical Practition	er Ho	Homeopath			Traditional Chinese Medicine Practitoner			Professional Nurse								
SECTION A: GENE	RAL INFORM	IATIO	N														
1. Title*																	
2. Surname of Applicant*																	
3. Full names of Applicant <sup>8</sup>	•																
4. Identity Number of Appl	icant*																
SECTION B: RESID	ENTIAL ADD	RESS															
1. Street Address of Applica	ant*																
	Code																
2 Dootel Address of Amelia	a4.*																
2. Postal Address of Applic	ant*																
	Postal Code*																
SECTION C: BUSIN	ESS ADDRES	S (who	ere d	ispe	nsin	g wi	ll tal	ke pl	ace)								
1. Street Address of Premis	ses*																
	Code									Prov	ince*			<u> </u>			
0 D . 1 4 11 CD	ale.																
2. Postal Address of Premis	es*																
Postal Code* Home Teleph						mber				-			-				
Business Phone										-			-				
	ber of	f App	licant				-			-							
Cell Number of A										-			-				
	E-mail addre	ess															
SECTION D: QUAL	IFICATIONS																
Profession (specify)*																	
Qualification*																	
Name of Statutory Coun	cil*																
Statutory Council Regist																	
Qualification					•				•								
Name of Statutory Coun-																	
Statutory Council Regist																	
SECTION E: DISPE	NSING COUR	SE						•									ļ
Name of SAPC Accredited Provider*																	
Name of Course Completed*																	
Date of Completion*																	

*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 $^{0}$ 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.								
2. Certified copy of Proof of current registration with the Statutory Council								
3. Certified copy of Identity Document								
4. Proof of payment of application and/or annual fees.								
SECTION H: FOR NURSES ONLY (see page 4)*								
1. Section 56(6) authorisation signed by authorising doctor*								
2. Proof of Areas of Specialisation and Protocol Competencies (certified)*								
3. Confirmation of employment on company letter head and signed by authorised manager*								
SECTION I: DECLARATION BY THE APPLICANT*								
1. I hereby give consent for an inspection of the premises in terms of the applicable legislation.  2. The information furnished herewith is true and correct.  APPLICANT'S SIGNATURE:  DATE:  DATE:								
DATE:								
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.								

Review date: 19/06/2014



DIRECTORATE: AFFORDABLE MEDICINES

DEPART Sapa.	MENT OF HEALTH Mic of South Africa	EMAIL: dispe	ensepps@	health.gov.z		FACSIMILE : 0866 210 829
SECTI	ON H: AU	THORITY UNI	DER SECT	FION 56(6)	OF THE NURS	ING ACT, 2005 (ACT 33 OF 2005)
1. Nan	ne of Nurs	Э				
2. Nan	ne of Clinic	:/Facility				
the sta clinic a Regula You ar registe Substa	anding order according to ations to Some the to maintain ar required ances Act	ers of the clinic the treatmer ection 38A of ain legible, co- under the lice (Act 101 of 19	c accordii nt protocc the Nursi mprehens nce issue 65) as an	ng to the tro ls listed be ng Act. sive clinical ed in terms nended.	eatment protocolors subject to I notes in the pof section 220	nedicines for the conditions listed in cols listed in the standing orders of the the limitations imposed by the catient file and to complete the drug C (1) (a) of the Medicines and Related
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Addre	ss:  ()			 oyment on		ter head, <u>signed</u> by the authorised
		of Specialisa proof of com		Mark with X	Proof Attached (state YES or NO)	
	Primary He	alth Care				
	Occupation	nal Health				
	Other(specif	col Compete	ncies	Mark with	Proof Attached (state YES or NO)	
	STI				(	
	EPI					
	TB					
	Diabetes					
	Hypertensi	on				
	Travel Med					
	Other(specit					
	Other(specit					

Review date:19/06/2014