health Department: Health REPUBLIC OF SOUTH AFRICA	**NATIONAL DEPARTMENT OF HEALTH** **AFFORDABLE MEDICINES DIRECTORATE** **LICENSING AND REGULATION SUB-DIRECTORATE**
	GUIDELINE AND APPLICATION FORM: A permit issued in terms of Section 22A(15) the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) Tel: 012 395 8314/8315 email to ndohpermits@health.gov.za

GUIDELINE

General Information

1. Section 22A(15) of the Medicines and Related Substances Act (Act 101 of 1965) states that the Director-General of the National Department of Health, may issue Section 22A(15) permits to health professionals in order for them to acquire, possess, use or supply any specified Schedule 1 to 5 substance, with conditions as the Director-General may determine.
2. Section 22A(15) further states that this process must take place in consultation with the South African Pharmacy Council (SAPC). For this reason, your application must be submitted in duplicate in order for a copy of the application to be submitted to the SAPC for consideration and recommendation.
3. Section 22A(15) Permits are issued with a list of conditions and medication that the permit holder may access in order to provide the relevant service. This list is in line with the Department of Health's latest Standard Treatment Guidelines and Essential Medicines List (STG EML). It is the permit holder's responsibility to keep abreast with changes in the STG EML.
4. Refer to 'Step 3' for supporting documents to be submitted with this application.
5. There is no application fee payable for a Section 22A(15) Permit.
6. The following permits may be applied for by the professional nurses:
   - Immunisation Services
   - Family Planning Services
   - Home Based Care Services (treatment of minor ailments)
   - Hemodialysis Services
7. The permit issued in terms of Section 22A(15) remains valid for 5 years from date of issue, or until it is suspended or revoked by the Director-General in terms of Section 22E of the Act.
8. A permit may be withdrawn if the holder thereof fails to comply with any condition of the permit

Required Supporting Documents

Ensure that certification is not older than 6 months

- Certified copy of existing permit (if you are currently in possession of a valid permit)
- Certified copy of South African identity document/passport or other relevant document issued by the Department of Home Affairs
- Proof of current registration with the applicable Statutory Council (e.g. SANC)
- Proof of payment of current annual fees with applicable Statutory Council
- Certified copy of qualifications

Step 3: Submission of Application

Applications must be sent by email to ndohpermits@health.gov.za – with the subject line:

- **Section 22A(15) Permit Application – Initials,Surname, SANC Number**
  (e.g. Section22A(15) Permit Application – A.B. Permit, SANC12345678)

Application Outcome

Applications are processed within 60 days of receipt of the recommendation from the South African Pharmacy Council (SAPC). Your application outcome will be communication by email.

The collection address is:

National Department of Health Address
National Department of Health Affordable Medicines Directorate: Licensing Unit AB Xuma Building 1112 Voortrekker Road Pretoria Townlands 351-Jr Pretoria, 0187

health Department: Health REPUBLIC OF SOUTH AFRICA	**NATIONAL DEPARTMENT OF HEALTH** **AFFORDABLE MEDICINES DIRECTORATE** **LICENSING AND REGULATON UNIT**
	APPLICATION FORM: Permit issued in terms of **Section 22A(15)** the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) Effective Date: 01/01/2024

Section A: Applicant's General Information

SECTION 22A(15) APPLICATION TYPE	**New**		**Renewal**		**Relocation**		**Additional**		**EXISTING PERMIT NUMBER:**
Service required (Mark with X)	**Immunisation Services**		**Family Planning Services**		**Home Based Care Services (Minor ailments)**				

1	*** Title**							
2a	*** Name(s)**							
2b	*** Surname**							
3	*** Gender**	Female		Male				
4	**Race** (for statistical purposes)	**African**	**White**	**Indian**	**Asian**	**Coloured**		
5	***Date of Birth** [DD-MM-YYYY]		-		-			
6a	***Are you a South African citizen?**	Yes		No			*If no, continue with Q6c*	
6b	***Identity No.**						*Continue with Section B*	
6c	**Passport No.**							
	Country of Issue							
	Passport Expiry Date [DD-MM-YYYY]		-		-			
	Visa Expiry Date [DD-MM-YYYY]		-		-			

Section B: Applicant's Contact Details

1a	***Email** preferred	
2a	*** Cellphone No**	
2b	***Alternative No.**	
3	**Home Address**	

***Complex/Building Name** *(if applicable)*		***Unit No.**								
***Street Name**		***Street No.**								
***Suburb**										
***City / Town**		***Province**	EC	FS	GP	MP	NC	NW	LP	KZN	WC

4	**Domicilium Citandi et Executandi** - ***Address to be used for all correspondence***

Is Domicilium Citandi et Executandi the same as the home address?	Yes		No		*If yes, continue with Section C* *If no – please completed this section*
Complex/Building Name *(if applicable)*		Unit No.			
Street Name		Street No.			
Suburb					

City / Town																						
Province											**Postal Code**											

Section C: Statutory Council Details

1	***Statutory Council Name** *(abbreviation)*																					
2	***Council Registration No.**																					
3	***Profession**																					

Section D: Facility / Business Details

1	**Facility/Business Name**																					
2	**Facility Phone No.**																					
3	**Facility/Business Physical Address**																					
Complex/Building Name																		**Unit No.**				
***Street Name**																		***Street No.**				
***Suburb**																						
***City**																						
***Province**																		***Postal Code**				
4	**Facility Postal Address**																					
4a	**Is the Facility Postal Address the same as the above Facility Physical Address?**	**Yes**		**No**		*If yes, continue with Section E*																
Complete appropriate section																						
4b	**PO Box Number**																					
	Private Bag																					
	PostNet Suite																					
	City																					
	Province																					
	Postal Code																					

Section E: Compliance

By initialing this section of the application form, the applicant agrees to ensure compliance with the conditions/standards listed in this section upon approval of the permit.

PREMISES – GENERAL The premises will have**:** • A suitable waiting area, in accordance with Good Pharmacy Practice guidelines • A suitable private area, for provision of information and advice while dispensing, in accordance with Good Pharmacy Practice standards • A suitable area for screening and performing tests • The floor, working surfaces and countertops will be finished with smooth, impermeable, and washable material • The walls, floors, ceilings, fixtures will be kept clean at all times • Sufficient and adequate lighting • A designated, lockable medicine room / lockable cupboard for storage of medicines • A separate, designated area for receiving stock • A separate facility for washing hands • A separate facility for washing equipment, with cold and hot water • A fire extinguisher on the premises, with records of annual maintenance	**Initials:** _____
SECURITY & CONTROL OF ACCESS The following will be done to ensure controlled access and security of premises: • There will be sufficient security to prevent unauthorised access to the medicine room/cupboard • Only the authorised permit holder will have keys to the medicine room/cupboard	**Initials:** _____
STORAGE CONDITIONS The following will be done to ensure correct storage conditions: • Measures will be taken to prevent unauthorised entry into the medicines room / area where medicines are kept • There will be sufficient shelving for pharmaceuticals • The medicines room / consulting room with a medicine cupboard will be air-conditioned • No medicines will be exposed to direct sunlight • Inflammable products will be kept in a separate storage place • There will be a designated refrigerator for thermolabile medicines • There will be an emergency power supply for the fridge, during a power failure • Only medicines will be stored in the fridge • There will be an approved thermometer in the fridge • The temperature in the fridge is monitored twice daily & recorded on a schedule • Only patient ready or original packs will be kept • No bulk stock will be kept on the premises	**Initial:** _____
DISPENSING EQUIPMENT The following minimum equipment will be available at all times: • Clean tablet / capsule counting trays for tablets and capsules • Adequate graduated measures for reconstituting medicines from powder form • Sufficient appropriate containers for dispensing • Labels suitable for dispensing, including warning labels • Suitable containers for the disposal of sharps	**Initial:** _____

SCHEDULED MEDICINES & RELEVANT RECORD BOOKS • Patient records will be readily retrievable and will include patient demographic information, consultation date, diagnosis, prescriber (who should be the dispenser), medicine dispensed, allergies, adverse drug reactions, family history, comorbid diseases, concomitant medication, etc.) • The relevant prescription books / records of scheduled medicines dispensed will be kept for at least 5 years	**Initials:** _____
STANDARD OPERATING PROCEDURES (SOP) **The following SOPs will be in place and there will be records of staff training on the SOPs:** • Handling, storage of medicines, which will include stock rotation • Issuing of medicines to patients • Disposal of expired or obsolete medicines • Prevention of pest infestation • Effective stock rotation • Reporting of adverse drug reactions • Recall of medicines • Room temperature control • Handling of Schedule 5 and 6 medicines, including the balancing of registers • Handling of thermolabile substances, and actions to be taken in case of a power failure	**Initials:** _____

Section F: Declarations and Undertakings

Please Initial each undertaking to confirm that you will comply with the undertakings

		Initials:
1.	* I undertake to comply with all applicable laws, regulations, rules and professional obligations and to familiarise myself with all legislation relating to the permit for which this application is made	
2.	* I undertake to remain abreast of revisions and updates to the Primary Health Care Level Standard Treatment Guidelines (PHC STG) and Essential Medicines List (EML) as applicable to any permit issued	
3.	*I undertake to partake in continued professional development pertaining to the permit applied for	
4.	*I have not been convicted of an offence that is of such a nature that renders me unsuitable to perform any function or provide a service authorised by any permit issued	
5.	*I declare that I am registered with, and in good standing with my statutory council(s)	
6.	*I undertake comply with all conditions upon which the permit may be issued	
7.	*I understand that any permit issued will only entitle me to provide services within my scope of practice	
8.	*I am aware that any permit issued is not transferable to any other person(s)	
9.	*I hereby give consent for an inspection of the premises in terms of the applicable legislation either before a permit is issued, while any permit issued is valid, or after it has been cancelled / withdrawn	
10.	*I undertake to only handle medicines in accordance with the applicable list provided as an annexure to the permit issued to me.	
11.	*I undertake to display any permit issued conspicuously at the premises for which I have applied	
12.	*I undertake to inform the Director General of any changes pertaining to any permit issued, including but not limited to loss or damages, and changes in name, physical address and contact details	

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Section G: Supporting Documents

A copy of each of the supporting documents, as specified below, must be submitted with the application. (*Certified copies must not be older than 6 months*)	***Mark with X below***
• Certified copy of existing permit (if you are currently in possession of a valid permit)	☐
• Certified copy of South African identity document/passport or other relevant document issued by the Department of Home Affairs	☐
• Certified proof of current registration with the applicable Statutory Council(s)	☐
• Proof of payment of current annual fees with applicable Statutory Council	☐
• Certified copy of applicable primary nursing qualification certificates	☐
• Certified copies of secondary qualifications (list below): _____ _____ _____ _____	☐

Section H: Declaration by Applicant (To be signed in front of commissioner of oaths)

1. I, _____ (name and surname) hereby give consent for an inspection of the premises in terms of the applicable legislation.
2. The information furnished herewith is true and correct and all supporting documents are valid.

.....	.....	.....
APPLICANT'S FULL NAME	**SIGNATURE**	**DATE:** *dd/mm/yyyy*

SECTION I: 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.

.....

NAME, DESIGNATION & SIGNATURE OF COMMISSIONER OF OATHS **COMMISSIONER STAMP**