



## ISSUING OF SECTION 22A(15) PERMITS

**THE 22A (15) PERMIT IS FOR THE PURPOSES OF ACQUISITION, POSSESSION, USE AND SUPPLY AS OPPOSED TO DISPENSE:**

### **LICENCING UNIT**

Contact Phone numbers: 012 395 8213/4 and 8314

### **Background:**

Certain nurses have traditionally enjoyed concessions in terms of section 22A(15) of the Medicines and Related Substances Act No 101 of 1965. A permit in terms of Section 22A(15) may also be issued to the following categories of health workers:

#### ➤ **Category:**

- Nurses - Well-Baby Clinics
  - Hospices
  - Schools, Boarding Schools, Special Schools
- Optometrists
- Ambulance assistants
- Dialysis units

➤ **Guidelines** for the completion of the application form for a permit in terms of section 22a(15) of the Medicines And Related Substances Control Act, 1965 (Act 101 [ f 1965) as amended – Nurses, Optometrist, Paramedic, Midwife & Dialysis Unit

#### ➤ **Additional Information:**

- Licencing Process
- Legislative Requirement
- Additional Information Required

#### ➤ **Application forms**

- Permit Section 22(A)15
- Midwife



**GUIDELINES FOR THE COMPLETION OF THE APPLICATION FORM FOR A PERMIT IN TERMS OF SECTION 22A(15) OF THE MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 1965 (ACT 101 OF 1965) AS AMENDED – NURSES, OPTOMETRIST, PARAMEDIC, MIDWIFE & DIALYSIS UNIT**

**PLEASE NOTE ALL APPLICATIONS MUST BE POSTED, COURIED OR HAND DELIVERED TO THE DEPARTMENT. NO FAXED COPIES WILL BE ACCEPTED.**

**SECTION A:**

- In this section general information such as Title, Name and Surname of the applicant must be supplied

**SECTION B:**

- Supply information indicating the residential street Address and Postal Address of the applicant

**SECTION C:**

- Supply information indicating the Business address of the premises, postal address etc

**SECTION D:**

- In this section the applicant must indicate his/her qualifications as well as the applicable Statutory Council and Registration Number.

**SECTION E:**

- In this section the applicant must indicate what type of services will be rendered, etc
- This information refers to the requirements to comply with Good Pharmacy Practice. This is to ensure that the norms and standards as required by the South African Pharmacy Council are complied to. The size of the pharmacy, the facilities available in the pharmacy, prevention of unauthorized entry, controlled temperature, location of the pharmacy, smooth impermeable and washable material used for working areas, cupboards and shelves etc. needs to be taken into consideration

**SECTION F:**

This section indicates documentation that must be submitted together with the application form for Permit in terms of Section 22A(15)

**SECTION G:**

This section is a declaration by the applicant that the information is true and correct and that permission is granted for an inspection of the premises.

**SECTION H:**

This section has to be completed by a Commissioner of Oaths indicating that the applicant understands the contents of the declaration

**DELIVERY ADDRESS**

**Postal address:**

DEPARTMENT OF HEALTH  
AFFORDABLE MEDICINES, LICENSING UNIT  
4<sup>TH</sup> FLOOR, ROOM 414, SOUTH TOWER, CIVITAS  
PRIVATE BAG X828  
PRETORIA  
0001

**Courier / Hand delivery:**

DEPARTMENT OF HEALTH  
AFFORDABLE MEDICINES, LICENSING UNIT  
4<sup>TH</sup> FLOOR, ROOM 414, SOUTH TOWER, CIVITAS  
C/o STRUBEN & THABO SEHUME STREETS  
PRETORIA CENTRAL  
0002

**CONTACT NUMBERS FOR ENQUIRIES**

012 395 8213  
012 395 8214  
012 395 8314

**Fax Number:**

012 395 8824

## ADDITIONAL INFORMATION

### **PERMIT PROCESS:**

- The permit process will take three months from date of receipt of a **complete** application.
- Your application will be acknowledged in writing on receipt of a complete application.
- The Director-General, Pharmacy Council or delegated senior official, is entitled to issue or decline such a permit application.
- On approval, a permit shall be issued. If an application is declined, a letter of decline will be issued.
- A copy of the permit/letter will be faxed or emailed (if requested) and the original be posted via registered mail.

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

### **LEGISLATIVE REQUIREMENTS:**

Please note the following

- The Director-General or Pharmacy Council may withdraw a Permit should the permit holder not comply with any applicable Legislation.
- Should you wish to cancel your permit, kindly inform the Department and return the original permit 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.**

### **REQUIREMENTS WHEN APPLYING FOR A PERMIT:**

- All qualifications (nursing qualifications certified)
- Application form - original
- Copy of current SANC receipt (certified)
- Copy of identity document (certified)
- Married certificate / divorce certificate (if surnames are different)



**DEPARTMENT OF HEALTH**  
**DIRECTORATE: CHQTF CDNG'O GF KEKGU**

**PRIVATE BAG X828, PRETORIA 0001**

**TELEPHONE : 012-395-8213/4 & 8314 FACSIMILE : 012-395-8824**

**APPLICATION FOR A PERMIT IN TERMS OF SECTION 22A(15) OF THE MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 1965 ( ACT 101 OF 1965 ) AS AMENDED - NURSE, OPTOMETRIST, PARAMEDIC**

**\*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																				
	Code																			

**\*SECTION C: BUSINESS ADDRESS**

1. Street Address of premises																				
	Code																			
2. Postal Address of premises																				
	Code																			
3. Home Telephone Number										-						-				
4. Business Phone										-						-				
5. Fax Number of Applicant										-						-				
6. Mobile Phone Number										-						-				
7. E-mail address																				

**\*SECTION D: PARTICULARS OF APPLICANT**

1. Qualification(s)	a)																			
	b)																			
	c)																			
2. Name of Statutory Council	d)																			
	e)																			
3. Statutory Council Registration Number	f)																			

APPLICATION FOR A PERMIT IN TERMS OF SECTION 22A(15) OF THE MEDICINES AND RELATED  
SUBSTANCES CONTROL ACT, 1965 ( ACT 101 OF 1965) AS AMENDED

<b>*SECTION E: PARTICULARS OF CLINIC: SERVICES AND PREMISES</b>			
1. Type of service .which will be rendered.			
Optometry			
Paramedic			
Other , eg Well Baby Clinic			
Home-based Care			
2. Explanation of the duties with regard to medicine:			
3. Estimated number of patients who will be treated.			
4. Estimated number of consultations per day			
5. Suppliers of Medicine			
		Private Sector	
		Government	
		Other Specify	
6. I, the above applicant declare that:			
6. 1 The size of the premises is			m <sup>2</sup>
<b>Please Mark <math>\checkmark</math> / X</b>			<b>Yes</b>
			<b>No</b>
6. 2 The key, key card or other device or the combination of any device, which allows access to the medicine room is kept on the person of the authorized prescriber .			
6.3 There is sufficient security to prevent unauthorised access to medicines.			
6.4 The medicine room will be suitably located in the consulting rooms.			
6.5 There is/ will be a separate facility for washing hands			
6.6 There is/ will be a separate facility for cleaning of equipment			
6.7 The premises will be kept clean, orderly and tidy.			
6.8The floor surface will be of impermeable material.			
6.9 All working surfaces will be finished with a smooth impermeable and washable material			
6.10 All countertops and shelves will be finished with a smooth, impermeable and washable material which is easy to keep clean			
6.12 Walls are finished with a smooth, impermeable and washable material, which is easy to keep clean			
6.13 There will be sufficient and adequate lighting.			

APPLICATION FOR A PERMIT IN TERMS OF SECTION 22A(15) OF THE MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 1965 (ACT 101 OF 1965 ) AS AMENDED

**\*SECTION E: PARTICULARS OF THE PREMISES: SERVICES AND PREMISES - CONTINUED**

Please mark X	Yes	No
6.14 There is an air conditioner in the medicine room which is in good working condition.		
6.15 The temperature in the medicine room will be below 25 °C.		
6.16 There is at least one fire extinguisher or fire hose in the medicine room.		
6.18 There will be a suitable waiting area, in accordance with Good Pharmacy Practice (GPP)		
6.17 There is a suitable private area for the provision of information and advice, in accordance with GPP standards.		
5.19 There is a suitable area for the screening and performing of tests.		
6.20 The professional image of the medicine room is not affected by the display of commercial material not directly linked with health.		
6.22 The medicine room is designated as a non-smoking area.		
6.23 The receiving area for deliveries will be clearly defined and separated from the rest of the medicine room		
6.24 A fridge for heat sensitive pharmaceuticals and vaccines will be available.		
6.25 A nurse prescriber - only patient ready packs or original packings		
6.26 No bulk stock		

**SECTION F: SUPPORTING DOCUMENTATION**

1. A certified copy of qualifications must be attached
2. For Optometrist please submit optometry qualifications (CAS)
3. Supply a certified copy of registration with the relevant Statutory Council for the current year.
4. Copy of Identity document

**\*SECTION G: 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:**

D	D
---	---

M	M
---	---

 - 

Y	Y	Y	Y
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**\*SECTION I: DECLARATION BY COMMISSIONER OF OATHS**

SIGNED and SWORN TO before me on this ----- day of -----

The deponent (applicant) having acknowledged that he/she understands the contents of this declaration

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

**DATE:**

D	D
---	---

M	M
---	---

Y	Y
---	---

<b>STAMP</b>



**DEPARTMENT OF HEALTH**  
**DIRECTORATE: AFFORDABLE MEDICINES**

PRIVATE BAG X828, PRETORIA 0001  
 TELEPHONE : 012-395 8213/4 & 8314  
 FACSIMILE : 012-395 8824

**APPLICATION FOR A PERMIT IN TERMS OF REGULATION 47 OF THE MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 1965 ( ACT 101 OF 1965 ) AS AMENDED - MIDWIFE**

**SECTION A: GENERAL INFORMATION**

1. Title																				
2. Surname																				
3. Full names																				
4. Identity Number																				

**SECTION B: RESIDENTIAL ADDRESS**

1. Street Address																				
	Code																			
2. Postal Address																				
	Code																			

**SECTION C: BUSINESS ADDRESS**

1. Street Address of premises																				
	Code																			
2. Postal Address of premises																				
	Code																			
3. Tel. No.: Work										-										
4. Tel No.: Home										-										
5. Tel No.: Cell										-										
6. Fax No.: Work										-										
7. E-mail address																				

**SECTION D: PARTICULARS OF APPLICANT**

1. Qualification(s)	a)																			
	b)																			
	c)																			
	d)																			
2. Name of Statutory Council																				
3. Statutory Council Registration Number																				



APPLICATION FOR A PERMIT IN TERMS OF SECTION 22A(15) OF THE MEDICINES AND RELATED  
SUBSTANCES CONTROL ACT, 1965 ( ACT 101 OF 1965) AS AMENDED

<b>SECTION E: PARTICULARS OF CLINIC</b>		
1. Type of service .which will be rendered.		
Midwifery		
2. Estimated number of patients who will be treated.		
3. Estimated number of consultations per day.		
4. Suppliers of Medicine		
5. Specify Pharmacies from which medicines will be obtained		
6. Explanation of duties with regard to medicine		
<b>7. THE ABOVE APPLICANT DECLARE THAT:</b>		
7. 1 The size of the premises is		m <sup>2</sup>
<b>Please Mark with <math>\sqrt</math> / X</b>	<b>Yes</b>	<b>No</b>
7.2 The key, key card or other device or the combination of any device, which allows access to the medicine room is kept on the person of the permit holder		
7.3 There is sufficient security to prevent unauthorised access to medicines		
7.4 The medicine room will be suitably located in the consulting rooms		
7.5 There is/ will be a separate facility for washing hands		
7.6 There is/ will be a separate facility for cleaning of equipment		
7.7 The premises will be kept clean, orderly and tidy		
7.8.The floor surface will be of impermeable material		
7.9All working surfaces will be finished with a smooth impermeable and washable material		
7.10 All countertops and shelves will be finished with a smooth, impermeable and washable material which is easy to keep clean		
7.11 Walls are finished with a smooth, impermeable and washable material, which is easy to keep clean		
7.12 There will be sufficient and adequate lighting		
7.13 There is an air conditioner in the pharmacy which is in good working condition		
7.14 The temperature in the dispensary will be below 25 <sup>0</sup> C		
7.15 There is at least one fire extinguisher or fire hose in the medicine room		
7.16 There will be a suitable waiting area, in accordance with Good Pharmacy Practice (GPP) guidelines		
7.17 There is at least one fire extinguisher or fire hose in the medicine room		
7.18 There is a suitable private area for the provision of information and advice, in accordance with GPP standards		
7.19 There is a suitable area for the screening and performing of tests		
7.20 The professional image of the dispensing area is not affected by the display of commercial material not directly linked with health		

APPLICATION FOR A PERMIT IN TERMS OF SECTION 22A(15) OF THE MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 1965 (ACT 101 OF 1965 ) AS AMENDED

<b>SECTION E: PARTICULARS OF THE PREMISES - CONTINUED</b>			
	Please Mark with $\checkmark$ / X	Yes	No
7.21 The clinic is designated as a non-smoking area			
7.22 The receiving area for deliveries will be clearly defined and separated from the rest of the			
7.23 A fridge for heat sensitive pharmaceuticals and vaccines will be available			
7.24 A nurse prescriber - only patient ready packs or original packings			
7.25 No bulk stock			

<b>SECTION F: SUPPORTING DOCUMENTATION</b>
1. A certified copy of qualifications
2. A certified copy of registration with the relevant Statutory Council for the current year.
3. Copy of identity document

**SECTION G: 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: .....

**\*SECTION H: DECLARATION BY COMMISSIONER OF OATHS**

SIGNED and SWORN TO before me on this ----- day of ----- in the year -----

The deponent (applicant) having acknowledged that he/she understands the contents of this declaration

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

**DATE: .....**

