* An application form for the purpose of **obtaining** a licence **or renewing/amending** a licence in terms of the provisions of the Medicines and Related Substance Act, 1965 Section 22C and 22D read together with Regulation 23 and 24 of the General Regulations to the Medicines Act as the case may be.
* This form should be completed by each Applicant who intends to import and distribute scheduled substances, who is not exempted from the requirement to hold a licence and still wishes to import and distribute scheduled substances or wishes to renew/amend their existing licence.
* Incomplete forms may be rejected. Please type or print in **black ink**. Any alterations must be initialled and dated. All required copies of certificates should be certified.
* The application will only be recognised if accompanied by the prescribed application fee for a licence. For the amount, refer to the summary of fees and charges available on the SAHPRA website: <https://www.sahpra.org.za/document/regulations-regarding-fees-payable-in-terms-of-the-provisions-of-the-medicines-and-related-substances-act-1965-act-no-101-of-1965/>
* The completed form and supporting documents should be emailed to:

gmplicensing@sahpra.org.za

* The licence is the property of South African Health Products Regulatory Authority and must be returned upon demand. The licence remains valid for the period of five years from the date of issue unless otherwise suspended or revoked by South African Health Products Regulatory Authority.
* Licensing guidelines are available at the SAHPRA website: <https://www.sahpra.org.za/inspectorate-and-regulatory-compliance/>
* **An application for renewal of the licence must be submitted at least 180 days before expiry of the existing licence**.
* **Prescribed Annual Licence retention fee for the licence holder is payable by end of June each year for licences issued by the 31 December of the preceding year which are active/valid**.

**Guidance notes for General information**

**The Applicant’s Business Name**

Full, legal name of licence applicant or owner of the business who wishes to import and distribute Scheduled Substances (must be full, *legally identifiable name* e.g., ‘ABC Pty Ltd’, ‘Newcorp Ltd’ trading as XYZ’, ‘Gillian Linda Smith trading as MNR). Spaces are provided for the following options. Please insert as applicable.

a) The individual's full name if trading as an individual trader.

b) The name of the registered corporation or company under the Companies Act and **the registration number,** allocated by the Registrar of Companies.

c) The business name, or name under which you propose to trade for purposes of the Act [if different from (a) or (b)].

**Declaration**

This declaration seeks assurances that the requirements of Section 22C and 22D and Regulation 23 and 24 of the Act have been satisfied and that the information provided in the application is current and correct at the time it was signed by the wholesaler. The declaration in A (iii) is intended to establish whether a wholesaler has received a notice that its wholesaling operations do not comply with current acceptable quality assurance principles and good wholesaling practices as determined by South African Health Products Regulatory Authority. A penalty applies for false and misleading statements made in relation to this application.

**Persons signing the declaration**

Persons signing the declaration must be the owner of the business or the duly appointed designee who is responsible to South African Health Products Regulatory Authority for compliance with the Act – refer Regulation 23(2)(b).

Name Full name

Position The role in the organization e.g., Owner, Designee.

**Site Master File**

Part of the reporting aspects of the audit can be addressed by receiving information on related company details, e.g., details of the company's facilities, personnel structure and operating procedures including manufacturing activities, prior to audit.

It is expected that a Site Master File be prepared and submitted to the Inspectorate that should be in line with the guidelines on the preparation of a Site Master File, which can be obtained from the office of the Chief Executive Officer or the SAHPRA website: <https://www.sahpra.org.za/inspectorate-and-regulatory-compliance/>

**Date of audit**

Before a licence may be granted or renewed, the Inspectorate may have to conduct an audit of the company's operations of importing and distributing scheduled substances to assess conformity with the Good Wholesaling Principles, Good Manufacturing Principles and Good Distribution Principles as determined by South African Health Products Regulatory Authority. In order to schedule an audit, the applicant should indicate an approximate date by which they will be ready for an audit. If this date changes after the application is submitted the Inspectorate should be notified as soon as possible. The inspector assigned to undertake the audit will advise the Applicant of the actual date of the audit in advance in order to accommodate the necessary logistics.

**Good Wholesaling, Good Manufacturing and Good Distribution Practices**

Pursuant to the current GWP, GMP and GDP Guidelines, SAHPRA may determine written principles to be observed by an Applicant who intends to import and distribute scheduled substances. These principles will primarily comprise the Guidelines on Good Wholesaling Practice (GWP), Good Manufacturing Practice (GMP) and Good Distribution Practice(GDP). A copy of the current guidelines on these practices may be obtained by the Applicant who intends to import and/or distribute schedule substances from the office of the Chief Executive Officer or the website of the SAHPRA at <https://www.sahpra.org.za/inspectorate-and-regulatory-compliance/>

**Note: If any of the details contained in this Application Form should change after this document has been signed, the Applicant will be obliged to submit an updated application form within 30 days, otherwise the Licence will automatically become null and void.**

|  |
| --- |
| **GENERAL INFORMATION** |

**1.1 NAME OF PROPOSED LICENCE HOLDER**

|  |
| --- |
|  |

 **NOTE:** A Licence is granted to persons who, in the course of a business, intents to import and/or distribute scheduled substances. This can include:

 (i) A legal person

 (ii) A natural person

**1.2 PROPOSED LICENCE HOLDER BUSINESS DETAILS**

|  |  |
| --- | --- |
| Name of business owner |  |
| Registered company name if Corporation  |  |
| Name if trading under other business name |  |
| Company or Corporation Registration number issued by the registrar of Companies |  |

**1.3 SITE/PHYSICAL ADDRESS**

|  |
| --- |
|  |
|  |
|  |
| **Town/City** | **Postal Code** |
| **Province** |

**1.4 ADDRESS FOR COMMUNICATIONS (IF DIFFERENT FROM PHYSICAL ADDRESS)**

|  |
| --- |
|  |
|  |
|  |
| **Town/City** | **Postal Code** |
| **Province** |

**1.5 LICENCE HOLDER CONTACT**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Surname** |  | **Initials**  |  | **Title**  |  |

|  |  |
| --- | --- |
| **Telephone number** |  |
| **Fax number** |  |
| **E-mail address** |  |

**1.6 HAS THE SITE previously held A SAHPRA licence? If YES, PROVIDE THE LICENCE NUMBER**

|  |
| --- |
|  |

**1.7 IS YOUR BUSINESS REGISTERED WITH THE SOUTH AFRICAN PHARMACY COUNCIL AS A WHOLESALE PHARMACY?**

|  |  |
| --- | --- |
| **YES** | **NO** |

**If yes, supply the Y registration number and copy of certificate of recording**

|  |
| --- |
| **Y** |

**1.8 SUPPLY REGISTRATION NUMBER AND COPY OF CERTIFICATE OF RECORDING OF PHARMACY OWNER WITH PHARMACY COUNCIL**

|  |
| --- |
|  |

|  |
| --- |
| **SITE INFORMATION** |

|  |
| --- |
| **Please complete separate forms for each site (including admin offices) from which storage, distribution or related activities take place** |

**2.1 SITE MASTER FILE (Tick the appropriate block)**

**Enclosed Submitted before 20**

**Note:** Before a licence audit is conducted Applicants are required to submit a Site Master File. SMF previously submitted must not be older than **2 years**.

**Note:** Ensure to include the full list of Imported/Distributed Scheduled Substances and the list of Licenced/Authorised Professionals/Facilities**.**

**2.2 SITE MASTER FILE NUMBER**

|  |
| --- |
|  |

 **Note:** If not known, request a Site Master File Number from smf@sahpra.org.za

**2.3 SUPPLY LICENCE NUMBER AND COPY OF LICENCE FOR THE PREMISES OBTAINED FROM THE DEPARTMENT OF HEALTH**

|  |
| --- |
|  |

**2.4 SITE TYPE**

|  |  |  |
| --- | --- | --- |
| Is this site used for distribution (the onward dispatch of ready packed orders) only? | **YES** | **NO** |
| Is this site used for other purposes? | **YES** | **NO** |
| Please specify these other purposes below (e.g., order receipt, invoicing, assembly/picking of orders, handling of goods returned from customers). |
|  |

Does the proposed licence holder also hold a Manufacturer's Licence naming this site?

|  |  |
| --- | --- |
| **YES** | **NO** |

Is this site named on any other wholesaler or manufacturer's licence?

If so please give the name of the company and their licence number.

|  |
| --- |
|  |

 **AUTHORISED IMPORTING AND DISTRIBUTION ACTIVITIES**

**2.5 SCHEDULED SUBSTANCES IMPORTED AND HANDLED AT THE SITE**

Please indicate by ticking the appropriate box

|  |  |
| --- | --- |
| Scheduled Substances; S0  |  |
| Scheduled Substances; S1-S4 |  |
| Controlled Substances; S5 -S6 |  |
| Thermolabile Products (Cold Chain Products) |  |

**2.6 DISTRIBUTION ACTIVITIES**

 Please indicate by ticking the appropriate box

|  |  |
| --- | --- |
| Distribution to Lawfully Authorised/Licensed Facilities |  |
| Distribution to Lawfully Authorised/Licensed Professionals |  |

**2.7 METHOD OF DISTRIBUTION**

Please indicate by ticking the appropriate box

|  |  |
| --- | --- |
| Post |  |
| Courier/Van service |  |
| Own courier/Van service |  |
| Customer collection |  |
| Other, please specify below |  |
|  |
|
|

**2.8 FACILITIES ON SITE**

|  |  |  |
| --- | --- | --- |
| Is the description of the facilities available for the storage and distribution of scheduled substances detailed in the Site Master File? | **YES** | **NO** |
| If not, please provide a brief description (approximately 500 words) of the facilities available for the storage and distribution of scheduled substances on a separate sheet of paper. |

**2.9 EQUIPMENT ON SITE**

|  |  |  |
| --- | --- | --- |
| Is a description of the major items of equipment other than transport available for the storage and distribution of scheduled substances detailed in the Site Master File? | **YES** | **NO** |
| If not, please provide a brief description (approximately 500 words) of the equipment available for the storage and distribution of scheduled substances on a separate sheet of paper. In particular please provide details of any refrigeration equipment available. |

**3 THE RESPONSIBLE PHARMACIST**

Please give the following details of the person who is to carry out the functions of the Responsible Pharmacist.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **3.1** | **Surname** |  | **Initials** |  | **Title** |  |

**3.2 Business Address**

|  |
| --- |
|  |
|  |
|  |
| **Town** | **Postal Code** |

|  |  |
| --- | --- |
| **Business telephone number** |  |

**3.3 The Responsible Pharmacist**

Please give the following details of the pharmacist who is to control the importing and/or distribution activities of scheduled substance on behalf of the owner in terms of the provisions of Regulation 23 of the Act.

|  |  |
| --- | --- |
| Surname |  |
| First Names |  |
| Position In Company |  |
| SAPC Registration Number |  |

**Relevant qualifications**

|  |  |  |  |
| --- | --- | --- | --- |
| Degree/Diploma | Field of Study | Institution | Year Graduated |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**Relevant experience (last job first)**

|  |  |  |
| --- | --- | --- |
| Number of Years | Employer | Position Held |
|  |  |  |
|  |  |  |

Please submit a certified copy of the candidate's Registration Certificate from the SA Pharmacy Council with this application.

I confirm that the above particulars are to the best of my knowledge and belief accurate and true.

I agree to be nominated as the Responsible Pharmacist to be in charge of the Wholesaler.

|  |  |
| --- | --- |
| Signed (designee): | Date: |
| Signed (responsible pharmacist): | Date: |

**4 PROPOSED DATE OF AUDIT**

Approximate date when ready for audit

|  |
| --- |
|  |

**5 list of supporting documents to be submitted**

|  |  |  |
| --- | --- | --- |
|  | **Yes** | **No** |
| Proof Of Payment |  |  |
| Existing SAHPRA Licence for Renewal and Amendment Applications |  |  |
| Cover Letter |  |  |
| Site Master File |  |  |
| Signed Declaration |  |  |
| Sahpra Inspection Resolution |  |  |
| CIPC/CIPRO/DTI Certificate (Docs) |  |  |
| BBBEE Certificate/Accreditation/Exemption |  |  |
| The List of Imported and Distributed Scheduled Substances  |  |  |
| The List of Lawfully authorised/Licensed facilities and professionals  |  |  |
| NDOH Premises Licence |  |  |
| Registration of Responsible Pharmacist |  |  |
| SAPC Record of a Pharmacy |  |  |
| SAPC Record of a Pharmacy Owner |  |  |

|  |
| --- |
| **DECLARATION** |

*Applicants should note that in terms of the provisions of the Medicines and Related Substance Act, 1965 it is an offence to make false and misleading statements in connection with an application for a licence to Import and Distribute Scheduled Substances.*

|  |  |
| --- | --- |
|  | *Tick () one box only in each case* |
| A. I declare that: | Yes | No |
| (i) The Applicant had a licence revoked after being granted such a licence. |  |  |
| (ii) The Applicant has been convicted of an offence against the Medicines and Related Substance Act, 1965 or a law of a state or territory relating to medicines or scheduled substances. |  |  |
| (iii) The applicant failed on more than one occasion to observe all the principles in connection with the importing and distribution of scheduled substances. |  |  |
| (iv) The information provided in this application is current and correct. |  |  |

If parts (i), (ii) or (iii) of the declaration were answered in the affirmative, details should be provided on additional pages.

B. I / We apply for the **granting of the new/ renewed/ amended** (*indicate by crossing out the non-applicable section*) Wholesaler Licence to the proposed holder named in this application form in respect of the activities to which the application refers.

1. The licence is subject to all the Standard Provisions applicable to Wholesaler Licences under regulations for the time being in force under Section 22C of the Medicines and Related Substance Act, 1965 (Act 101 of 1965).

2. The activities are conducted only in accordance with the information set out in the application or furnished in connection with it.

3. To the best of my / our knowledge and belief the particulars I / we have given in this form are correct and complete.

**The above declaration must be signed:**

* in the case of a corporation or company, by the designee / natural person who shall be responsible to SAHPRA for compliance with the Act.
* in the case of other enterprises, by the owner.

|  |  |
| --- | --- |
| Name |  |
| Signature |  |
| Position within Organization |  |
| Date |  |

**Note: This is a legal document. Any changes to the application once submitted must be made in writing detailing the requested variation and be signed by the authorized person above.**