

## PHARMERS LICENSING SERVICES

### **PROFESSIONAL LICENSING CONSULTING INFORMATION SHEET**

Hey there, welcome to Pharmers' professional license consulting information sheet!

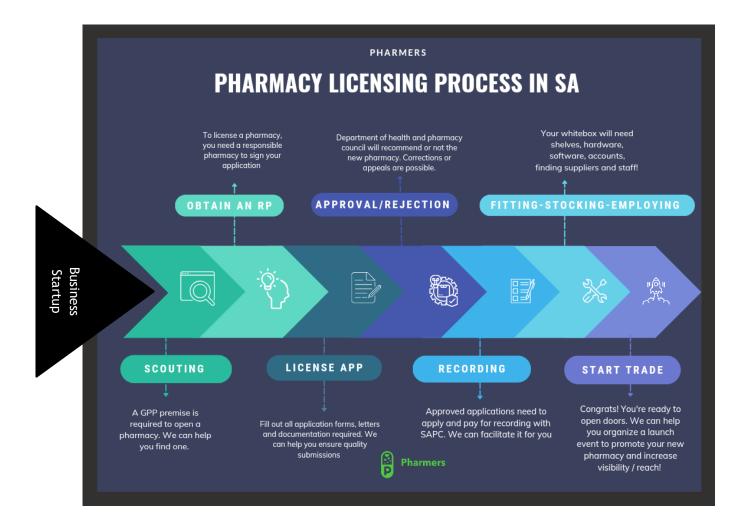
In this sheet you will find:

1.	Service information for pharmacy licenses (PL)	Page	2
2.	Service information for Medical device licenses (MD)	Page	6
3.	Service information for medication licenses (SAHPRA) (SM)	Page	8
4.	Service information for Business Development Services (BDS)	Page	9

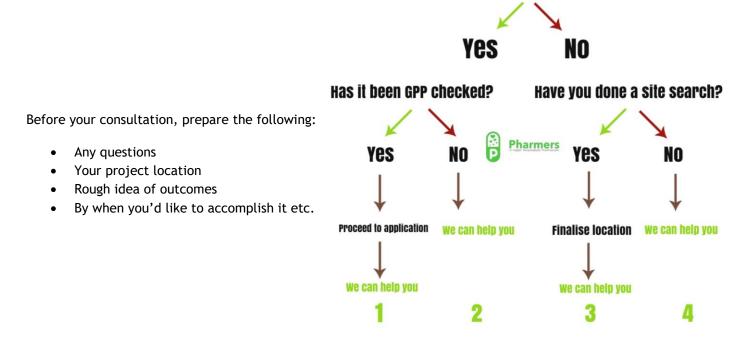
### 1. PHARMACY LICENSES

We have several curated options of licencing services available depending on your needs. Whether you require a pharmacy licence (*community, institutional, consultant, wholesale, or manufacturing*) a medicines import/export license, or a medical device one (including IVDs) for manufacturing, distribution or wholesale, you've come to the right place.

The National Department of Health as well as the South African Pharmacy Council are the two authorities who process pharmacy license applications. This takes approximately 4 months from date of submission. The steps are as outlined below:



# Do you have a pharmacy premise?



### **Pharmacy Licence Service Descriptions:**

Code	Name	Description	Duration	Costs (excl VAT)
PLAC	Project consultation	Discuss your specific project timelines, risks, gaps and mitigation options, requirements, budgets, deliverables and alternatives and report	2 x 40 minutes	R1 000
DFUPL	Done-for-you license	Full service from start to finish, including: CIPC company registration, RP + cover letters, CSD application (MAAA), SOP pack, 6-part online application, hardcopy application (PL01-06), Interim RP, confirmation of services, municipality population stat check	14 days	R40 000 (including SAPC fee R1000)
A-la-cart	e services Choose i	ndividual services from below.	L	

Service Code	Service	Service Description	Approx. Days	Cost
BSS	Business Startup	CIPC & CSD registration, written business Plan, 24 months forecasts & graphs, startup & annual budgets, branding (logo, positioning, strategy).	10 days	R20 000
SCO	Scouting	Search for GPP premises suitable for the desired pharmacy type in 3 chosen geographical locations within SA x2 cycles as needed.	15 days	R6 500
IRP	Interim RP	4 months x responsible pharmacist who endorses the application with the possibility of extension of time (longer application process durations).	4 months	R25 000
PLSRP	Full License Submission without RP	All requirements for a quality submission, such as application forms (paper & online), letters, floorplans, 3D images, documents, & payments.	10 days	R25 000
CRA	Corrections & Rejection Appeals	If needed, specific case adjustments and resubmissions (corrections and appeals) are made with research into the findings.	10 days	R5 000
REC	Recording of Pharmacy	Paper and online application with applicable fees after the pharmacy is recommended and approved.	7 days	R2 000
SSS	Suppliers & Staffing	Application to Suppliers, providers (accounts) to fit, furnish and stock your white box as well as staff it (recruit cashiers, cleaners, Pas, Rx, RPs).	10 days	R4 000
LT	Launch & Trade	Launch planning event (online and in person) to widely advertise new pharmacy services in your community (a full month ahead of the open day).	10 days	R5 000
CIPC	CIPC registration	Full business registration (pharmacy or medical device business) with the registrar of companies	2 days	R1 200
CSD	Full online CSD registration	Create an online CSD profile and complete all 13 fields to generate an MAAA number (needed for partnerships and tenders with the government (CCMDD, contraceptives etc.)	1 day	R1 200
SAPCF	SAPC application fee	SAPC application fee for all pharmacy license applications (new, change of ownership, relocation)	n/a	R1 000
SITE (Gauteng Only)	Site Visit	Pre-licensing, assess location, distance to neighbouring pharmacies, premise size for intended use, access & Safety	2 days	R1 200
INSP (Gauteng Only)	SAPC inspection prep	Post-licensing project, premise size for intended use, internal GPP items (counters, restricted areas, private room access, scheduled med access, etc.), documentation (SOPs, policies), walkabout (patient flow)	2 days	R1 500
POSC	Population Statistics check	Checking the latest local geographical / population density and census with municipality checks/zoning of the site	2 days	R600
PLSB	Start-up budget	In depth budget & financial allocations designed for optimal efficiency of starting a pharmacy	1 day	R1 000

PLOA	Online application	We create online login, complete online 6-segment requirements.	3 days	R2 000
РНСА	Hard copy application	We complete the hard copy application on your behalf.	3 days	R1 200
PLFP	Professionally drawn floor plans	Obtain a GPP-compliant maquette of your premise based on your initial floor plans.	10 days	R7 500
PLSD	Support documents	X4 [Application cover letter (x2), appointment + acceptance compliant letters].	1 day	R4 000
CONF	Confirmation	Confirmation of services by the applicant of other pharmaceutical services in the area (affidavit). Including landlord confirmation form on letterhead (if in a shopping centre)	3 days	R1 000
PLSOP	SOPs	Compile your necessary standard operating procedures (community +/-31)	5 days	From R2 300
POL	Policies	Personalised policy documents (30) to correctly manage staff and enforce company mandates and values	5 days	R3 000
CONT	Contracts	Cleaners, Cashiers, Locums, Responsible Pharmacist Pharmacists, Assistants (all)	5 days	R500 each
RECR	Recruitment of staff	We design the advert and advertise on our 4 platforms: YouTube, Instagram, Facebook & LinkedIn for 5 days.	5 days	R2 000 once off plus 20% of first months' salary if successful
VLC	License Changes (various)	Any changes to existing application (ownership, relocation, tradename). All letters, online application, hard copy & floorplans.	14 days	R10 000
EMS	Emergency submission	Jump the queue, get there first by obtaining a case number before anyone else when we submit your pharmacy application in 24h.	24 hours	R3400
BRR	Business Rescue & Revamp	Is your pharmacy in ICU on the verge of death? Before you sell, let us come in and revive it	2 months	R25 000

You're welcome to start with visiting the online portal at: <a href="https://interns.pharma.mm3.co.za/PasswordRequests/GroupOwnerPasswordRequestEmail">https://interns.pharma.mm3.co.za/PasswordRequests/GroupOwnerPasswordRequestEmail</a> to create a profile.

These steps are explicit enough for you to do it on your own, but if you still require assistance during our consultation, we will help you complete the online forms.

The time frame for applications varies. The minimum time is 3 months, according to the SAPC publishing. To minimise time wasted, ensure your submission is correct the first time you apply. GPP compliance is crucial. Your premises are the most likely area to be non-compliant, so pay extra attention to their requirement.

Remember, we are here to help: should you want us to take over your application process, refer to the add-on services that follow and select all that apply. To be discussed during your consultation

### 2. MEDICAL DEVICES:

Welcome to Pharmers' professional medical devices (including IVDs) licensing information sheet! We have several curated options of licencing services available depending on your need. Whether you require a manufacturing (manufacture, pack, label, service, import, export), distribution import, export, distribute) or wholesale (storage, transportation, delivery) license, you've come to the right place. 3 types exist: manufacturing, distribution and wholesaling (quality manual or SMF required). The <u>SAHPRA fees are R25 200 for manufacturing, R15 200 for distribution and R15 200 for wholesale</u>. The first step to understand the process and requirements.

The fourth one is an export only but requires an existing wholesale license. You've come to the right place. We provide license application services with SAHPRA.



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#### **Medical Devices**

The Medical Devices Unit of SAHPRA regulates the licencing of medical device establishments and the registration of medical devices (in vitro diagnostics (IVDs) and non-IVD medical devices) in South Africa to ensure the availability of medical devices that comply with an acceptable level of safety, quality and performance.



### Medical Devices Licence Service Descriptions:

Code	Name	Description	Duration	Costs (excl VAT)
MDAC	Project Consultation	Discuss your specific project timelines, risks, gaps and mitigation options, requirements, budgets, deliverables and alternatives and report	2 x 40 minutes	R1000
DFUMD Done-for-you		10 devices - Comprises of full 6.22 pdf & excel application, company registration + brand, AR + LH letters, SMF for wholesale, CSD registration, Special LOA, quality manual	10 working days	R40 000 Excluding SAHPRA fees
MDED	Extra devices	up to 10 additional devices	5 days	R5 000
A-la-carte options				
EMDA	Emergency MD application	Submit your application within 48h	48h	R4 000
MD application PDF	MDPDF	Complete MD application 6.22	1 day	R3 000
MD application Excel MDEXC		Complete MD application 6.22	1 day	R4 000
Support documents SAHPRA	SUPL	X4 [Application cover letter, appointment (x2), acceptance AR]	1 day	R4 000
Quality Manual	QUM	Required for MD applications (manufacturing and distribution)	10 days	R25 000
ADDD	Additional devices	Submit a certificate amendment to add 5 new devices	5 days	R10 000
MDSP Business management		Receive personalised SOPs and policies which will help you run your new business	5 days	R5 000
TMAN	Tender management	Let Pharmers manage your license and obtain tenders on your behalf.	Monthly	R15 000
GSV	Site visit (Gauteng Only)	If needed, we will come to your site and assess feasibility of license premise (manufacturing / wholesale only)	1 day	R1 500

### 3. MEDICINES (SAHPRA) LICENSES

To hold medicines in South Africa, you need a pharmacy license, and to move them around you require a SAHPRA license in addition to that. To import, export, manufacture or wholesale or distribute medicines in SA, the following services are available. For medicinal cannabis as well, you will require cultivation license and SOPs for all the intended daily processes.



## **Medicines Licence Service Descriptions:**

Code	Name	Description	Duration	Costs (excl VAT)
WSL	Wholesale license	SAPC wholesale application with full SAHPRA application (including SMF, interim RP)	14 days	R40 000
DSL	Distribution license	SAPC distribution application with full SAHPRA application (including SMF, interim RP)	14 days	R40 000
ISL	Import license	SAPC consultant application with full SAHPRA application (including SMF, interim RP)	14 days	R40 000
ESL	Export license	SAPC-relevant application with full SAHPRA application (including SMF, interim RP)	14 days	R40 000
MSL	Manufacturing license	SAPC application with full SAHPRA application	14 days	R40 000

		(GMP, including SMF and interim RP)		
MQM	Medicines Quality Manual	As part of your QMS you will need a quality manual to establish the quality goals, objectives and standards of the organisation	10 days	R15 000
MSOP	Medicine SOPs	Get a comprehensive pack for manufacturing, cultivating, warehousing or distribution activities	10 days	R10 000
POL	Company Policies	Personalised policy documents (+/-30) to correctly manage staff and enforce company mandates and values	5 days	R3 000
CONT	Contracts	Locums, Responsible Pharmacist, assistants etc.	5 days	R1000 for 2

MSOP also includes medicinal cannabis plants. If you have any specific SOP requirements don't hesitate to request a personalised pack.

### 4. BUSINESS DEVELOPMENT SERVICES

We have services available depending on your needs. Whether you require a pharmacy license, a medical device license, startup financial risk advice, a startup budget, or CIPC company registration, you have come to the right place. Start your business with expert advice. The first step to effectively resolving your query is for us to define and understand it adequately. Kindly complete the attached Pre-Consultation questionnaire fully. This is not a compulsory step, but it ensures that you do not waste your resources (time and money) unnecessarily by embarking on a project that is not feasible or has some disqualifying element. We review your project and discuss your project deliverables and timelines. We are here to be partnering with you on this exciting new journey and wish you the very best outcome.

Entrepreneurs who wish to begin in various projects can opt for helpful services such as:



### **Business Service Descriptions:**

Code	Name	Description	Duration	Costs (excl VAT)
BUSPRO	Business projections	24 months cashflow, start up budget, financial risk advice, 2 x 40minutes project discussion	10 days	R10 000
BUSPLA	Proposal presentation	CIPC registration, organogram, branding, strategy, risk evaluation, core service description (differentiation), 10-slide presentation, 2 x 40 minutes project discussion	10 days	R15 000
BUSCAS	Cashflow forecast & budget	36 months cashflow, start up budget (opening), ongoing budget, 2 x 40 minutes project discussion	10 days	R15 000
MFR	Mini Feasibility Report	Let's do an online desktop assessment of your prospective project location and surroundings	3 days	R2 500

### TERMS & CONDITIONS

Before you make a booking (or payment confirmation), please note the following:

- Online bookings are required to generate zoom link through the software, must be made at least 3 days before the intended consultation date. Invoice must be paid in full before confirmation.
- Face-to-face consultations will be booked at our office either on a Friday at least 3 days before.
- When you book for a consultation, an invoice for payment will be sent to you soon after. Make payment into Pharmers account (as shown below) within 24hours to confirm the appointment.
- If this payment is not received through a proof of payment email (send pdf to <u>info@pharmers.co.za</u>) then the booking will automatically be cancelled.
- Pharmers provides confidentiality in all projects and consultations. If you desire a written & signed NDA, please request one by email.
- Floorplans drawn have a maximum of 3 alterations and the timelines will be subject to availability of our architects.
  We cannot predict how quickly this will be.
- Licencing services are limited to full initial submissions of applications. These services do not include any subsequent need for recordings or providing shop fittings etc. see our post-licensing services for more information.
- Although Pharmers has an excellent track record of approvals, we cannot guarantee any outcome deliberated by the national authorities (SAPC, NDoH, SAHPRA), we will assist in correcting or appealing for reconsideration.

- All additional payments required to SAPC or SAHPRA are to be paid by the applicant directly and the proof of payment sent to pharmers.
- You may request that Pharmers make those payments on your behalf as an applicant, by including these payments to your invoice.
- For projects above R20 000, a 60/40 % split can be requested to commence the project and pay the 40% balance on submission
- No liability for unauthorised changes will be taken by Pharmers.
- No late replies or responses will be accepted if a project is deemed cancelled after 2 weeks of inaction from the client side.
- Balance payments for split payment agreements are due 10 days after project begins or on the day of submission of the project.
- Penalty fees for late payments will apply at 5% increase immediately after first date of delay

Thanks again for your interest in Pharmers. We trust that you have found excellent value in your experience with us thus far.

### TO MAKE PAYMENT USE FOLLOWING DETAILS:

#### To pay Pharmers

### FIRST NATIONAL BANK

ACCOUNT NAME: PHARMERS (PTY) ACCOUNT NUMBER:62835950280 ACCOUNT TYPE: CHEQUE SWIFT CODE: FIRNZAJJ REFERENCE: SERVICE CODE / INVOICE NUMBER

### SAHPRA Payments

### **ABSA BANK**

ACCOUNT NAME: SOUTH AFRICAN HEALTH PRODUCT REGULATORY AUTHORITY ACCOUNT NUMBER: 40-5939-2080 ACCOUNT TYPE: CHEQUE BRANCH CODE: 632005

**REFERENCE: SPECIFIC CODE** 

SAPC payments

#### STANDARD BANK

ACCOUNT NAME: SOUTH AFRICAN PHARMACY COUNCIL

ACCOUNT NUMBER: 011 885 866

ACCOUNT TYPE: CHEQUE

BRANCH CODE: 010145

#### REFERENCE: PHARMACY NAME

The next page is a pre-consultation / pre-project questionnaire that may help you describe your need better before we begin your project. Use it if needed and return to <u>info@pharmers.co.za</u>

We're here to partner with you on this exciting new journey and wish you the best outcome.

### PRE-CONSULTATION QUESTIONNAIRE (FILL IF FURTHER CLARITY IS NECESSARY)

WHERE ARE YOU BASED GEOGRAPHICALLY?
WHAT URGENCY DO YOU HAVE?
WHAT IS THE NATURE OF YOUR REQUEST?
WHAT OUTCOMES/ DELIVERABLES DO YOU REQUIRE FOR SATISFACTION?
WHAT IS YOUR END-GOAL OBJECTIVE AFTER ACQUIRING THIS SERVICE?
WHAT IS YOUR PAIN-POINT FOR NOT DOING THIS ON YOUR OWN?
IS PERSONAL AND EXPERIENTIAL GUIDANCE SOMETHING YOU NEED?
LIST ALL ADD-ON SERVICES YOU REQUIRE ABOVE THE CONSULTATION.
DO YOU REQUIRE ADDITIONAL STRATEGIC GUIDANCE?
WHEN WOULD YOU LIKE TO BOOK? DATE AND TIME?
BY WHEN WOULD YOU LIKE THE PROJECT TO START AND FINISH? / DEADLINES?
ANY OTHER REMARKS TO NOTE?

Thanks again for your interest in Pharmers. We trust that you have found excellent value in your experience with us thus far.

Kindly familiarise yourself with our general Ts & Cs as listed on our website.

Disclaimer: Pharmers has successfully assisted hundreds of applicants on their various projects. We will not be held accountable of any failures in obtaining a license once correct application is submitted. The recommendations we give are according to GPP. Non-compliance liabilities will not be accepted. Please note that this purchased herein is non-refundable. If you are not satisfied, we may investigate the cause, adjust or replace the service at the discretion of the managing director.





PHARMERS CONSULTING - VARIOUS LICENSING SERVICES						
Applicant Title:		First Name:				
Last name:		Current Position:				
Company:		Email:				
Contact Number:		Physical Street Address:				
Country:		City/ Town:				
Current industry:						
SERVICE CODE SELECTION (please use all codes in above info sheet that apply)						
Service Code	Done-For-You	A-La-Carte	Apply Discount Code			
Service Code	Done-For-You	A-La-Carte	Apply Discount Code			
Service Code e.g., DFUMD	Done-For-You	A-La-Carte	Apply Discount Code			
Service Code e.g., DFUMD 	Done-For-You	A-La-Carte	Apply Discount Code			
Service Code e.g., DFUMD 	Done-For-You	A-La-Carte	Apply Discount Code			
Service Code e.g., DFUMD 	Done-For-You	A-La-Carte	Apply Discount Code			
Service Code e.g., DFUMD  	Done-For-You	A-La-Carte	Apply Discount Code			
Service Code e.g., DFUMD  	Done-For-You	A-La-Carte	Apply Discount Code			
Service Code e.g., DFUMD   	Done-For-You	A-La-Carte	Apply Discount Code			
Service Code e.g., DFUMD   	Done-For-You ✓	A-La-Carte	Apply Discount Code e.g., LEAP30			

or A-la-carte; if you (last) column

Total Services (Cost):	R	Other Comments:	
TOTAL Payment Due including 15% VAT :	R		

	PAYMENT OPTIONS SELECTION (please tick box which applies)						
One Full Payment		<b>2 x 50%</b> (full MD or PL done-for-you services only, over a maximum 10 day processing period)					

Please return completed form to info@pharmers.co.za for an invoice to be generated for your selection.

I have read all the terms and conditions and agree	
Applicant Signature:	Date: / / 2024