* An application form for the purpose of **obtaining** a licence **or renewing/amending** a licence in terms of the provisions of Section 22C(1)(b) and Section 22D of the Medicines and Related Substance Act 101 of 1965 as amended, read together with Regulations 23 and 24 of the General Regulations to the Medicines Act as the case may be.
* This form should be completed by or for each manufacturer of cannabis who is not exempted from the requirement to hold a licence and who wishes to cultivate, manufacture or import or who wishes to renew or amend their existing licence to cultivate, manufacture or import.
* 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/wp-content/uploads/2021/01/Published-SAHPRA-Fees.pdf>
* 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/>
* **Application for renewal of the licence must be submitted at least 180 days before expiry of the existing licence**.

**Guidance notes & General information**

**Definitions and Acronyms**

DALRRD – Department of Agriculture, Land Reform and Rural Development GAP – Good Agricultural Practices

GMP – Good Manufacturing Practices

SAHPRA – South African Health Products Regulatory Authority

# Name of the proposed licence holder

Full, legal name of licence applicant or owner of the business who wishes to cultivate, manufacture or import (must be a 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.

* 1. Name if sole individual trader

The individual's full name if trading as an individual trader

* 1. Name of corporation or company

If a corporation or company, the name of the registered corporation or company under the Companies Act and the **registration number** allocated by the Registrar of Companies.

* 1. Name if trading under other business name

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, as the case may be, have been satisfied and that the information provided in the application is current and correct at the time it was signed by the cultivator, manufacturer or importer. The declaration in A (iii) is intended to establish whether a manufacturer has received a notice that its manufacturing operations do not comply with current acceptable quality assurance principles and good manufacturing practices as determined by the 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 should be the cultivator, the manufacturer, or the cultivator/manufacturer's duly appointed designee who is responsible to the South African Health Products Regulatory Authority (SAHPRA)for compliance with the Act – refer Regulation 23 (1)(c)(iii).

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 Law Enforcement 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 CEO of SAHPRA or the South African Health Products Regulatory Authority (SAHPRA) website at: <https://www.sahpra.org.za/>

# Date of audit

Before a licence may be issued or renewed, the Law Enforcement/Regulatory Compliance will conduct an audit of the company's growing or manufacturing operations to assess conformity with the GAP and GMP as determined by the DAFF and SAHPRA respectively. 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 Law Enforcement should be notified as soon as possible. The inspector/s assigned to undertake the audit will advise the manufacturer of the actual date of the audit approximately five working days beforehand.

# Good Agricultural Practices

The GAP in South Africa is a set of practices that addresses environmental, economic and social sustainability for on-farm processes and result in safe and quality of agricultural products.

# Good Manufacturing Practices

Pursuant to the current GMP Guidelines the Authority may determine written principles to be observed by a cultivator or manufacturer of Cannabis. These principles will primarily comprise the Guidelines on Good Manufacturing Practice. A copy of the current guidelines on GMP may be obtained by the manufacturer of medicines, biologicals or medical gas products from the office of the CEO of SAHPRA or the website of the South African Health Products Regulatory Authority (SAHPRA): <https://www.sahpra.org.za/>

# Responsible Pharmacist

Responsible Pharmacist (RP) means a natural person who is a pharmacist and who is responsible to the South African Pharmacy Council for complying with all the provisions of the Pharmacy Act and other legislation applicable to services that specially pertain to the scope of practice of a pharmacist.

|  |
| --- |
| **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. |
|  |
| **PART A: GENERAL INFORMATION** |
|  |
| **1.1 APPLICATION TYPE** |
|  New |
|  Renew | SAHPRA Licence Number: |  |
| **1.2 APPLICANT DETAILS** |
| Title |  |
| Full Name |  |
| Telephone Number (Office) |  |
| Mobile Number |  |
| Fax Number |  |
| E-Mail Address |  |
| **1.3 BUSINESS REGISTRATIONS** |
| 1.3.1 Is the business registered with the SAHPRA as a Manufacturing Facility? |  Yes No |
| 1.3.2 Is the business registered with the National Department of Agriculture, Land Reform and Rural as a Farming Facility? |  Yes No |

|  |
| --- |
| **2.1 BUSINESS DETAILS** |
| Name of individual / owner |  |
| Registered Company Name (if Corporation) |  |
| Trading Name (if applicable) |  |
| Company or Corporation Registration number issued by Registrar of Companies |  |
| **2.2 ADDRESS FOR COMMUNICATIONS** |
| Line 1 |  |
| Line 2 |  |
| Town/ City |  |
| Province |  |
| Postal code |  |

|  |
| --- |
| **PART B: SITE INFORMATION** |
|  |
| **Note:** Separate forms must be completed for each site where cultivation, manufacturing and/or packaging activities take place. |
|  |
| **3.1 SITE DETAILS** |
| Site Name |  |
| Has this site previously held any licence under the Act? |  Yes (**Note:** If yes, please attach details) No |
| **3.2 SITE ADDRESS** |
| Line 1 |  |
| Line 2 |  |
| Town/ City |  |
| Province |  |
| Postal code |  |
| **3.3 SITE LOCATION COORDINATES** |
| Coordinates required for Cultivation purposes only |  |
| **3.4 DOCUMENTS ENCLOSED** |
| Property Owners (if application) |  Yes No |
| Police clearance documents of business owner |  Yes No |
| **3.5 SITE MASTER FILE (SMF)** |
| **Note:** Before a licence audit is conducted, manufacturers are required to submit a Site Master File. A SMF previously submitted must not be older than **2 years**. |
| Is the SMF enclosed? |  Yes No |
| Has the SMF been submitted before? |  Yes No |
| SMF number (if known) |  |

|  |
| --- |
| **4 SITE CONTACT (RESPONSIBLE PERSON)** |
| Title |  |
| Full Name |  |
| Identity number |  |
| South African Pharmacy Council Reg. No. |  |
| Telephone Number |  |
| Mobile Number |  |
| Fax Number |  |
| E-mail address |  |
|  |
| **5 SITE USAGE** |
| Describe below any other activities on this site which are not connected with medicine. |

|  |
| --- |
| **6 ACTIVITIES AT SITE** |
| If the Licence is for **packaging only**, go to section B3. |
| Please tick: **C** for (cultivation) or **MP** (Manufacture, Testing and Packaging) or **M** (Manufacture and Testing only) as appropriate for each category of production below. |
|  |
| **A** | **CULTIVATION (Provide details in the Site Masterfile)** |  |  |  |
| A1.1 | Types of seeds |  |  |
| A1.2 | The area for growing (m2) |  |
|  |
| **B** | **MANUFACTURING (Provide details in the Site Masterfile)** |  |  |
|  | **C** | **MP** | **M** |
| **B1.1** | **Unit and multi dose liquids** |  |  |  |  |
| B1.1.1 | Internal |  |  |  |  |  |
| B1.1.2 | External |  |  |  |  |  |
| B1.1.3 | Aerosols (pressurised) |  |  |  |  |
| **B1.2** | **Semi-solid & other liquid dosage forms** |  |  |  |
|  | Please specify belo | w |  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| **B1.3** | **Solid dosage forms** |  |  |  |  |  |
| B1.3.1 | **Unit dose forms:** | Tablets |  |  |  |
| Capsules, hard gelatin |  |  |  |
| Capsules, soft gelatin |  |  |  |
| Suppositories/pessaries |  |  |  |
| B1.3.2 | **Multi-dose forms (including powders and granules)** |  |  |  |
| B1.3.3 | **Other solid non-sterile dosage forms** |  |  |  |
|  | Please specify belo | w |  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| **B1.4** | **Other dosage forms** |  |  |  |  |
| Veterinary premixes/ feed mills |  |  |  |
|  |

|  |  |  |
| --- | --- | --- |
| **C** | **PACKAGING ONLY (Provide details in the Site Masterfile)** |  |
| Filling of sterile products is classified as manufacturing, not as packaging. |
| Please tick the appropriate boxes. |
| **C1** | **Packaging activities** |  | **P** |
| C1.1 | Filling of primary containers |  |  |
| C1.2 | Labelling of primary containers |  |
| C1.3 | Liquid dosage forms |  |  |
| C1.4 | Semi-solid dosage forms (including creams and ointments) |  |
| C1.5 | Solid dosage forms (including tablets and powders) |  |
| C1.6 | Other dosage forms, please specify below |  |
|  |
|  |
|  |
| **7 ANALYTICAL TESTING SITES (Provide details in the Site Masterfile)** |
| This refers to the site(s) at which analysis or testing of starting materials, packaging materials, intermediate, bulk and finished products take place. This may also include one or more of the sites where manufacturing and/or packaging takes place. |
| **7.1 Site name** |
|  |
| **7.2 Site address** |
| Line 1 |  |
| Line 2 |  |
| Town/ City |  |
| Province |  |
| Postal code |  |
| **7.3 TESTING ACTIVITIES AT THIS SITE** |
| Please tick the appropriate boxes. |
| D1 | Chemical/ physical |  |  |
| D2 | Microbiological/ sterility/ environmental/ LAL |  |
| D3 | Pyrogens (rabbit test method) |  |
| D4 | Stability testing |  |  |
| D5 | Other, please specify |  |  |
|  |
|  |

|  |
| --- |
| **8 STORAGE AND HANDLING OF HARVEST MATERIALS (Provide details in the Site Masterfile)** |
| **8.1 SITE NAME** |
|  |
| **8.2 SITE ADDRESS** |
| Line 1 |  |
| Line 2 |  |
| Town/ City |  |
| Province |  |
| Postal code |  |
| **8.3 SITE CONTACT PERSON** |
| Title |  |
| Full name |  |
| Telephone number |  |
| Mobile number |  |
| Fax number |  |
| E-mail address |  |
| **8.4 SITE USAGE** |
| Is this site used for distribution only (i.e. onward dispatch of ready packed orders)? |  Yes No |
| OR Is this site used for other purposes? |  Yes No |
| If used for other purposes, please specify below |
| **8.5 EQUIPMENT AND FACILITIES ON SITE** |
| Is a description of facilities available for the storage and distribution of medicinal products detailed in the Site Master File? |  Yes No |
| Is a description of the major items of equipment other than transport available for the storage and distribution of medicinal products detailed in the Site Master File? |  Yes No |
| If these descriptions are not included in the SMF, please provide brief descriptions (approximately 500 words each) of the facilities available and the equipment available for the storage and distribution of medicinal products on a separate sheet of paper. |
| **8.6 ACTIVITIES RELATING TO IMPORT/EXPORT** |
| Are medicines imported/exported by the Applicant? |  Yes No |
| If yes, please provide a list of products being imported/exported. |
| 9 STORAGE AND HANDLING OF FINISHED PRODUCT MATERIALS (Provide details in the Site Masterfile) |
| 9.1 SITE NAME |
|  |
| 9.2 SITE ADDRESS |
| Line 1 |  |
| Line 2 |  |
| Town/ City |  |
| Province |  |
| Postal code |  |
| **9.3 SITE CONTACT PERSON** |
| Title |  |
| Full name |  |
| Telephone number |  |
| Mobile number |  |
| Fax number |  |
| E-mail address |  |
| **9.4 SITE USAGE** |
| Is this site used for distribution only (i.e. onward dispatch of ready packed orders)? |  Yes No |
| OR Is this site used for other purposes? |  Yes No |
| If used for other purposes, please specify below |
| **9.5 EQUIPMENT AND FACILITIES ON SITE** |
| Is a description of facilities available for the storage and distribution of medicinal products detailed in the Site Master File? |  Yes No |
| Is a description of the major items of equipment other than transport available for the storage and distribution of medicinal products detailed in the Site Master File? |  Yes No |
| If these descriptions are not included in the SMF, please provide brief descriptions (approximately 500 words each) of the facilities available and the equipment available for the storage and distribution of medicinal products on a separate sheet of paper. |
| **9.6 ACTIVITIES RELATING TO IMPORT/EXPORT** |
| Are medicines imported/exported by the Applicant? |  Yes No |
| If yes, please provide a list of products being imported/exported. |

|  |
| --- |
| **PART C: LIST OF ACTIVITIES** |
| **10.** Please specify the list of activities to be performed at this site in accordance with the following matrix. ***Note:*** *The entire matrix will be included on the actual licence that will be issued.* |
|  | **YES** | **NO** |
| **10.1** | **CULTIVATION ACTIVITIES** |  |  |
| Storage of seeds |  |  |
| Growing of seeds |  |  |
| Seeds and Labelling Material |  |  |
| Cultivation |  |  |
| Harvesting |  |  |
| Primary Processing |  |  |
| Drying |  |  |
| **10.2** | **MANUFACTURING ACTIVITIES** |  |  |
| **Sterile manufacturing (includes filling, but not cartoning or labelling)** |  |  |
| Large volume parenteral products |  |  |
| Small volume parenteral products |  |  |
| Other sterile dosage forms (please specify) |  |  |
| **Non-sterile Manufacturing** |  |  |
| Tablets |  |  |
| Capsules |  |  |
| Liquids |  |  |
| Semi-solids (Creams or ointments) |  |  |
| Suppositories |  |  |
| Other non-sterile dosage forms (please specify) |  |  |
| **Complementary Medicines Manufacturing** |  |  |
| **10.3** | **PACKAGING ACTIVITIES** |  |  |
| Packaging of bulk product and labelling |  |  |
| Re-labelling or redressing |  |  |
| Cartoning or secondary packaging |  |  |
| **10.4** | **TESTING ACTIVITIES** |  |  |
| Analytical |  |  |
| Microbiological |  |  |
| Sterility |  |  |
| Stability |  |  |
| Animal |  |  |
| Other (please specify) |  |  |
| **10.5** | **DISTRIBUTION ACTIVITIES** |  |  |
| Bulk distribution to wholesale pharmacies |  |  |
| Fine distribution to retail pharmacies and other clients |  |  |
| Import |  |  |
| Export (please specify products exported on a separate list) |  |  |

|  |
| --- |
| **PART D: PERSONNEL INFORMATION** |
| **Guidance notes on nomination of responsible personnel****The Medicines and Related Substance Act, 1965**The Act requires that the applicant shall identify the persons who will have and maintain control of the cultivation, manufacture or import medicinal Cannabis. The Regulations to the Act require that changes be notified promptly to the South African Health Products Regulatory Authority.**Relevant Qualifications for Manufacturing**Relevant qualifications are those relevant to the manufacture of medicines and scheduled substances including those in related sciences and management.**Relevant Experience**Relevant experience is that relevant to the manufacture (including quality management) of medicines and scheduled substances involving comparable good manufacturing practice or experience, which the applicant believes should be taken into consideration as relevant.All applications should include a relevant CV and each pharmacist nomination shall include a letter of appointment by the licence holder and a letter of acceptance. |
|  |
| **11 THE RESPONSIBLE PERSON** |
| Please give the following details of the pharmacist who is to control the manufacture or import of medicinal Cannabis in terms of the provisions of Regulation 23 of the Act. Please submit a certified copy of the candidate’s Registration Certificate from the SA Pharmacy Council with this application. |
| **11.1 PERSONAL INFORMATION** |
| Surname |  |
| First Name |  |
| Position in company |  |
| Qualification |  |
| SAPC Registration number |  |
| **11.2 RELEVANT QUALIFICATIONS** |
| Degree/ Diploma | Field of study | Institution | Year graduated |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| **11.3 RELEVANT EXPERIENCE (last job first)** |
| Employer | No. of years | Position held |
|  |  |  |
|  |  |  |
|  |  |  |

|  |
| --- |
| **11.4 BUSINESS ADDRESS AND PHONE NUMBER** |
| Line 1 |  |
| Town/ City |  |
| Province |  |
| Postal code |  |
| Telephone number |  |

|  |
| --- |
| **11.5 NOMINATION OF RESPONSIBLE PHARMACIST** |
| 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 Pharmacist responsible for the manufacture or import of medicinal Cannabis substances as detailed in this licence application. |
| Name (Responsible pharmacist): |
| Signed | Date: |
| Name (designee) |
| Signed (designee) | Date: |
|  |
| **12 NOMINATION OF PERSON WHO WILL HAVE CONTROL OF PRODUCTION** |
| **12.1 PERSONAL INFORMATION** |
| Surname |  |
| First Name |  |
| Position in company |  |
| **12.2 RELEVANT QUALIFICATIONS** |
| Degree/ Diploma | Field of study | Institution | Year graduated |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| **12.3 RELEVANT EXPERIENCE (last job first)** |
| Employer | No. of years | Position held |
|  |  |  |
|  |  |  |
|  |  |  |

|  |
| --- |
| **13 NOMINATION OF PERSON WHO WILL HAVE CONTROL OF QUALITY CONTROL/ASSURANCE** |
| **13.1 PERSONAL INFORMATION** |
| Surname |  |
| First Name |  |
| Position in company |  |
| **13.2 RELEVANT QUALIFICATIONS** |
| Degree/ Diploma | Field of study | Institution | Year graduated |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| **13.3 RELEVANT EXPERIENCE (last job first)** |
| Employer | No. of years | Position held |
|  |  |  |
|  |  |  |
|  |  |  |
|  |
| **14 PERSON(S) RESPONSIBLE FOR SECURITY** |
| **14.1 PERSONAL INFORMATION** |
| Surname |  |
| First Name |  |
| Position in company |  |
| **14.2 RELEVANT QUALIFICATIONS** |
| Degree/ Diploma | Field of study | Institution | Year graduated |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| **14.3 RELEVANT EXPERIENCE (last job first)** |
| Employer | No. of years | Position held |
|  |  |  |
|  |  |  |
|  |  |  |
| **14.4 NAME AND FUNCTION TO WHOM HE/SHE REPORTS** |
|  |
| **15 PROPOSED DATE OF AUDIT** |
|  |

|  |
| --- |
| **PART E: DECLARATION** |
| Applicants should note that in terms of the provisions of the Medicines and Relates Substances Act, 1965 it is an offence to make false claims and misleading statements in connection with an application for a licence to manufacture, import or export medicine or scheduled substances. |
|  |
| A. **I declare that:** (Tick one box only in each case) | **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 Substances Act, 1965 or a law of a state or territory relating to medicines and related substances. |  |  |
| (iii) The applicant has been convicted of an offence against use or dealings in illicit drugs. |  |  |
| (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 **new/ renewal** (indicate by crossing out the non-applicable section) of a Manufacturer’s Licence to the proposed holder name in this application form in respect of the activities to which the application refers. |
| 1. The licence to be subject to all the Standard Provisions applicable to Cultivator / Manufacturer's Licences under regulations for the time being in force under Section 22C of the Medicines and Related Substance Act, 1965. |
| 2. The cultivation, manufacturing or import operations are conducted only in accordance with the information set out in the application or furnished in connection with it. |
| 3. I / We declare that we hold the relevant product registrations or are named on the relevant product registrations as cultivators or importers or manufacturers and / or packaging relating to the Cannabis products we wish to cultivate or import or manufacture and / or pack pursuant to this application. |
| 4. 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 as follows:** |
| * in the case of a corporation or company: by the designee / natural person who shall be responsible to the Authority for compliance with the Act.
 |
| * in the case of other enterprises: by the owner.
 |
| Full Name |  |
| Signature |  |
| Position within organisation |  |
| 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 authorised person above.* |